

## **Do exercise trials for hypertension adequately report interventions? A reporting quality study**

Non-pharmacological treatment, including exercise, is an important therapy option for patients with hypertension. The study assessed the reporting quality of exercise-based interventions included in the latest meta-analysis on that topic in order to evaluate the transferability of findings into clinical practice. Reporting quality of 24 randomised controlled trials from a meta-analysis assessing blood pressure lowering effects of endurance training in 1,195 hypertensive patients was evaluated using TIDieR (Template for Intervention Description and Replication) and CERT (Consensus on Exercise Reporting Template) guidelines. Associations between reporting quality, publication year and impact factor of the publishing journals were examined. None of the studies described all intervention components completely. On average 61% (95%CI: 52-69) (TIDieR) and 57% (95%CI: 49-64) (CERT) of core items required for replication were reported. Frequent shortcomings were the reporting of adherence, intervention provider, and adverse events. Details about exercise dosage were missing in 22% (95%CI: 4-40). Publication year was related to the adherence to TIDieR ( $r=0.549$ ,  $P=0.007$ ) but not to CERT. No associations with journal impact factor were found. Reporting of exercise-based interventions for hypertension is not sufficient to allow for replication and limits translation of evidence into clinical practice. Researchers should apply, and review authors, journal editors and reviewers should check adherence to reporting guidelines.

## INTRODUCTION

Hypertension is the most common modifiable risk factor for cardiovascular diseases and has been estimated to cause 13% of deaths worldwide [36]. Evidence suggests a positive association between blood pressure level and the incidence of cardiovascular diseases and events (e.g. coronary heart disease, stroke, or heart failure) [21]. The 2016 Global Burden of Disease Study found once more that arterial hypertension was the most important risk factor of loss in life quality and life years [13].

To estimate benefits and harms of an intervention, systematic reviews of randomised controlled trials (RCTs) have the greatest potential to inform on the best available research evidence [2]. As such, they rank highest in the hierarchy of evidence for clinical questions related to the efficacy of treatments and interventions ("levels of evidence" [25]), and the results of such analyses commonly influence national and international recommendations. Accordingly, several systematic reviews and meta-analyses support the hypotensive effects of exercise and are incorporated into numerous guidelines for the prevention and management of hypertension [12,23,34]. However, investigations on the reporting quality of non-pharmacological therapeutic interventions have revealed clear deficiencies [1,7,9-11,14-16,18,19,22,26,28,30,37], resulting in a lack of replicability which may impact translation to clinical practice.

The aim of the present study was to assess the quality of intervention reporting in RCTs assessing the effect of exercise therapy in patients with hypertension. The largest and most up-to-date published meta-analysis was used to identify relevant RCTs for assessment of intervention reporting [8] according to TIDieR (Template for Intervention Description and Replication) [17] and CERT (Consensus on Exercise Reporting Template) [29] guidelines. Consistent with existing research findings adopting TIDieR and CERT reporting standards, it

was hypothesized that inadequate reporting would also be evident in published studies of exercise trials in individuals with hypertension.

## **METHODS**

The primary objective of both the TIDieR [17] and the CERT [29] guidelines is to offer authors guidance for structured and detailed reporting of interventions, to subsequently facilitate research replication and improve the clinical uptake of effective exercise therapy. Both can also be used by systematic review authors, and journal editors and reviewers, to evaluate completeness and quality of exercise intervention descriptions.

Published in 2014, TIDieR (Table 1) expands on existing guidelines regarding reporting of RCTs (CONSORT statement [27]), clinical study protocols (SPIRIT [5]) and observational studies (STROBE statement [32]); and recommends addressing 12 items, which can be complemented with further details if necessary [17]. The majority of these 12 items apply to both pharmacological and non-pharmacological studies.

The CERT guideline (Table 2) was developed as an extension of TIDieR in 2016 and published as a guideline specifically for the reporting of exercise studies [29]. CERT comprises 16 items for a possible maximum score of 19 points and allows for an explicit description of the key elements considered essential to report replicable exercise interventions or exposures. The CERT guideline is applicable to any exercise intervention for both prevention and treatment studies across all evaluative study designs.

### **Assessment of Intervention Description**

The application of the guidelines is demonstrated with the example of 24 RCTs that were included in a meta-analysis assessing the effects of endurance exercise training on arterial blood pressure [8]. The selected meta-analysis was chosen for two reasons – firstly it is the largest

and most-up-to date meta-analysis of RCTs assessing the efficacy of exercise therapy in hypertensive patients. Secondly, endurance (or aerobic) exercise is the most consistently recommended form of exercise therapy across hypertension guidelines [23,34] .

The meta-analysis revealed a significant decrease in both systolic blood pressure of -8.3 mm Hg (95 % CI: 10.7 to -6.0) and diastolic blood pressure of -5.2 mm Hg (95% CI: -6.8 to -3.4).

The original RCTs included in the meta-analysis are evaluated here for their quality of intervention reporting according to TIDieR and CERT guidelines. Completeness of intervention description was assessed based on both guidelines by two independent authors. Additional sources, e.g. protocols or online supplementary material, were included. Sufficiently or completely described items were marked with “1”, incomplete or missing items with “0”, and not applicable items with “NA” (Supplemental File 1). Discrepancies were discussed based on the explanation and elaboration statements of both guidelines [17,29].

## **Data Analysis**

TIDieR and CERT guidelines items were extracted into Excel for each of the 24 RCTs and results were analyzed descriptively. We also evaluated the association of intervention reporting quality with publication year and impact factor of the publishing journals. The impact factor was determined based on the respective publication year of the articles or the last available impact factor after publication of the study. Spearman correlations were computed when examining the associations between reporting quality (measured as the percentage of completely described items of an intervention), publication year and impact factor (IBM SPSS Statistics 23, Chicago, IL). Statistical significance was set at an alpha level of 0.05.

## **RESULTS**

24 RCTs of endurance exercise training comprising 1,195 hypertensive patients were included in the source meta-analysis [8] (Supplemental File 2). Primary studies were published between

1980 and 2010. The reference of one original study was found to be incorrect [20] and could therefore not be included in the present analysis.

## **Description of Endurance Exercise Training Interventions**

### **TIDieR Guideline**

The completeness of intervention descriptions according to TIDieR is presented in Figure 1. Within publications, on average 8 out of 12 items of the TIDieR guideline were adequately reported, corresponding to 67% (95% CI: 61-73; range: 33 to 92) completely described intervention components. Adequate reporting of those items considered essential for replication (items 3 to 9 [17]) was on average given for 4 out of the 7 items. Therefore only 61% (95% CI: 52-69, range: 14 to 100) of the core intervention components were reasonably well reported.

### **CERT Guideline**

The completeness and quality of intervention reporting according to the CERT guideline is illustrated in Figure 2. On average 9 out of 19 items were sufficiently reported, corresponding to 49% (95% CI: 43-56; range: 21 to 79) of studies identified with adequate descriptions of intervention elements. A lack of information on core intervention items was evident. Only 57% (95% CI: 49-64, range: 27 to 87) of the key items (items 1-4, 6, 7a, 7b, 8-10, 12, 13, 14a, 14b, 15 [29]) were reported transparently; out of these 15 core elements only 8 were sufficiently addressed on average. The presence of illustrations, protocols, or descriptions of each performed exercise is assessed with the CERT guideline; for a quarter (26%) of all interventions it was unclear which exercises were exactly carried out based on the completeness of reporting for this item.

## **Reporting on Adverse Events**

The CERT guideline offers a judgement on the methods and reporting related to the occurrence of adverse events, which is not taken into account in the TIDieR guideline. Only 13% of all studies reported adequate information on adverse events using CERT.

### **Association between Reporting Quality, Publication Year, and Journal Impact Factor**

The completeness of intervention reporting was evaluated across the timeframe of included studies in Figure 3 (based on 5 year intervals) and subsequently analyzed in association with the publication year. Basically, studies demonstrated a lower reporting quality if the CERT guideline was used, and recent studies were in tendency better reported than earlier published studies. Overall, a positive association between reporting quality and publication year was detected when adopting the TIDieR guideline ( $r=0.549$ ,  $P=0.007$ ), whereas no statistically significant association was found when based on the CERT guideline ( $r=0.369$ ,  $P=0.083$ ).

The impact factor of the respective publication year could be found for 19 studies. For another 4 studies the impact factor of the year 1991 was used. The median impact factor was 2.61 (inter quartile range: 0.99 to 5.31). Overall, no significant association between journal impact factor and quality of intervention reporting was observed for either TIDieR ( $r=0.140$ ,  $P=0.524$ ) or CERT ( $r=0.225$ ,  $P=0.302$ ).

## **DISCUSSION**

The aim of the present study was to assess the quality and completeness of RCTs examining exercise interventions in individuals with a diagnosis of hypertension. Poor reporting impacts on the ability to translate empirical findings into clinical practice and ultimately impacts the potential benefit to patients [1,24,28]. Our analysis found the reporting quality of key intervention components to be poor and insufficient to allow for their replication regardless of whether TIDieR [1,18,30,37] or CERT guidelines [6,22] were applied. None of the original

studies provided complete information for all essential intervention elements, making accurate replication of the included interventions more difficult. Just over half of the core TIDieR items were adequately described, and reporting quality was marginally lower based on the CERT guideline. Some intervention components, such as material, exercise dosage, and intervention tailoring/progression were better reported than adherence or fidelity, intervention provider, or adverse events.

Our analysis suggests an improvement in the quality of reporting of exercise-based interventions across the timeframe of included studies. In contrast to findings derived from the review of exercise-based cardiac rehabilitation [1] and in patients with knee pain [18], our results show an increasing adherence to the TIDieR guideline over time. This association may be due to the growing awareness of international standards and guidelines in research reporting that were only established in recent years. However, with regard to the completeness of intervention description based on items that are captured in the CERT guideline, our study does not provide significant evidence for better reporting over time. This could be attributed to the more specific guidance to authors to give adequate intervention description when using the CERT guideline. Earlier studies showed that word limits by the journals go along with poorer descriptions of interventions [7]. Modern publication avenues however allow for supplementary information to be provided online and could contribute to an improvement in reporting and transparency. Another potential explanation could be that the development of training methods in recent years came along with more complex treatment options. Therefore an accurate description of intervention contents could become more difficult, and this would lower the probability to comply with CERT. In addition, our data indicate that observed differences in reporting quality between study publications cannot be explained by the difference in journal impact factor.

## **Comparison with other Studies Reporting on the Description of Exercise-Based Interventions**

Previous studies have identified deficiencies in the reporting of other non-pharmacological therapies [10,15,16,28]. With regard to exercise-based interventions, a few studies have evaluated the reporting of exercise programmes according to the F.I.T.T. principle [3,4,6,14,18,22,35,37]. This concept is well established in exercise prescriptions and refers to the Frequency, Intensity, Time and Type of exercise [31]. Knowledge on such intervention components are necessary for replication of interventions and essential for subsequent physical exercise recommendations. In the present study 22% of the original trials did not provide complete information on these components. However, this does represent an improvement in comparison with the previous studies (33-74%). As far as we are aware, the only other evaluations of the reporting quality of exercise trials within cardiovascular research are based on the TIDieR framework and have been carried out for cardiac rehabilitation [1] and peripheral arterial disease (PAD) trials [30]. These studies demonstrated similar or even more frequent missing information on F.I.T.T. items (47% and 24%, respectively). With respect to the completeness of the central intervention components (43% and 32%, respectively), our results show better reporting quality.

## **Reporting of Modifications and Adherence or Fidelity**

Information on intervention modifications and adherence or fidelity are important for judgements on intervention feasibility and potential barriers to implementation. Such information also facilitates the interpretation of published results [33]. In our example of exercise studies for hypertension, only a quarter (26%) of all publications reported measures to quantify or improve the adherence or fidelity; in less than half of all study reports (48%) the extent to which the intervention was delivered as planned was described. These deficiencies are



similar to the previous cardiac rehabilitation (26% and 66%, respectively) and PAD (47% and 49%, respectively) exercise trials.

It is further worth noting that the TIDieR guideline is not explicitly clear on the description of adherence or fidelity, in contrast to CERT, which differentiates between adherence of the patient and provider (items 5 and 16a). Of particular note, none of the studies used measures to evaluate the adherence of the intervention provider, or strategies to improve it.

Only 13% of all studies reported adequate information on adverse events, which makes it almost impossible to estimate the potential risk of an intervention with any degree of certainty.

Regarding the presence of illustrations, protocols, or descriptions of each performed exercise, the CERT guideline also provides the base for more detailed information. Accordingly, for a quarter (26%) of all interventions it was unclear which exercises were exactly carried out based on the completeness of reporting for this item.

## **Strengths and Limitations**

Strengths of this study include the first to identify serious flaws in intervention reporting for exercise-based interventions in hypertensive patients using available but underused tools (TIDieR and CERT). Taken together, three studies with CERT assessments have now identified a problem with reporting in studies of exercise therapy. Consequently, there is a need for a systematic assessment of CERT reporting across all trials of exercise therapy. Our findings have important implications for research and practice as they are based on trials from a systematic review that underpins the evidence-base in numerous publications and guideline recommendations (Google Scholar Citation Rate: 479) for exercise therapy for hypertension [34]. Given the quality of reporting, it is not possible to offer specific exercise prescriptions in accordance with the evidence-base supporting such recommendations. In combination with

others, our study highlights the importance of poor intervention reporting for trials of exercise therapy across disciplines.

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## Conclusion

Our study found that the current best available evidence for exercise therapy in the management of hypertension does not report interventions sufficiently for replication and application to clinical practice. This may underpin the lack of uptake of exercise, and similar lifestyle interventions in practice despite their importance and recommendations. We therefore recommend all agents involved in the exercise-therapy evidence pipeline including trial researchers, systematic review authors, journal editors and reviewers, and health care professionals, to familiarise themselves with available reporting guidelines and ensure adherence throughout planning to publication.

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## FIGURE CAPTIONS

**Figure 1** Percentage of studies which completely reported the Template for Intervention Description and Replication (TIDieR) item [17] in the main trial publication (n=23).

**Figure 2** Percentage of studies which completely reported Consensus on Exercise Reporting Template (CERT) item [29] in the main trial publication (n=23).

**Figure 3** Adherence to the Template for Intervention Description and Replication (TIDieR) [17] and Consensus of Exercise Reporting Template (CERT) [29] guidelines, by publication timeframe (n=23)

## **SUPPLEMENTAL FILES**

Supplemental File 1. Tables that illustrate the evaluation of intervention description completeness using TIDieR and CERT guidelines.

Supplemental File 2. Text file that lists references of primary studies.