Outcome Measures Used in the Evaluation of Gluteal Tendinopathy: A scoping review protocol

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Introduction

Gluteal tendinopathy (GT) is a condition characterized by lateral hip pain that is aggravated by weight bearing on the affected leg, pain with palpation over the greater trochanter and difficulty lying on the affected side. Tendinopathy of the gluteus medius and/or minimus tendon/s may be accompanied by changes in the adjacent bursae and fascia.[1-4] GT refers to pain associated with these local soft tissue sources of nociception and does not include referred pain from the trunk, abdomen, pelvis or lumbar spine. This condition is prevalent in older adults, particularly in peri- and post-menopausal women, with substantial impacts on quality of life [5] and healthcare demands. The number of studies investigating interventions targeting the population suffering with this condition is growing, and yet there is wide variation in both patient-rated and physical measures selected for evaluating outcomes. Selection of outcome measurement instruments that have not been recommended, developed or validated for use in specific populations, or selection of instruments from only a limited number of health-related outcome domains, may bias outcome reporting [6, 7]. Homogeneity in selection and reporting of outcomes is important for interpretation and comparison of outcomes of interventions [8]. This is critical for allowing meta-analyses which form the basis for evidence-informed practice [9] (Williamson et al 2017). Therefore, a need exists to define a core outcome set (COS) of validated outcome measures that evaluate established core health-related domains.

A Delphi study of healthcare professionals and researchers with expertise in the field of tendinopathy, with additional consultation with patients with tendinopathy at varying anatomical locations, established a tendinopathy-specific core domain set of 9 items (patient rating of condition, participation in life activities, pain on activity/loading, function, psychological factors, physical function capacity, disability, quality of life and pain over a specified time) [10], providing the foundation for subsequent identification of a COS for specific tendinopathies.

In order to develop and disseminate a COS specific for GT, a necessary first step is to identify all reported outcome measures currently used in studies of people with GT. Once identified, these instruments will be assessed for quality and fit to the previously identified outcome domains before undergoing a 3-stage Delphi process with two online surveys and a face-to-face consensus meeting of those healthcare professionals involved in studying and/or clinicians with recognised expertise in managing people with GT, as well as patients with GT, to establish the COS for GT.

Objective

This scoping review addresses the question of 'What outcome measures have been used in evaluating people with Gluteal Tendinopathy?' It aims to identify and provide an overview of the outcome measures used to assess and evaluate interventions in those with GT. This is a necessary first stage in the systematic development of a COS for GT.

Ethics

Since a scoping review aims at synthesizing information from available publications, this study does not require ethics approval.

Protocol Design

The scoping review will be informed by the framework recommended by the Joanna Briggs Institute [11], which provides recommendations for organisation of the review process, including an initial identification of the research question and then relevant studies, data extraction and presentation and interpretation of results. The research question for this study is:

What outcome measures have been used in evaluating people with Gluteal Tendinopathy?

Identifying relevant studies

It is important to initially identify the criteria that will be used to select the studies for inclusion. Although this scoping review is designed to cover a very broad spectrum of literature, initial criteria will be established to help guide the search.

Inclusion Criteria

Types of participants

In order to identify articles that will address the aims of this review, the included papers must indicate that a clinical diagnosis of GT has been made. Due to the discrepancies and development over the years of acceptable terminology for the condition, studies that use the terms GT, greater trochanteric pain syndrome, lateral hip pain, abductor tendinopathy and trochanteric bursitis will be included. The diagnosis may be a clinical diagnosis, with or without radiological confirmation. Participants in the studies must be aged 18 years and over, and studies must have a minimum sample size of ten participants.

Concept

As the objective of this scoping review is to identify all existing outcome measures employed in studies of people with GT, all studies that report the outcome measure used, or a specific outcome measurement instrument will be included. All outcome measures will be eligible for inclusion.

The source of the information will be left open, in order to allow for the inclusion of all types of studies. Thus, the study design may include any of the following:

- Randomised controlled trials, observational cohorts, single-arm intervention (cohort) studies, case series, longitudinal or prognostic studies, and systematic reviews (in order to cross check reference lists to identify further papers)
- Protocol papers
- Papers relating to the development of condition specific outcome measures.
- Studies assessing impairments (e.g. Strength, kinetics, kinematics, electromyography and sensory impairments), or activity and participation limitations.
- Any intervention studies in which a treatment outcome for GT has been measured, providing outcome measures are reported. Interventions may include (but are not limited to) advice/education, exercise, injection (corticosteroid, platelet rich plasma (PRP), autologous blood injection (ABI), stem cell injection), surgery, shockwave therapy, dry needling and medication.

Context

There will be no restriction on the context of the papers, thus any specific setting of research will be accepted (such as acute care, primary health care or the community).

Exclusion criteria

Papers in languages other than English will be excluded due to limited resources and the cost of funding for translation services. Additionally, when a full text article is not available for review, the paper will be excluded.

Other types of papers that will be excluded include animal studies and in-vitro experiments, diagnostic utility papers, trial registrations, case reports, surgical technique papers, opinion pieces or clinical papers, studies that examine the risk of developing the condition (risk factor studies), papers that use only imaging (e.g. MRI, ultrasound) parameters as outcome measures, and papers that report on trochanteric pain or tendon pathology that is associated with infective or systemic/rheumatological conditions.

Search Strategy

The literature search will be performed by a librarian from the Biological Sciences Library, University of Queensland, Australia, who will help advise on the most appropriate Medical Subject Headings terms for the search and how they should be modified for the different databases. The search strategy will be as comprehensive as possible, to identify both published and unpublished (grey literature) studies, as well as reviews.

Relevant key words and index terms will be identified and established and used to undertake searches across all relevant databases. These key words will be based on a brief preliminary review of key articles that encompass research on interventions for management of GT.

The online data bases to be searched will be Cochrane, PubMed, EMBASE, Scopus, Web of Science, PEDro, CINAHL, and SPORTDiscus. In order to capture outcome measures reported in the grey literature, Proquest dissertations and Theses Global, NICE, OpenGrey, and Google will be searched.

All identified articles will be collected in Endnote and imported into Covidence (a web-based software platform to streamline the production of systematic reviews: www.covidence.org). Duplicates will be removed firstly by using an inbuilt function in Endnote, then manual screening of the Endnote library by one of the reviewers, and finally after exporting into Covidence, using an inbuilt function.

Study selection

The initial screen will be by title and abstract examination, performed by members of the research team. Each article will be screened by two reviewers independently, and any disagreements will be resolved by a third reviewer. The selection of articles will be based on the pre-specified inclusion and exclusion criteria. For all articles appearing to fulfil the eligibility criteria, the full article will be retrieved.

Full texts will then be examined by two independent reviewers, and any disagreements will be resolved firstly by discussion and if necessary, a third reviewer will be decisive. Additionally, the reference lists of the included full text articles will be examined to determine if any relevant study has not previously been identified by the search.

The process of the study selection will be reported using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart (PRISMA) [12].

The search strategy for some of the included data bases has been included as an appendix.

Data Extraction

Once all relevant articles have been identified, the data extraction process will be performed by all members of the team of researchers. A draft charting table has been developed in Excel in order to record key information from the identified studies. It is likely that this table will be further refined throughout the process of review and updated as necessary. (Appendix X)

In addition to standard bibliographical information (e.g. author, title, journal, year of publication), for each article, information on the characteristics of the study populations, definitions of the outcomes measured and the outcome measurement instruments used, how they were obtained and any information on the validity of the outcome measures will be obtained. Contact information for the corresponding author/s will also be extracted in order to contact researchers in this field for the subsequent Delphi process.

Key information that will initially be charted includes:

- Authors
- Year of publication
- Title
- Contact details of corresponding author

- Journal/source
- Type of study
- Total number of GT participants included
- Age, BMI/height/weight
- Bilateral/unilateral symptoms
- Diagnostic criteria for diagnosis of GT
- Imaging used for confirming clinical diagnosis (if applicable)
- Mean duration of symptoms
- Outcome definitions –verbatim definitions of 'what' was measured e.g. pain, gait speed.
- Outcome measurement instrument(s) – verbatim definitions of outcome measurement instruments used
- How the outcome measurement instrument(s) was/were obtained
- Outcome measurement time points
- Intervention type
- Whether assessment of validity of outcome measures used were reported, studied or absent
- Whether reliability of the outcome measures used were reported, studied or absent

This extraction framework will be tested by two members of the research team on a small sample of the included studies in order to ensure consistent application of the coding framework. Any questions arising during this testing process will be discussed by the team, and the data extraction framework revised accordingly.

Two members of the team will then independently chart the data from each included study, following the agreed extraction framework. Early in this process, a small sample of the included articles independently reviewed will be compared by another member of the team (in order to ensure inter-rater reliability). Any discrepancies found in the extracted data will be discussed between the two reviewers until consensus is reached, or by arbitration of a third reviewer if necessary.

Presentation of Results

The results from this scoping search fulfil a first necessary step in the development of a COS for GT, within a five-stage process. The data collected from this scoping review will provide information on the scope and extent of outcome measures reported in the literature used in studies investigating GT. The outcome measures identified will be tabulated and matched to one of the previously established core domains for tendinopathy [10], as the next stage in the process. This information will be used to design an online Delphi survey in which an international panel of health care professionals (researchers and clinicians) and patients with GT will evaluate

the Truth and Feasibility of the identified outcomes measures, before proceeding through the further stages of development. The results of this scoping review will be presented in an aggregate and visual form (using tables and charts, as appropriate), Figure 1 and Table 1.

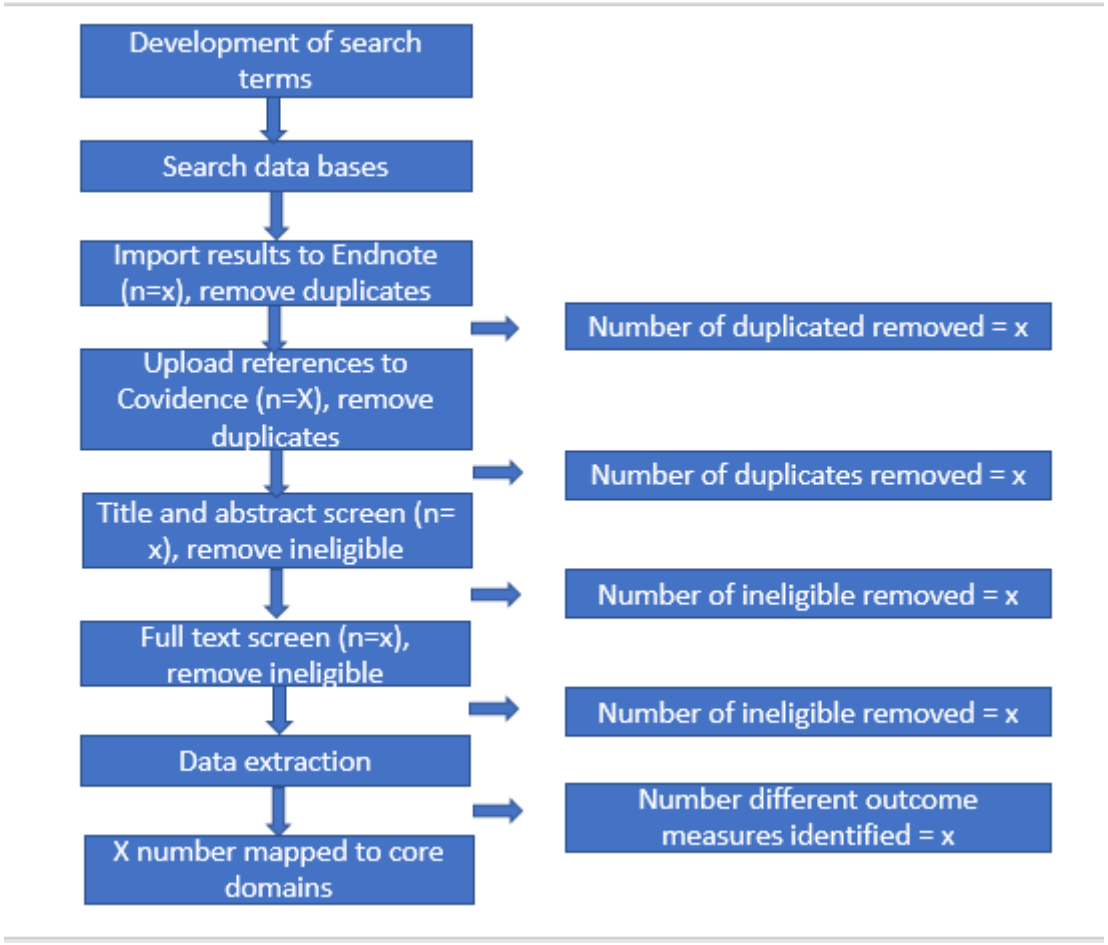

Figure 1 PRISMA Diagram of Flow Through Study. This figure illustrates the process of identifying relevant outcome measures.

Table 1 Summary of Outcome Measures Identified, their Reliability and Validity, and Draft Mapping to Core Tendon Domains.

Clinical outcome measured, e.g. pain	Outcome Measurement Instrument	Reliability	Validity	Draft identification and mapping to core domain
Pain	VAS	ICC: 0.98	Face, construct, criterion	pain on activity/loading
Pain	NRS	ICC: 0.96	Face, construct, criterion	pain on activity/loading

APPENDIX

Search Strategy for Selected Data Bases

PubMed

(“Gluteal tendinopathy" OR "Greater trochanteric pain syndrome" OR abductor tendinopathy OR "lateral hip pain" OR “trochanteric bursitis” OR (GTPS NOT (Guanosine-triphosphate OR "green tea" OR "grapevine trunk pathogens")) OR ((gluteal OR "gluteus medius" OR "gluteus minimus") AND (tendinitis OR tendonitis OR tendinosis OR tendinopathy OR “tendon pathology” OR enthesis OR enthesopathy OR tear OR tendon)))

AND

("therapy"[Subheading] OR "therapy"[All Fields] OR treat*[All Fields] OR "interventions" OR "intervention" OR "managements" OR "management" OR "manages" OR "managed" OR "manage" OR "rehabilitation"[Subheading] OR "rehabilitation"[All Fields] OR "rehabilitation"[MeSH Terms] OR "rehab"[All Fields] OR physiotherapy OR "physical therapy")

EMBASE

'gluteal tendinopathy'/exp OR 'gluteal tendinopathy' OR (gluteal AND ('tendinopathy'/exp OR tendinopathy))

OR 'greater trochanteric pain syndrome'/exp OR 'greater trochanteric pain syndrome'

OR 'abductor tendinopathy' OR (abductor AND ('tendinopathy'/exp OR tendinopathy))

OR 'lateral hip pain'

OR 'trochanteric bursitis'/exp OR 'trochanteric bursitis' OR (trochanteric AND ('bursitis'/exp OR bursitis))

OR gtps NOT ('guanosine triphosphate'/exp OR 'guanosine triphosphate' OR 'green tea'/exp OR 'green tea' OR 'grapevine trunk pathogens')

OR (gluteal OR 'gluteus medius' OR 'gluteus minimus') NEAR/4 (tendinitis OR tendonitis OR tendinosis OR 'tendon pathology' OR enthesis OR enthesopathy OR tear OR tendon)

AND

'therapy' OR treat* OR 'intervention'/exp OR intervention OR 'interventions'/exp OR interventions OR 'management'/exp OR management OR managements OR manages OR managed OR manage OR 'rehabilitation'/exp OR rehabilitation OR rehab OR 'physiotherapy'/exp OR physiotherapy OR 'physical therapy'/exp OR 'physical therapy'

Scopus

(("Gluteal tendinopathy" OR "Greater trochanteric pain syndrome" OR "abductor tendinopathy" OR "lateral hip pain" OR "trochanteric bursitis") OR ((gtps) AND NOT (guanosine-triphosphate OR "guanosine triphosphate" OR "green tea" OR "grapevine trunk pathogens")) OR ((gluteal OR "gluteus medius" OR "gluteus minimus") AND (tendinitis OR tendonitis OR tendinosis OR tendinopathy OR "tendon pathology" OR enthesis OR enthesopathy OR tear OR tendon))) AND ("therapy" OR treat* OR "interventions" OR "intervention" OR "managements" OR "management" OR "manages" O

R "managed" OR "manage" OR "rehabilitation" OR "rehabilitation" OR "rehab" OR physiotherapy OR "physical therapy")

SPORTDiscus

("Gluteal tendinopathy" OR "Greater trochanteric pain syndrome" OR "abductor tendinopathy" OR "lateral hip pain" OR "trochanteric bursitis")

OR gtps NOT (guanosine-triphosphate OR "guanosine triphosphate" OR "green tea" OR "grapevine trunk pathogens")

OR (gluteal OR "gluteus medius" OR "gluteus minimus") AND (tendinitis OR tendonitis OR tendinosis OR tendinopathy OR "tendon pathology" OR enthesis OR enthesopathy OR tear OR tendon)

AND ("therapy" OR treat* OR "interventions" OR "intervention" OR "managements" OR "management" OR "manages" OR "managed" OR "manage" OR "rehabilitation" OR "rehabilitation" OR "rehab" OR physiotherapy OR "physical therapy")

Grey Literature

Proquest Dissertations and Theses Global; NICE; OpenGrey; Google; Pedro

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