Review Article

Participant characteristics are poorly reported in exercise trials in tendinopathy: A systematic review

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A B S T R A C T

Objective: To evaluate the reporting of eligibility criteria and baseline participant characteristics in randomised controlled trials investigating the effects of exercise interventions in tendinopathy.

Methods: Randomised controlled trials investigating the effects of exercise therapy compared to a non-exercising intervention in upper and lower limb tendinopathy were included. Data extraction was categorised into the following domains: participant demographics, tendinopathy descriptors, general health, participant recruitment and eligibility criteria.

Results: The review included the following tendinopathies: Achilles (n = 9), gluteal (n = 2), lateral elbow tendinopathy (n = 15), patellar (n = 3) plantar (n = 3), and rotator cuff (n = 13). Age, sex, duration of symptoms and symptom severity were commonly reported across the review, while prior history of tendinopathy was poorly reported (6/45). Variables such as physical activity level (17/45), sleep (0/45), psychological factors (2/45), medication at baseline (8/45), co morbid health complaints (10/45) and sociodemographic factors (11/45) were poorly reported across the included studies. Substantial variation existed between studies in the specific eligibility criteria used.

Conclusion: The findings of this systematic review demonstrate that participant characteristics are poorly reported in exercise trials in tendinopathy. To improve effectiveness of exercise interventions in tendinopathy, improved reporting of participant characteristics may allow better comparisons and targeted interventions for specific subgroups.

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1. Introduction

Hippocrates presaged the importance of individual characteristics in healthcare when he stated: “It is more important to know what sort of person has a disease than to know what sort of disease a person has.” Tendon pain was likely a common complaint in his time as it is now (Albers et al., 2016) and then, as now, we believe exercise interventions are a mainstay of management (Malliaras et al., 2013) (Littlewood et al., 2012).

Randomised controlled trials (RCTs) are the gold standard for assessing the efficacy of interventions in healthcare, but to understand the effectiveness of our interventions, a clear depiction of the relevant characteristics of the individual with tendinopathy is required (Hariton & Locascio, 2018). This principle has been acknowledged in both the CONSORT statement (for RCTs generally), and, more specifically in the recent international scientific tendinopathy consensus (Vicenzino, de Vos, & Alfredson, 2019). Despite an ever increasing body of tendon research into the efficacy of exercise interventions, the burden and impact of this musculo-skeletal (MSK) disorder remains high (Blyth et al., 2019). This suggests that while the internal validity of studies can be evaluated robustly during the peer-review process, applying the results of
exercise RCT’s in tendinopathy at an individual level is challenging (Wertli et al., 2013).

To ascertain the effectiveness of exercise interventions in the broader population, clinicians must be able to determine whether the results of a particular trial are representative of the patient in front of them (i.e. external validity). Multiple factors determine the external validity (i.e., generalisability or applicability) of RCTs: patient characteristics, condition under investigation, costs, compliance, co-morbidities, and concomitant treatments (Gartlehner et al., 2006). Many of these participant characteristics have been identified as important prognostic indicators in the management of individuals with musculoskeletal pain (Tseli et al., 2019) (Matthews et al., 2017). Furthermore some of these factors have been identified as treatment modifiers in other MSK conditions (Benecki et al., 2017; Hayden, Wilson, & Stewart, 2019; Smeets et al., 2006). It is therefore important to ascertain if the aforementioned characteristics are present among trial participants in tendinopathy research, or indeed if such characteristics would lead to an individual being excluded from the trial. Strict eligibility criteria may be advantageous in efficacy trials, but they may not reflect the typical presentation of tendinopathy patients in routine practice or in the community. Research in other painful MSK conditions (e.g. back pain) has highlighted that participant characteristics are poorly reported in RCT’s (Wertli et al., 2013). To our knowledge, neither the reporting of participant characteristics nor eligibility criteria have been systematically analysed in exercise trials for tendinopathy.

The objective of this study was to evaluate the reporting of eligibility criteria and baseline participant characteristics in RCTs which were included in a systematic review assessing the effects of exercise treatment outcomes in patients with tendinopathy.

2. Methods

2.1. Protocol registration

A secondary analysis of a larger systematic review and meta analysis investigating the efficacy of exercise versus non-exercise interventions in tendinopathy was performed according to the registered protocol outlined (PROSPERO - CRD42018110086). The preferred reporting items for systematic reviews and meta analyses (PRISMA) was used to guide reporting of the findings of the review (Shamseer et al., 2015).

2.2. Eligibility criteria

2.2.1. Types of participants

Studies involving both sedentary and athletic participants, aged 18 years and over with Achilles tendinopathy, patellar tendinopathy, gluteal tendinopathy, rotator cuff tendinopathy, plantar fasciopathy, or lateral elbow tendinopathy were deemed eligible for inclusion. Studies investigating acute tendon injuries and tears, ruptures, or postoperative rehabilitation were excluded.

2.2.2. Types of interventions

Randomised controlled trials investigating the effects of exercise therapy in upper and lower limb tendinopathy were included. Exercise interventions were deemed suitable if they involved any type of muscle-tendon unit stretching, or loading, including eccentric, concentric, combined eccentric-concentric, isometric and stretch-shortening cycle (SSC) loading as a component. Studies were considered eligible if they compared an exercise therapy intervention (alone or in combination with other standard physiotherapy interventions) with a non-exercising strategy (e.g. surgery, corticosteroid injection, platelet rich plasma injections-PRP, shockwave therapy, wait and see). Studies where the only comparative group involved any exercise or post-operative rehabilitation were excluded. The exercise program needed to follow a structured protocol and the training dose needed to be described. No limits on duration of symptoms was implemented and there were no restrictions on the setting (e.g. class, home exercise program, hospital, gymnasium) or duration of the intervention.

2.3. Information sources and literature search

2.3.1. Electronic search

An electronic literature search was performed in November 2019 of the following databases PubMed, CINAHL, Cochrane Library, Web of Science, and MEDLINE. The searches combined terms related to exercise (e.g. eccentric, concentric, loading, strengthening), tendon location (e.g. Achilles, patellar tendon, rotator cuff, lateral elbow pain OR tennis elbow) and trial intervention type (e.g. random OR placebo OR RCT) without language restriction and adjusted according to individual database specifications (Table 1).

2.3.2. Searching additional resources

Grey literature was searched via OpenGrey, as well as the following registries: Clinical Trials.gov and ANZ clinical trials register. Reference lists, citation tracking results, and relevant systematic reviews (Cochrane reviews = 6) were also manually searched for additional studies. Additional searches were also performed of the proceedings from previous International Scientific Tendinopathy Symposia (ISTS) (2009, 2011, 2013, 2015 and 2017).

2.4. Study selection

After removing duplicates, the two reviewers (SMA, VK) screened the titles and abstracts independently by applying the specified inclusion and exclusion criteria to the full-text reports. The full text was obtained if a study was deemed eligible by at least one reviewer. A third reviewer (KOS) was consulted if consensus was not reached.

2.5. Data extraction and synthesis

Two reviewers (SMA and KOS) extracted data from the included randomised controlled trials, including bibliographic data (authors, year of publication), eligibility criteria, and relevant baseline participant characteristics.

As proposed in the international tendinopathy consensus statement (ISTS) (Rio et al., 2020), data extraction was performed according to four participant domains: participant demographics, tendinopathy descriptors, general health and comorbidities, and participant recruitment. These domains represent a spectrum of important participant characteristics to assist clinicians in deciding whether the results of interventional trials are applicable to their patients. For completeness, we also extracted data on characteristics which did not reach consensus at the ISTS including sleep, pain location (number of pain sites, unilateral versus bilateral), nicotine use, socioeconomic factors, and psychological variables. Data pertaining to the eligibility criteria used across the included studies were also extracted. Since there are no consistent definitions to discriminate between inclusion and exclusion criteria (Van Spall et al., 2007), we preferred the term eligibility criteria to describe predetermined criteria whereby patients were recruited into trials (Koog et al., 2013).

A data extraction sheet (Microsoft Excel) was used to extract the data following identification of eligible studies. Prior to extraction of the data, the two reviewers (SMA and KOS) pilot tested the data extraction template using five randomly chosen trials from the review.
2.6. Assessment of risk of bias

A comprehensive assessment of bias was conducted in the accompanying primary review on efficacy (CRD42018110086 - https://www.crd.york.ac.uk/prospero/displayrecord.php?ID=CRD42018110086). However, this is not presented here, as treatment outcomes were not assessed in this review.

2.7. Data analysis

Descriptive statistics were used to summarise the findings for both the eligibility criteria used and the degree to which participant characteristics were reported in line with the ICON recommendations. Adobe illustrator software, a vector graphics editor, was used to generate graphical representation of the data.

3. Results

3.1. Search results

The primary search resulted in 13,862 potential eligible studies after removal of duplicates. Following screening of the abstracts 123 full-text papers were assessed for suitability with 45 studies finally included in the review. This process is presented in the PRISMA (Shamseer et al., 2015) flowchart (Fig. 1).

A detailed description of the data extracted from each of the 45 included randomised controlled trials is provided in the supplementary file 1.

The review included studies investigating rotator cuff tendinopathy (n = 13), lateral elbow tendinopathy (n = 15), Achilles tendinopathy (n = 9), gluteal tendinopathy (n = 2), plantar fasciopathy (n = 3), and patellar tendinopathy (n = 3). The total sample size of the 45 studies included in the review was 3,632, with a mean sample size of 81.

Considerable variation existed in relation to the degree of reporting of participant characteristics across the included studies, with some characteristics (e.g. age, sex, duration of symptoms) reported very frequently (>75%) whereas others (e.g. history of tendinopathy, medication use, comorbid health complaints, sleep) were reported very infrequently (<25%).

The reporting of the relevant participant characteristics across three of the four domains are summarised in Fig. 2. The remaining domain outlining the participant recruitment and eligibility criteria is displayed further in Fig. 5, and discussed further in the results.

Age and sex were commonly reported across the review, with a mean (SD) participant age of 46 (7.7) years (median 48 years). The sex of the included participants was not reported in 6/45 studies (Cherry et al., 2012; Engebretsen et al., 2009; Koch et al., 2015; Nagrle et al., 2009; Tonks et al., 2007; Yelland et al., 2019) with the majority of studies using a mixed sample, with an almost even breakdown in male:female ratio (Males 1618; Females 2014). Height and weight were reported in only 14/45 and 13/45 studies respectively, with a mean of 173 cm and 78 kg for height and weight respectively.

3.1.2. Severity of symptoms

The majority (38/45) of studies reported baseline measures of severity, predominantly pain severity using a visual analog or numerical rating scale. There was large variability regarding the context of pain severity reported, including: pain over the past 24 h, pain during activity, pain over the past week, load induced pain, and pain with gripping. Details of the severity of symptoms reported across the included studies and tendon sites is specified in detail in online supplementary file 1.

3.1.3. Disability

Measures of disability were commonly reported in 42/45 studies, while the remain 3 studies did not specify the use of a disability outcome measure (Rompe et al., 2009) (Knobloch et al., 2007) (Wen et al., 2011). Several disability outcome measures were reported within, and between tendon sites. For the shoulder the most common disability measure reported was the Shoulder Pain and Disability Index (SPADI) in 4/13 of the included studies with a mean score of 48 (A score of 0 indicates best 100 indicates worst. A higher score shows more disability). In relation to lateral elbow tendinopathy the Patient Rated Tennis Elbow Evaluation Questionnaire was the most commonly reported in 4/15 studies with a mean score of 39 (scored out of 50 with higher scores indicating higher disability). The Victorian Institute of Sport Assessment VISA was the most commonly used outcome in the Achilles (5/9) and Patellar tendinopathy (3/3) studies with means of 52 and 61 reported amongst included participants respectively (scored 0–100 with higher scores indicating less disability). Finally, disability measured varied considerably for gluteal tendinopathy and plantar fasciopathy studies. A summary of the disability outcomes used across the included studies is presented in Table 3, with additional information on the disability outcome measures across the included studies provided in the online supplementary file 2.

3.1.4. Loading tests

Objective loading tests were a common feature of the clinical examination specified in 27/45 studies. Interestingly, studies of some tendon sites appeared more likely to incorporate loading tests as part of the clinical examination. For example, all elbow (15/15 studies, three loading tests), all gluteal (2/2 studies, 6 loading tests) and most, or the majority of rotator cuff tendinopathy studies...
Included objective loading tests. In contrast, a very different approach was seen in the knee, ankle and foot where no Achilles (0/9 studies) or plantar fascia (0/3 studies) study specified a loading test, instead reporting a subjective confirmation of pain during loading tasks (Fig. 4).

ROM: Range of motion; FABER Flexion Abduction External Rotation; FADER Flexion Adduction External Rotation.

3.1.5. Previous history of tendinopathy

Only 6/45 included studies provided details on previous symptoms of tendinopathy amongst participants (Yelland et al., 2019) (Bisset et al., 2006; Peterson et al., 2011; Smidt et al., 2002; Winters et al., 1997; Yelland et al., 2011). A further study by Struijs et al. (Struijs et al., 2004a) reported recording previous symptoms but did not provide any details.

(iii) General health and comorbidities

3.1.6. Physical activity

Physical activity level was reported in 17/45 studies, most commonly in lower limb tendon sites (11/17 studies), especially the Achilles tendon (7/9 studies). Little detail was provided on the level, type or duration of time spent engaging in physical activity, with most studies only reporting the type of physical activity participants were engaged in (online supplementary file 1).

3.1.7. Sleep

No study explicitly provided details on sleep variables amongst participants in the review. However, one study by Vuvan et al. (Vuvan et al., 2019) reported the percentage of participants with sleep disturbed by pain.

3.1.8. Psychological factors

Only two studies (Mellor et al., 2018) (Engelbrehtsen et al., 2011) provided details on psychological factors (pain catastrophising, pain self-efficacy and emotional distress).

3.1.9. Medication at baseline

Medication use at baseline amongst participants was reported in 8/45 studies (Engelbrehtsen et al., 2009) (Rompe et al., 2009) (Knobloch et al., 2007) (Smidt et al., 2002) (Bennell et al., 2010; Engelbrehtsen et al., 2011; Hay et al., 1999; Murtezani et al., 2015).

3.1.10. Co-morbid health complaints

Co-morbid health complaints were reported in only 10/45 studies (Knobloch et al., 2007) (Smidt et al., 2002) (Winters et al., 1997) (Struijs et al., 2004a) (Mellor et al., 2018) (Chester et al., 2008; Hay et al., 1999; Kearney et al., 2013; Murtezani et al., 2015; Piirimäki et al., 1996). The most commonly reported co-morbid health complaint was co-morbid pain (Rompe et al., 2009) (Smidt et al., 2002) (Hay et al., 1999) (Chester et al., 2008) (Struijs et al., 2004b). A key consideration which will be covered in more detail further in the manuscript is that many studies excluded participants with co-morbid health complaints, such as people with concurrent musculoskeletal or systemic complaints (Fig. 5).

3.1.11. Sociodemographic factors

Sociodemographic factors, usually relating to employment status and educational level, were reported in 11/45 studies.

(iv) Participant recruitment.
Participant characteristic domains proposed by ISTS recommendations

Fig. 2. Percentage of eligible studies which detailed participant characteristics across three domains.

(i) Participant demographics
3.1.12. Recruitment source and setting
Details in relation to the recruitment source were provided in 40/45 studies, (Bae et al., 2011; Ersen et al., 2017; Liu et al., 2014; Rompe et al., 2010; Walther et al., 2004). The most common recruitment strategies utilised included general practitioner referral and recruitment using email, poster or flyer adverts. Trials most commonly took place in community outpatient clinics and University clinics. Details summarising the recruitment source and strategy used are outlined in the online supplementary file 1.

3.1.13. Eligibility criteria
In addition to providing information on the four domains recommended at ISTS, (Vicenzino, de Vos, & Alfredson, 2019), the eligibility criteria used in the trials were also extracted. Substantial variation existed between studies in the specific eligibility criteria used (Fig. 5).

Many studies (24/45) specified age in the eligibility criteria, commonly limiting to participants aged between 18 and 75 years. One study by Nejati et al. (Nejati et al., 2017) outlined a minimum age of 40 years, while another study by Visnes et al. (Visnes et al., 2005) included participants between 18 and 35 years old. Ten studies in the review specified a minimum severity of symptoms and/or disability for inclusion (Yelland et al., 2019)( Cherry et al., 2012)( Visnes et al., 2005)( Yelland et al., 2011)( Vuvan et al., 2019)( Bennell et al., 2010)( Rompe et al., 2010)( Lombardi et al., 2008)( Roos et al., 2004). The minimum level of severity specified for inclusion varied across tendons and was based on both

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Fig. 3. Disability outcome measure reported.

Fig. 4. Loading tests reported as part of the clinical examination.
subjective patient reported questionnaires (Patient Rated Tennis Elbow Evaluation (PRTEE), Victorian Institute of Sport Assessment (VISA-A)) and severity of pain during a clinical examination (Yelland et al., 2019) (Cherry et al., 2012) (Visnes et al., 2005) (Yelland et al., 2011) (Vuvan et al., 2019) (Mellor et al., 2018) (Bennell et al., 2010) (Rompe et al., 2010) (Lombardi et al., 2008) (Roos et al., 2004). 31/45 of the studies included in the review specified a minimum duration of symptoms for inclusion of participants, varying from 4 weeks to >3 months. Participants were often excluded based on the presence of concurrent systemic (21/45) or musculoskeletal and neurological disorders (29/45). The precise systemic disorders excluded varied but included: infection, tumor, diabetes mellitus, severe cardiac disease, local arthritis, thrombopathy, and rheumatological complaints. A number of musculoskeletal and neurological disorders were specified as exclusion criteria: chondromalacia, muscle strains, pain at another site, and radicular pain. In addition, 17/45 excluded participants based on traumatic injury (mainly fractures), 9/45 studies excluded participants with arthritic conditions, 9/45 studies excluded participants with bilateral tendon complaints, 4/45 excluded pregnant participants, and 4/45 excluding participants with the presence of insertional tendinopathy in Achilles tendinopathy trials.

4. Discussion

Multiple factors may determine the external validity and clinical effectiveness of RCT’s, namely: patient characteristics, costs, compliance, co-morbidities, and concomitant treatments (Gartlehner et al., 2006). Findings of this systematic review suggest that the reporting of participant characteristics in randomised controlled trials investigating exercise for tendinopathy is suboptimal. The eligibility criteria used in these RCTs varied considerably between studies and were often restrictive, which may not reflect the typical presentation in clinical practice. The current review highlights that beyond knowing that the individuals in these trials were mostly adults (mean 46 years), both male and female, with symptoms for an average of 15 months, we can be confident about little else as regards participant characteristics. We acknowledge that inadequate reporting of participant characteristics is not unique to the topic of tendinopathy with similar issues identified in other MSK disorders such as low back pain (Wertli et al., 2013) (Chevan & Haskvitz, 2015). Nevertheless, the suboptimal reporting of participant characteristics, and the eligibility criteria utilised, have important clinical implications for the generalisability of findings from RCTs of exercise in tendinopathy.

4.1. Knowledge of loading demands to ensure targeted loading interventions

Tendinopathy is a challenging and complex MSK disorder, affecting a broad spectrum of athletic and non athletic populations (Albers et al., 2016) (Challoumas et al., 2019; Johannsen et al., 2018; Van Middelkoop et al., 2008). Exercise interventions are commonly recommended in the management of tendinopathy (Malliaras et al., 2013) (Desmeules et al., 2016; Murphy et al., 2018a, 2018b). Despite the relative success of exercise interventions to date, the associated outcomes indicate exercise is far from a panacea. Chronic symptoms persist in approximately a quarter of patients 10 years after treatment, with tendinopathy impairing both quality of life and physical activity (Ceravolo, Gaida, & Keegan, 2018) (van der Vlist, Winters, & Weir, 2020). In fact, in individuals with Achilles tendinopathy as many as 60% experience continued symptoms, around 40% develop contralateral symptoms, while up to 50% rate their satisfaction following treatment as moderate-poor (Gajhede-
people are most likely to respond to exercise, and/or what might constitute optimal content of an exercise programme (Tseli et al., 2019) (Holden et al., 2018).

4.3. What can be done to address inadequate reporting of participant characteristics in tendinopathy trials?

Exercise is often the conservative treatment of choice in tendinopathy. Despite the positive effects of exercise interventions, the response to these interventions is variable across tendons and even within tendon sites (Van der Plas et al., 2012) (Hudák et al., 1996) (Waugh et al., 2004). It is reasonable to suggest that the observed variability an effectiveness of treatment to date in tendinopathy may relate to inadequate knowledge and consideration of individual participant characteristics. Published trials to date have focused on implementing treatment protocols used strict eligibility criteria for a short period of time. Although this helps inform the efficacy of these interventions, it does little to inform the generalisability of the findings, leading the observed effects in trials to date.

In order to assist with the challenge of determining the generalisability of research findings in exercise trials it is important to document and adequately describe the characteristics of the participant sample in a given trial. In addition it is also important to document the range of exercise variables used within an exercise trial. Ideally this would include information regarding the frequency, intensity, type, of the prescribed exercise, as well as details on exercise adherence and any adverse events. In order to assist with this need for adequate documentation various checklists and reporting templates such as the Consolidated Standards of Reporting Trials (CONSORT) and the Consensus on Exercise Reporting Template (CERT) have been developed to improve the quality and transparency of reporting in exercise trials (El-Kotob & Giangregorio, 2018; Schulz et al., 2010; Slade et al., 2016).

4.4. Limitations

Several potential limitations should be acknowledged. Firstly, this was a secondary analysis of an ongoing systematic review investigating the efficacy of exercise interventions in tendinopathy. The review included studies that compared the effectiveness of exercise interventions to non exercise interventions in tendinopathy, thus potentially there are many more exercise intervention trials that compared different exercise interventions to each other, so we cannot say how the findings of this review reflects those trials, but we expect similar issues arise. Secondly, the domains of participant characteristics reported in the review were based on a modification of the recommendations made by the ISTS Consensus meeting in 2018. Is conceivable the additional domains may be important to report, and could be investigated in future.

5. Conclusion

The findings of this systematic review demonstrated that participant characteristics are poorly reported in exercise trials in tendinopathy. This includes information on participant demographics, tendinopathy descriptors, general health, and participant recruitment. Furthermore, individuals are often excluded from tendinopathy trials due to the presence of characteristics which are common, and are known to influence outcomes in MSK pain, such as co-morbid health complaints. This greatly limits our ability to ascertain the applicability of the findings from exercise trials into clinical management of tendinopathy. To improve effectiveness of exercise interventions in tendinopathy, better reporting of participant characteristics may allow better comparisons and targeted interventions for specific subgroups.
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Declaration of competing interest
None to declare.

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Appendix A. Supplementary data
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