

# Consensus on Exercise Reporting Template (CERT): Explanation and Elaboration Statement

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## ABSTRACT

Exercise is effective for prevention and management of acute and chronic health conditions. However, trial descriptions of exercise interventions are often suboptimal, leaving readers unclear about the content of effective programmes. To address this, the 16-item internationally endorsed Consensus on Exercise Reporting Template (CERT) was developed. The aim is to present the final template and provide an Explanation and Elaboration Statement to operationalise the CERT. Development of the CERT was based on the EQUATOR Network methodological framework for developing reporting guidelines. We used a modified Delphi technique to gain consensus of international exercise experts and conducted 3 sequential rounds of anonymous online questionnaires and a Delphi workshop. The 16-item CERT is the minimum data set considered necessary to report exercise interventions. The contents may be included in online supplementary material, published as a protocol or located on websites and other electronic repositories. The Explanation and Elaboration Statement is intended to enhance the use, understanding and dissemination of the CERT and presents the meaning and rationale for each item, together with examples of good reporting. The CERT is designed specifically for the reporting of exercise programmes across all evaluative study designs for exercise research. The CERT can be used by authors to structure intervention reports, by reviewers and editors to assess completeness of exercise descriptions and by readers to facilitate the use of the published information. The CERT has the potential to increase clinical uptake of effective exercise programmes, enable research replication, reduce research waste and improve patient outcomes.

## INTRODUCTION

Complete and explicit reporting of the components of complex interventions, including contextual factors, in clinical trials evaluating their effects is essential to the interpretation, translation and implementation of research findings into clinical practice. Yet, these interventions are often incompletely described in study reports.<sup>1–6</sup> To address this issue, the Template for Intervention Description and Replication (TIDieR) checklist was developed to provide recommendations for the explicit reporting of complex interventions in clinical trials.<sup>7</sup>

Various types of exercise, including aerobic, resistance or balance training, yoga, Pilates, flexibility and movement retraining programmes are examples of complex interventions that have been reported to be effective for prevention and treatment of a range of acute and chronic conditions,<sup>8–10</sup> yet have been

poorly described in clinical trial reports.<sup>11</sup> While the TIDieR checklist provides useful guidance for how to report some aspects of an exercise intervention, further precise information about the type of exercise, as well as details such as its dosage, intensity and frequency, and whether or not it requires supervision or individualisation, are also required to fully understand the intervention and how to replicate it.<sup>8</sup>

We therefore developed the Consensus on Exercise Reporting Template (CERT) to provide additional direction for reporting exercise interventions.<sup>12–13</sup> It provides guidance on a minimum set of key items considered essential to report replicable exercise programmes. These items should be reported in all studies irrespective of exercise type, recognising that additional information may be needed for individual studies, depending on the exercise programme under study. While its development was stimulated by a metaepidemiological review of exercise interventions for chronic health conditions,<sup>11</sup> it is equally applicable to describe exercise interventions for acute conditions, injury prevention or general health.

## Aim

The aim of this Explanation and Elaboration Statement is to facilitate the understanding, uptake and dissemination of the CERT to improve reporting of essential components of exercise across all evaluative study designs for exercise research. It is intended to be used as an extension of Item 5 of the CONSORT Statement,<sup>14</sup> Item 11 of the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) Statement<sup>15</sup> and the TIDieR checklist.<sup>7</sup> We summarise the development of the CERT, explain each item in detail and give examples of good and explicit reporting based on published studies.

## METHODS

### Overview of the CERT and its development

Readers are referred to the study protocol<sup>12</sup> and final report<sup>13</sup> for a full description of the CERT development. We followed the EQUATOR (Enhancing the Quality and Transparency of health Research) Network methodological framework and 18-step checklist for developing reporting guidelines (<http://www.equator-network.org>),<sup>16</sup> and the recommendations of Moher *et al.*<sup>17</sup> The Cabrini Institute Ethics Committee approved the project (HREC 02-07-04-14).

In brief, we performed a modified Delphi study involving a panel of 49 international multidisciplinary exercise experts (all with research backgrounds and 44 with clinical backgrounds), identified as authors of exercise systematic reviews or based on



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national or international profiles in exercise research and practice and peer recommendations. An initial list of 41 items was generated from a metaepidemiological study, that included 73 systematic reviews of exercise interventions for chronic health conditions.<sup>11</sup> Three sequential rounds of anonymous online questionnaires and a Delphi workshop were used.

For each item, participants indicated agreement on an 11-point rating scale. Consensus for item inclusion or exclusion was defined a priori as >70% of respondents rating an item 7 or above or 3 or below, respectively. If consensus could not be reached or changes were made to the item (eg, merging, rewording etc), the items were presented to participants in a subsequent round.

The final CERT (see online supplementary appendix 1) comprises 16 items listed under 7 sections/domains: what (materials); who (provider); how (delivery); where (location); when, how much (dosage); tailoring (what, how); and how well (compliance/planned and actual). For consistency, we harmonised domains and the ordering of items with the CONSORT Statement<sup>14</sup> and the TIDieR Checklist.<sup>7</sup> While some items are common to the CONSORT and TIDieR (study setting, provider characteristics, adverse events and adherence), Delphi panellists indicated that these items required further clarification for exercise interventions.

### How to use this paper

We modelled this Explanation and Elaboration document after those prepared for other reporting guidelines, such as the TIDieR,<sup>7</sup> CONSORT,<sup>14</sup> SPIRIT,<sup>15</sup> PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses<sup>18</sup> and STROBE: Strengthening the Reporting of Observational Studies in Epidemiology.<sup>19</sup> To optimise its value, we encourage readers to use it in conjunction with the CERT document (see online supplementary appendix 1). We used the qualitative data from the Delphi study participants, the Delphi panel feedback from the CERT manuscript review and the expertise of the steering committee (SCS, CED, MU, RB) to construct the Explanation and Elaboration Statement.

We present each checklist item and follow it with published examples of good reporting for that item. We edited some of these examples by removing citations or Web addresses, or by spelling out abbreviations. We explain the pertinent issue, the rationale for including the item and relevant evidence from the literature, whenever possible. While we present the items numerically from 1 to 16, authors need not address items in this particular order in their reports, although it is important that the information for each item is explicitly stated somewhere within the report. The checklist contains the minimum recommended items for describing an exercise intervention, recognising that there may be specific differences for reporting different types of exercise interventions (eg, aerobic vs resistance vs balance, etc), which may require difference types of reporting (eg, how relative intensity is assessed, exercise duration vs set and reps, rest intervals, etc). Authors should provide additional information, such as photographs, video, website links, etc, where they consider it necessary.

## RESULTS

### The CERT Explanation and Elaboration Statement

The complete checklist is available in online supplementary appendix 1 and table 1 provides an example pro forma for applying the CERT to an exercise intervention description. If an item is not applicable, the reasons should be stated. Where limitations of word count preclude reporting all items in the body of a study

report, we recommend that the contents of the reported CERT be included in online supplementary material linked to the primary paper with URLs that are designed to be stable over time. The intervention information may be published as a protocol or located on websites and other electronic repositories and options are described in online supplementary appendix 2. The reporting of mobile and web-based interventions can be informed by the CONSORT-EHEALTH<sup>20</sup> and the Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist.<sup>21</sup>

*Item 1:* Detailed description of the type of exercise equipment (eg, weights, exercise equipment such as machines, treadmill, bicycle ergometer, etc).

#### Text box 1: Examples

1. "...patients to perform the exercises with a sports rubber band to increase the relative load in the movement directions described"<sup>22</sup>
2. "...Treadmills, cross-trainers, stationary exercise bikes, rowing machines, and other types of indoor exercise equipment were used"<sup>23</sup>
3. "Figure 2. Photograph showing exercise set-up with the patient seated in an armchair with forearm support, holding the dumbbell (a plastic container with a specified amount of water) in the affected arm, and performing exercise by lifting and lowering the container by extension or flexion of the wrist"<sup>24</sup>

#### Explanation

Readers should be able to easily identify the type of exercise equipment that is used. These details will enable correct choice for replication and assist budget calculations. This list of materials can be regarded as comparable to the tools required to follow a recipe, for example, measuring utensils, size of dish, etc. The description can include, but is not limited to, the type and brand of exercise machines as these vary greatly, for example, a seated leg press may be set at different angles and this will influence force generation); type of weights (eg, hand held dumbbells, cuff weights, olympic bar); graded elastic bands. There should also be specific instructions regarding the setup of exercise equipment such as how saddle height of an ergometer was individually determined or the placement of elastic resistance bands.

*Item 2:* Detailed description of the qualifications, teaching/supervising expertise and/or training undertaken by the exercise instructor.

#### Text box 2: Examples

1. "All training sessions were conducted in groups of 15–20 people in a yoga studio by a certified professional yoga instructor"<sup>25</sup>
2. "Tai Chi movements taught by 2 certified and experienced instructors (average experience of 20 years)"<sup>26</sup>
3. "...Nine physiotherapists in private practices delivered both interventions. They had an average of 12 years (range 2–30 years) of clinical experience with musculoskeletal disorders. Three (30%) of these physiotherapists had postgraduate masters degree-level qualifications. All of the physiotherapists attended a 3-hour training session and were given a treatment manual"<sup>27</sup>

**Table 1** Proforma CERT assessment form

Author and year Title Journal Study location Reviewer and date					
Item	Description	Data extraction— details	Location (pg, URL etc)		'Reasons for rating': eg, 'not reported or not clearly described'
			Primary paper	Other*	
1	Detailed description of the type of exercise equipment		Eg, page, column, paragraph		
2	Detailed description of the qualifications, expertise and/or training				
3	Describe whether exercises are performed individually or in a group				
4	Describe whether exercises are supervised or unsupervised; how they are delivered				
5	Detailed description of how adherence to exercise is measured and reported				
6	Detailed description of motivation strategies				
7a	Detailed description of the decision rule(s) for determining exercise progression				
7b	Detailed description of how the exercise program was progressed				
8	Detailed description of each exercise to enable replication				
9	Detailed description of any home programme component				
10	Describe whether there are any non-exercise components				
11	Describe the type and number of adverse events that occur during exercise				
12	Describe the setting in which the exercises are performed				
13	Detailed description of the exercise intervention				
14a	Describe whether the exercises are generic (one size fits all) or tailored				
14b	Detailed description of how exercises are tailored to the individual				
15	Describe the decision rule for determining the starting level				
16a	Describe how adherence or fidelity is assessed/measured				
16b	Describe the extent to which the intervention was delivered as planned				
Total score					

\* eg, protocol paper, published reference papers, supplementary data, online appendices, websites.

4. "...Thirteen physiotherapists who have at least 2 years postgraduate musculoskeletal experience and work in private clinics in metropolitan and regional Victoria will provide the physiotherapy intervention. Physiotherapists were chosen to deliver the physical activity intervention as they have expertise in exercise prescription and are key providers of structured physical activity in the community for people with knee osteoarthritis. Three registered nurses who complete training and mentoring from Health Change Australia to develop skills in providing behaviour change support will provide the telephone coaching for the study"<sup>28</sup>

### Explanation

The term 'exercise instructor' refers to the person who provides and/or teaches and/or supervises the exercise programme. This is important to report as their expertise may affect the outcome of the intervention. Some issues to consider are the number of instructors, their professional or disciplinary background (physiotherapist, exercise physiologist, personal trainer, gym

instructor, etc); duration of experience with exercise instruction/supervision; verification of skills; provision of any programme-specific training either before or during the intervention; whether involvement was part of usual practice or per specific recruitment; or whether the relevant cultural contexts are equivalent regarding, for example, healthcare systems and equivalency of instructor qualifications. It is important to consider the expertise in exercise instruction and delivery of exercise programmes as well as the professional qualifications.

*Item 3:* Describe whether exercises are performed individually or in a group.

### Text box 3: Examples

1. "...the exercise class group treatment consisted of group therapy. ... The individual multimodal physiotherapy group received 2 sessions of individual physiotherapy treatment. ..." <sup>29</sup>
2. "...they trained with a physical therapist in groups of 10–15 women ... five physical therapists were involved in a total of 14 groups" <sup>30</sup>

3. "Subjects were tested in an individual and a group training condition, with each subject repeating these test sessions again the following week. In individual trials, subjects trained and were tested alone at different times/days from all others; in group trials, carried out on a different day from the individual trials, the 12 subjects were divided into two groups of six who worked out together as a virtual boat, working in synchrony. In each trial, athletes completed 45 min of continuous rowing on the ergometers"<sup>31</sup>

#### Explanation

Specify whether the intervention was provided to one person at a time ('one-on-one'), or to a group and, if so, the group's size. Descriptions should also include whether this delivery was face-to-face or by distance (telerehabilitation, DVD, booklet, etc) and any key delivery features that are considered essential or may affect the outcome. This information can be specific regarding logistics, amount of supervisory 'intensity', 'group effects', the number of staff or type of facility required, possible psychosocial benefits, social interaction, etc.

*Item 4:* Describe whether exercises are supervised or unsupervised and how they are delivered.

#### Text box 4: Examples

1. "...sessions were conducted in a public fitness centre near the hospital with one-to-one supervision by physiotherapists from the hospital"<sup>22</sup>
2. "...a suite of computer games...were used to promote engaging bilateral movement exercises. The participants were orientated, taught and observed sufficiently in the hardware set up, software use and game practice, before the systems were left with them. They then played the games at home"<sup>32</sup>
3. "...the Web site included interactive and animated features, stage-based personalized sections on goal setting, activity planning, determining target heart rates, and psychological and physical readiness questionnaires for assessing current stages of physical activity...the Web site was designed to assist sequential movements through relevant stage-based information, while allowing the healthcare providers to browse the entire site when necessary"<sup>33</sup>

#### Explanation

Specify whether exercise performance is undertaken with an instructor who, for example, observes exercise performance, corrects exercise technique, ensures the participant has the correct movement pattern (exercise 'form'), provides guidance, provides motivation and feedback and/or modifies exercises as appropriate/required by, for example, changing the resistance or number of repetitions, or whether exercise is undertaken in an environment where the participant has no guidance or feedback. The mode of supervision should be explained and may include methods such as face-to-face, follow-up phone calls, telemedicine, electronic prompts and devices such as email or SMS. The level or type of supervision may influence reporting of adverse events, observation of performance compared with perceived performance, levels of required assurance or modification and levels of adherence. The level of guidance and supervision influences exercise initiation, engagement and correct technique.

It may not be enough to only report that exercise is supervised, but rather the exact mechanism of that supervision. Levels of required or recommended supervision can provide information for estimation of budget and for logistical planning, for example, personnel, salaries, the type of facility or equipment that may be required and cost, etc.

An exercise programme may be self-directed and performed without supervision. It may be preceded by instruction by an exercise instructor or may have been learnt from a brochure, DVD, computer-assisted virtual reality, Smartphone app and YouTube, etc.

*Item 5:* Detailed description of how adherence to exercise is measured and reported.

#### Text box 5: Examples

1. "...the mobile phone and pedometer intervention phase will have three components 1) the daily message/video clip, 2) daily mobile phone diary, and 3) other functions ('Talk to us', 'Summary' and 'Help' menus). The mobile phone diary program was designed so participants had to answer questions sequentially. For example, when 'Diary' is selected, the first question is: 'Did you wear a pedometer all day today, except for showering, swimming, or sleeping?' If the answer is 'Yes', the woman will be directed to enter the number of steps taken that day. To increase accuracy of data entry, a range of steps (1000 and 35 000) was programmed in advance. The participant will immediately receive a daily step histogram showing the daily step count, enabling her to monitor/visualize her progress. If the answer is 'No' (i.e.—she didn't wear the pedometer), she will be asked to select the reason why and will receive suggestions based on her answer"<sup>34</sup>
2. "...attendance to scheduled rehabilitation appointments was calculated by dividing the number of rehabilitation sessions attended by the number of rehabilitation sessions scheduled. Second, the Sport Injury Rehabilitation Adherence Scale was utilized to assess adherence during clinic-based rehabilitation sessions. A total clinic rehabilitation adherence score was derived from summing each of the SIRAS responses for each item"<sup>35</sup>
3. "...the percentage of supervised exercise sessions completed, defined as the number of supervised exercise sessions attended divided by the number of supervised exercise sessions prescribed. ... Exercise adherence data were recorded by the exercise trainers at every supervised session"<sup>36</sup>

#### Explanation

Adherence can be defined as the degree to which behaviour corresponds to an agreed plan. It is a complex and multidimensional construct that can be affected by a number of factors related to the condition, the person (such as forgetfulness, self-efficacy, attitudes, mood states such as depression and socioeconomic status) and the relationship between the person and healthcare professional. During an exercise intervention, it may be unclear if any exercise has occurred or if people have engaged in enough exercise for long enough to obtain any therapeutic benefit. A valid and reliable assessment of exercise performance is essential for drawing valid conclusions about exercise effects.

*Item 6:* Detailed description of motivation strategies.



## Text box 6: Examples

1. "...the motivational program consisted of the following interventions: Extensive counselling and information strategies to ensure that patients received clear instructions, emphasizing the importance of regular and consistent exercise. Reinforcement techniques were used, with the therapist giving positive feedback and commending patients for their efforts. The oral agreements between the patient and the therapist were reinforced in writing in the form of a 'treatment contract'"<sup>37</sup>
2. "The physiotherapy intervention will be the same as for the physiotherapy only group and delivered by the same physiotherapists. The participants in this group will also receive a telephone coaching intervention aimed at improving their adherence to their home exercise program and increasing their levels of general physical activity through behaviour change support. They will receive additional written information that explains the behaviour change support process. Telephone coaching sessions will be delivered 6–12 times during the 6-month intervention period. Calls will occur in weeks 2, 4, 8, 13, 21 and 25. Up to six additional calls can be made at any time during the 6 months"<sup>28</sup>
3. "A pre-programmed daily message or video clip will be automatically sent at a predetermined time between 11 a.m. to 3 p.m. Each daily prompt begins with a message from the research staff, followed by a question relevant to the message. For example, on Day 5 of Week 4, subjects receive the following daily message: 'Have you let everyone around you know that you are trying to become more active so they can help you meet your goal?' 'No' or 'Yes' is selected by pushing the keypad. If 'No' is selected, the next screen will display 'Let others know your physical activity goal.' If 'Yes' is selected, the next screen will display 'Nice work!' It takes only one to two minutes to complete the daily prompt each day"<sup>34</sup>

## Explanation

Motivation strategies have demonstrated moderate additional effects on exercise outcome and can include goal setting, goal achievement, engagement in shared decision-making, acknowledgement of success, graphic, visual or verbal cues and/or feedback, motivational interviewing, preferred environments and problem-solving advice. These strategies aim to achieve engagement to sustain exercise activity and/or achieve higher or progressively more intense performance. Difficulty with engagement might be because people are no longer motivated and do not receive any feedback about their progress. Provision of explicit description of these motivation strategies may be essential to ensure comparable effects. In addition, provision of motivation during exercise performance can have an effect on the participant-perceived effort and force output as well as workload, particularly during maximal intensity exercise.

*Item 7(a):* Detailed description of the decision rule(s) for determining exercise progression.

## Text box 7a: Examples

1. "...when training at a specific repetition maximum (RM) load, it is recommended that 2–10% increase in load be applied when the individual can perform the current workload for one to two repetitions over the desired number. Progression in power training entails two general loading strategies: 1) strength training and 2) use of light loads (0–60% of 1 RM for lower body exercises; 30–60% of 1 RM for upper body exercises) performed at a fast contraction velocity with 3–5 min of rest between sets for multiple sets per exercise (three to five sets)."<sup>38</sup>

2. "The therapists adjusted exercise intensity as determined by the participant's ability to complete 10 repetitions for a given exercise"<sup>39</sup>
3. "...when the edema and acute pain have subsided and when the subjects could cope with gentle resistance and, while standing, could tolerate equal weight through their lower limbs"<sup>40</sup>
4. "The first goal was to reach a light to moderate training level Borg rating of perceived exertion (RPE) (11–13 out of 20), that corresponded to 50% of the estimated maximum oxygen uptake and 60% of the maximum heart rate. Second, during parts 2 and 4 of the exercise program, the goal was to reach an exertion level RPE (14–15 out of 20) that corresponded to 75% of the estimated maximum oxygen uptake and 80% of the maximum heart rate."<sup>41</sup>

*Item 7(b):* Detailed description of how the exercise programme is progressed (eg, numbers of repetitions, resistance, load, speed, etc).

## Text box 7b: Examples

1. "...progression was achieved by increasing the number of sets, the duration of the hold phase of the exercise, and the ankle weight or elastic band resistance, as guided by the physiotherapist"<sup>42</sup>
2. "...Progressively increase exercise duration to 30–40 min. ... Increase work load by 2–10% if one to two repetitions over the desired number are possible on two consecutive training sessions. ... Increase load as tolerated. ... Increase intensity (mA) until a visible muscle contraction occurs or to the maximum tolerated level..."<sup>43</sup>
3. "The individual exercise intensity was adapted during each session by adjusting the load or the cycling speed so that the exercise goals were achieved. Each patient was given 2 fitness goals for each exercise session."<sup>41</sup>

## Explanation (7a and b)

Progressive overload is the gradual increase in stress placed on the body during exercise training and requires a gradual increase in volume (repetitions multiplied by resistance), intensity (percentage of maximum capacity), frequency or time. The principle of progression implies that there is an optimal level of overload that should be achieved. A gradual and systematic increase of the workload over a period of time will result in improvements in fitness/strength without risk of injury. If overload occurs too slowly, improvement is unlikely, but overload that is increased too rapidly may result in injury or muscle damage. Progression can also be achieved by decreasing rest intervals, by changing the stimulus modality, moving from simple to more advanced exercises and adding complexity to the exercises to make them task-specific. Implementation of an exercise programme is assisted by explicit information about how this overload or change in complexity is managed.

*Item 8:* Detailed description of each exercise to enable replication (eg, photographs, illustrations, video, Smartphone app, website, protocol paper, etc).

## Text box 8: Examples

1. Online supplementary appendices provided with comprehensive text descriptions and photographs or videos for each exercise"<sup>26 44 45</sup>

2. "The exercises for the Hip group consisted of dynamic resistance strengthening and stretching exercises for the hip primarily using Thera-Band (Thera-Band, The Hygenic Corporation, Akron, Ohio) elastic bands. The exercises for the Leg group consisted of dynamic resistance exercises primarily using Thera-Band elastic bands for the muscles of the lower extremities (quadriceps, hamstrings, and calves). The exercises for each group are described in the Supplemental Digital Content 1 (see online supplementary appendix, <http://links.lww.com/JSM/A51>)"<sup>46</sup>

3. "The strength exercises were leg extension, leg curl, leg press, calf raises, chest press, seated row, triceps extension, biceps curls, and modified curl-ups. Aerobic exercise could be completed on a cycle ergometer, treadmill, elliptical, rowing ergometer, or combination"<sup>36</sup>

#### Explanation

To continue with the recipe analogy, this would equate to 'ingredients' (the list of exercise components), 'procedure' (the sequence of steps to be followed) and photographs of the preparation stages and plated dish (the components and completed exercise). For exercises to be executed as expected, explicit information is needed about, for example, starting position, that is, lying, sitting, standing; targeted muscle groups; position in which the exercise is performed; and range of movement. This enables the reader to replicate or decide on a substitute exercise and obviates ambiguity or misinterpretation. Interventions that consist of 'usual care' or 'standard of care' require further elaboration in the protocol, as these can vary substantially across centres, healthcare environments and countries.

*Item 9:* Detailed description of any home programme component (eg, other exercises, stretching, functional tasks, etc).

#### Text box 9: Examples

1. "All patients were encouraged to supplement the hip exercises with aerobic training on a stationary bike and by walking"<sup>20</sup>
2. "Patients were asked to perform exercises at home 4 times each week in addition to the supervised physiotherapy sessions"<sup>26</sup>
3. "Subjects in both exercise groups were requested to follow only the exercises assigned for their group and to not make any significant lifestyle or exercise regime changes during the time of the study"<sup>46</sup>

#### Explanation

The addition of a home programme may influence intervention outcomes and may require a record and explicit description of the content and a measure of adherence such as self-report by the participant. Depending on the type of home programme, for example, additional exercise or incorporation into functional tasks, this may alter the overall exercise dosage and intervention outcome.

*Item 10:* Describe whether there are any non-exercise components (eg, training or information materials, education, cognitive-behavioural therapy, massage, etc).

#### Text box 10: Examples

1. "Participants in the experimental group also received health coaching via telephone. The telephone coaching involved the application of health coaching principles by a physiotherapist with three years of clinical experience and three years of tertiary level teaching experience who had received three days of training in health coaching. A coaching protocol was developed to guide each coaching session"<sup>47</sup>

2. "Treatment included Maitland mobilizations that were progressed as the condition improved, soft tissue massage, myofascial trigger point release, heat, and stretches. The patients were also instructed on the specific shoulder exercises in the home exercise program and given the information booklet"<sup>29</sup>
3. "The intervention contained...education about duration and intensity of brisk walking and the health benefits of exercise; identification of barriers to increasing physical activity and development of strategies to overcome these barriers; value and identification of social support while increasing physical activity; relapse prevention; education about healthy diet and weight maintenance; and 7) physical activity safety"<sup>34</sup>

#### Explanation

The non-exercise components should be reported in detail as they may influence the overall measured effect of the intervention. A complete description of the intervention should include items such as written instructions, education materials or training manuals and where these can be located, for example, as online supplementary files.

*Item 11:* Describe the type and number of adverse events that occur during exercise.

#### Text box 11: Examples

1. "During Progressive Resistance Training (PRT), five patients experienced adverse effects during or after training sessions. Two patients had discomfort and dizziness due to hypotension; regulation of their anti-hypertensive medication solved the symptoms. In one patient, an accumulation of blood burst during the third training session, the bandage was changed and no further complications were observed. One became nauseous and vomited after the training session; this was...due to an earlier tumour in the brain, and led to discontinuation of the PRT. Knee pain in the contra-lateral leg also led to discontinuation of the PRT in one patient. In total, two patients discontinued the intervention due to adverse effects; they participated in follow up visits and are included in the analysis"<sup>22</sup>
2. "During the intervention period, 17/55 (31%) participants in the active group reported adverse events. These comprised increased short term pain during or after the treatment session (n=3), increased short term pain with the home exercises (12), and mild irritation to the tape used for postural taping (2). In the placebo group, 5/61 (8%) reported adverse events comprising increased short term pain during or after the treatment session. During the follow-up period, adverse events were reported only by the active group (7/49, 14%) and comprised increased short term pain with the home exercises"<sup>48</sup>
3. "Over the course of the walking program (WP) intervention, a small proportion of the participants complained of an increase in LBP (n 55), groin (n 51), or knee (n 51) pain. An additional 7 WP participants who complained of an increase in LBP (n 55), knee (n 51), or groin pain (n 51), despite modification of their weekly walking volume target were withdrawn, on average after 4 weeks of the programme (range, 2–5 weeks). There were no reported adverse events in the exercise class (EC) or usual physiotherapy (UP) groups"<sup>49</sup>

#### Explanation

An adverse event refers to an untoward occurrence, which may or may not be causally related to the intervention or other

aspects of trial participation. Information about harms, as well as benefits, is needed in order to make decisions about whether, and how, to engage in an exercise programme. The CONSORT Statement gives specific guidance about adverse events (and those associated with comorbidities); however, there are some considerations that are exercise-specific, for example: whether it is advisable to exercise into pain; which pain aggravations are acceptable; how much pain is acceptable; what is regarded as 'normal' muscle soreness after exercise; how to manage postexercise muscle soreness; decision rules for when to modify or cease exercise due to symptom aggravation or pain.

*Item 12:* Describe the setting in which the exercises are performed.

#### Text box 12: Examples

1. "Training will take place in groups, at one of two clinics under the supervision of one of two experienced physiotherapists"<sup>25</sup>
2. "...performed both in clinic and home settings"<sup>35</sup>
3. "...a 10-week intervention period receiving either physical exercise at work or physical exercise at home. All training sessions took place in designated rooms located close to the worksite departments"<sup>50</sup>

#### Explanation

A description of the setting in which an exercise programme takes place provides context in terms of applicability of study results as these may vary substantially within and between countries. The exercise intervention may be delivered in, for example, a clinical or rehabilitation setting, at home or in a gym or recreational facility. There may be features or circumstances about the type of setting that influence the delivery of the exercise intervention (funded or unfunded, provision or availability of equipment, accessibility, etc), that act as barriers or facilitators to engagement. The type of setting will also affect the degree of generalisability to broader populations and transferability to participants' environments in the longer term.

*Item 13:* Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, programme duration, etc.

#### Text box 13: Examples

1. "The moderate-to-vigorous intensity aerobic exercise (STAN) group ... the equivalent of a minimum of 75 min/week of vigorous aerobic exercise spread over 3 days/week (i.e., 25–30 minutes/session). The higher intensity aerobic (HIGH) group were asked to follow double the minimum guidelines of 150 min/week of vigorous aerobic exercise per week (i.e., 50–60 minutes/session). The combined aerobic and resistance (COMB) group were asked to complete the same aerobic exercise guideline as STAN plus a standard strength training program for 3 days/week consisting of two sets of 10–12 repetitions of 9 different strength exercises at 60–75% of their estimated 1 repetition maximum (i.e., about 50–60 minutes of combined exercise)"<sup>36</sup>
2. "Patients visited their physiotherapist 14 times during the 12 weeks: twice in the first and second weeks and weekly thereafter. Each visit lasted 30–40 minutes. Table 1 reports specific details of exercise execution, repetitions, sets and there is additional information in online supplementary data"<sup>26</sup>

3. "Table 1 reports training descriptors such as resistance load, sets and repetitions for the strengthening program"<sup>22</sup>

#### Explanation

The description of the exercises should enable the clinician, researcher, care-seeker or reviewer to know exactly how to administer or replicate the exercises that have been evaluated in a study. The dosage should include, for example, the exercise mode, the resistance or load, the muscle contraction mode, the relative time in each contraction type (concentric, isometric and eccentric phases), rest intervals (between repetitions or sets), exercise speed and sequence, the number of exercises, repetitions and sets of each exercise, session duration, sessions per day and per week and the duration of an evaluated programme. For interventions that include multiple sessions, the schedule of the sessions should be stated and if the number of sessions, their schedule and/or intensity was fixed, how they could be varied according to some decision rules.

*Item 14(a):* Describe whether the exercises are generic (one size fits all) or tailored.

#### Text box 14a: Examples

1. "The standardised exercise program consisted of unloaded exercises in the movement directions: hip flexion, -extension, -abduction and knee flexion/extension"<sup>22</sup>
2. "We developed the exercise programme ('back to fitness') ... comprises... group classes incorporating cognitive-behavioural principles. Classes ran in local community facilities. Up to 10 people took part in each session. We invited participants to attend up to eight 60 minute sessions over four to eight weeks and a 'refresher' class 12 weeks after randomisation"<sup>51</sup>
3. "Exercise trainers could modify the exercise prescription or progression based on the patient's response to the exercise"<sup>36</sup>

*Item 14(b):* Detailed description of how exercises are tailored to the individual.

#### Text box 14b: Examples

1. "The exercise prescription was individualized and followed guidelines from the American College of Sports Medicine (ACSM) for developing and maintaining cardiorespiratory fitness [20]. These guidelines suggest that individuals perform 60–120 min/week of aerobic exercise within their target heart rate zone (60–85% of maximal heart rate). Programmes were tailored to the individual depending on severity of fibromyalgia (FM), accessibility to equipment, time constraints and enjoyment of various activities. The intensity of the exercise began at 60–70% of maximal heart rate for all individuals and was gradually increased to as high as 75–85%, depending on the subject's adaptation to the exercise"<sup>52</sup>
2. "The three treatment protocols are summarized as follows: 1) Matched: Subjects were taught unidirectional end-range lumbar exercises matching the direction of their directional preference (DP) identified during baseline assessment. 2) Opposite: Subjects were also taught unidirectional end-range exercises, but in a direction opposite to their DP identified during baseline assessment. 3) Evidence-based care (EBC)"<sup>53</sup>



3. "A visual analog scale (VAS) graded from 0 to 10 was used for patient-reported pain after each training session, where 0 is 'no pain' and 10 'pain as bad as it could be'. Pain up to 2 on the scale was considered 'safe' (green zone), pain up to a level of 5 was considered 'acceptable' (yellow zone), and pain above 5 was considered 'high risk' (red zone)."<sup>54</sup>

#### Explanation (14 a and b)

Exercise programmes may be a predetermined and standardised set of exercises or tailored to the individual for reasons such as comorbidities, musculoskeletal restrictions, participant preferences and abilities or as part of the progression of exercise intensity or overload that is anticipated with a progressive programme. A rationale, description and guide or system of decision rules for the tailoring, as well as implementation time points, should be provided. This will facilitate those planning to use the programme to know exactly how to administer it. An example might be the 'intensity of the exercises was adapted to patient's pain level (ie, pain should not exceed 3 on a 0–10 numerical rating scale)'.

*Item 15:* Describe the decision rule for determining the starting level at which people start an exercise programme (eg, beginner, intermediate, advanced, etc).

#### Text box 15: Examples:

1. "...the dose was 2–3 sets of 10 repetitions, with the starting weight matched to the participant's 10-repetition maximum weight if possible or to a weight needed to achieve a self-rating of 5–8 of 10 on the modified Borg RPE CR-10 scale"<sup>26</sup>
2. "All exercises will be modified so that they can be performed at three levels of difficulty: basic, intermediate, and advanced. For novice training, it is recommended that loads correspond to a repetition range of an 8–12 repetition maximum (RM). For intermediate to advanced training, it is recommended that individuals use a wider loading range from 1 to 12 RM in a periodized fashion with eventual emphasis on heavy loading (1–6 RM) using 3- to 5-min rest periods between sets performed at a moderate contraction velocity (1–2 s CON; 1–2 s ECC)"<sup>38</sup>
3. "The ACSM recommends that most adults engage in moderate-intensity cardiorespiratory exercise training for ≥30 min/day on ≥5 days/week for a total of ≥150 min/week, vigorous-intensity cardiorespiratory exercise training for ≥20 min/day on ≥3 days/week (≥75 min/week), or a combination of moderate- and vigorous-intensity exercise to achieve a total energy expenditure of ≥500–1000 MET/min/week. On 2–3 days week, adults should also perform resistance exercises for each of the major muscle groups, and neuromotor exercise involving balance, agility, and coordination"<sup>55</sup>

#### Explanation

It is sensible to describe decision rules for determining the level at which participants start an exercise programme so that they are neither underexercised or overexercised as this may influence engagement, participation and rates of adverse events. Participants may present to an exercise programme as untrained, semitrained or highly trained. Measures may include strength testing using the one repetition maximum (1RM),<sup>56</sup> the Borg Exertion Scale<sup>57</sup> or maximum oxygen uptake (VO<sub>2</sub> max).<sup>58</sup>

*Item 16(a):* Describe how adherence or fidelity to the exercise intervention is assessed/measured.

#### Text box 16a: Examples

1. "The physiotherapists will attend a three-hour training session covering delivery of both exercise programs and receive a detailed treatment manual describing each exercise intervention. After initiation of the trial, telephone meetings will be held to discuss issues experienced in the clinic and solutions will be suggested. This procedure will reinforce similar treatment administration among therapists"<sup>26</sup>
2. "Separate training in the content and mode of delivery of each intervention was provided for therapists delivering the WP (i.e. 3 hours informed by co-author PA experts CB, W van M, and MT and delivered by the principal investigator and local trial team) and the EC (7 hours delivered by JKM, who developed the Back to Fitness programme)"<sup>49</sup>

#### Explanation

Fidelity refers to the extent to which the exercise intervention occurred as the investigators intended it. For various reasons, part or all of the exercise intervention may not be delivered as intended. A description should be given of who delivered the intervention and how it was delivered. Any strategies employed to improve or guarantee fidelity should also be reported, such as training, standardised therapist treatment notes or direct observation by a researcher to document adherence to the protocol.

*Item 16(b):* Describe the extent to which the intervention was delivered as planned.

#### Text box 16b: Examples

1. "The patients in the intervention group (IG) attended a median of 19 PRT sessions (IQR: 18; 20). The resistance training was initiated at a median 5 (IQR: 5; 6) days after surgery, postponed initiation was due to readmission for blood transfusion (n ¼ 1), wound oozing (n ¼ 1) and lack of energy (n ¼ 1). Home-based exercise was self-reportedly performed median 5 (IQR: 4e7) days a week in the IG as prescribed and 6 (range: 4e7) days a week in the control group (CG), where 7 days a week was prescribed"<sup>21</sup>
2. "...adherence with the protocol...they successfully completed the walking program (WP) under the supervision of their physiotherapist, who temporarily reduced their daily walking volume target until the pain improved. An additional 7 WP participants who complained of an increase in pain...were withdrawn, on average after 4 weeks of the program. The majority received usual physiotherapy (UP). ... Within the UP group, all participants (100%, n 577) received advice (stay active: 57%, n544; back care: 56%, n543; posture: 27%, n521), an individualized exercise approach (stretching: 55%, n 542, core stability: 45%, n 535; strengthening: 15%, n 512, Pilates: 15%, n 512), and a home exercise program"<sup>29</sup>

#### Explanation

There can be many reasons why an intervention is not delivered as planned and the extent to which this occurred should be reported. As well as providing an explanation for the effect or lack of effect of an intervention, it also provides valuable information to inform future studies.

## DISCUSSION

We have presented an explanation and elaboration of a 16-item exercise-reporting template that has been endorsed by an



international panel of exercise experts. It appears to be generalisable across all types of exercise interventions and conditions and complements other more generalist tools designed to improve the reporting of details of complex interventions in clinical trials. We suggest that authors use the CERT in conjunction with the reporting guideline that is appropriate for their study design (eg, CONSORT for randomised controlled trials). When completing CONSORT Item 5 or SPIRIT Item 11, the authors should insert a notation to refer to the CERT checklist, and provide a separate and completed CERT checklist for an exercise intervention.

Detailed information about exercise interventions evaluated in clinical trials is necessary for the optimal translation of evidence into clinical practice. The use of the template should facilitate provision of explicit details about exercise interventions in clinical trials as a basic standard and is likely to be an important adjunct to the CONSORT,<sup>14</sup> SPIRIT<sup>15</sup> and TIDieR<sup>7</sup> templates. For systematic reviews, it has been recommended to insert an 'intervention content' table to explicitly describe interventions,<sup>56</sup> and we suggest that for a synthesis of exercise programmes, the CERT can be substituted.

We encourage healthcare journals and editorial groups, such as the World Association of Medical Editors and the International Committee of Medical Journal Editors, to endorse the routine use of the CERT to accompany manuscript submission and for use by reviewers in assessing trial and systematic review manuscripts submitted for publication. Journal endorsement of the CONSORT Statement has demonstrated a beneficial effect on the completeness of reporting of the trials that they publish. The number of checklist items that are reported in a manuscript is improved when journals required completion as part of the submission process.<sup>59</sup> An evidence synthesis of systematic review methods has demonstrated that clear procedural details are required for the findings of clinical trials to be implemented into practice,<sup>60</sup> and the CERT would assist the completeness of systematic reviews of exercise efficacy.

Transition into routine editorial practice may be achieved by very specific guidance to authors to use the CERT, as recommended by Hoffman *et al* for the TIDieR: (1) by explicit instructions to authors; (2) the provision of the checklist and/or a link on the journal website; and (3) an editorial about the benefits of explicit reporting of exercise interventions.<sup>61</sup> An increasing number of journals have editorial policies stating that they will not publish trials unless detailed intervention protocols or full details are available on stable and enduring electronic and digital links.<sup>62 63</sup>

In summary, the CERT provides helpful recommendations for reporting exercise programmes. It can be used to aid study planning, protocol development and manuscript reporting, and act as a guide for journal reviewers and editors in evaluating manuscripts that report exercise interventions.

## IMPLICATIONS FOR RESEARCH

Future steps in the CERT initiative include full listing on the EQUATOR Network and piloting the checklist for utility and inter-rater reliability across a range of domains where exercise programmes have or are being tested. We are also investigating the possibility of a Smartphone app and/or a dedicated website to provide educational materials, a repository database of materials relevant to the reporting of exercise interventions and a mechanism for stakeholder feedback.

We would welcome support from groups such as the International Committee of Medical Journal Editors (ICMJE),

World Association of Medical Journal Editors (WAMJE) and the Council of Science Editors.

## CONCLUSIONS

The uptake of the CERT will ultimately lead to better reporting of exercise interventions in clinical trials, and enable replication in clinical practice. This Explanation and Elaboration Statement provides an explanation for how to operationalise each CERT item using examples from published trial papers of how good reporting may be constructed. The CERT can assist researchers to design exercise interventions; guide peer reviewers and editors in their evaluation of manuscripts; assist funding bodies to evaluate grant applications and policymakers in exercise recommendations; and assist clinicians to read published reports and implement effective programmes into everyday clinical practice. We anticipate that the CERT will be an evolving document, as have been other reporting guidelines, with a requirement for review and refinement as new evidence and critical comments accumulate.

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