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🌐 Reproducibility of the reporting of post-operative anterior cruciate ligament reconstruction rehabilitation programmes: a scoping review

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Sebastiano Nutarelli[1], Nicol Van Dyk[2,3], Chad Cook[4], Gabriele Severini[5], Catherine Blake[1], Eamonn Delahunt[1,6]

[1]School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin, Ireland;
[2]High Performance Unit, Irish Rugby Football Union, Dublin, Ireland. Section Sports Medicine;
[3]Faculty of Health Sciences, University of Pretoria, Pretoria, South Africa;
[4]Division of Physical Therapy, Duke Clinical Research Institute, Duke University, Durham, NC, United States;
[5]School of Electrical and Electronic Engineering, University College Dublin, Dublin, Ireland;
[6]Institute for Sport and Health, University College Dublin, Dublin, Ireland

👤 **Sebastiano Nutarelli**
School of Public Health, Physiotherapy and Sports Science, U...

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Abstract

Rupture of the anterior cruciate ligament (ACL), the primary stabilizing ligament of the knee joint, is one of the most significant problems in orthopaedic sports medicine with an annual incidence of 71 to 91 per 100,000 persons reported in some European Union (EU) countries (Granan et al, 2009). Taking the population of the EU countries as 500,000,000 the annual incidence of ACL ruptures equates to approximately 450,000 per year in the EU, with an associated approximate direct medical cost of > €4 billion. This cost estimate does not take into account further economic sequelae such as lost productivity and medical costs associated with the development of post-traumatic knee joint osteoarthritis (OA).

For athletes aiming to return-to-sport after ACL rupture, ACL reconstruction (ACL-R) is the recommended treatment of choice. The aim of ACL-R is to maximise the stability and functional capacity of the ACL-deficient knee, with an objective of facilitating return-to-sport. Clearance for return-to-sport indicates the medical team's confidence in the athlete's ability to participate in sporting activities that place large demands on knee joint sensorimotor control. However, the prevalence of ACL re-ruptures following primary ACL-R is increasing worldwide (Wright et al, 2011; Ratzlaff et al, 2010) with a prevalence of 6% to 25% being reported (Myklebust et al, 1997; Grassi et al., 2017). A conservative estimate of a re-rupture rate of 11.5% this would mean that there would be > 40,000 ACL re-ruptures per year in the EU, equating to an annual direct operative cost of €400,000,000.

Surgical intervention and postoperative rehabilitation program concur to the final outcome following ACL-R, therefore they should both be evaluated. While details of different surgical ACL-R procedures and grafts options have been extensively described and weighted in the literature, postoperative rehabilitation protocols are poorly described; their actual level of replicability is unclear.

Physical therapy following ACL-R is key to re-establish the pre-operative functional abilities and recover from the insult to the whole joint and lower limb complex associated with the combination of the initial injury and surgical procedure. This takes place with a peculiar neuromuscular control re-training, regaining the different muscle strength sub-components, functional stability, balance, psychological readiness through repetitively practicing sports-specific/athletic movements in a progressive ecologically valid environment, and testing for return to sport to eventually minimize the risk for re-injury.

Regardless the recognized pivotal role of post-surgical rehabilitation, yet paradoxically there is no universally accepted rehabilitation paradigm following ACL-R which pinpoints the cornerstones of such a long and crucial journey. Despite multiple publications on this topic, studies are characterized by an average poor level of reporting possibly invalidating the possibility to replicate programs. The aggregation of data on this topic could establish whether there's a sufficient and consistent level of evidence to guide practicing clinicians in replicating a postoperative rehabilitation protocol for patients following ACL-R or there's need for further and more solid clinical research in order to empower clinicians to implement a solid Evidence-Based Practice after ACL-R. The study protocol (PRISMA-P) and a protocol table following *Arksey & O'Malley (2005)* and *Levac et al (2010)* have been completed.

Guidelines

1) The authors adhere to the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P) reporting guidelines (**http://www.prisma-statement.org/** - https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/2046-4053-4-1) in the preparation and reporting of the current scoping review

2) The current scoping review will be developed upon a protocol table following the study published by Arksey & O'Malley (2005): https://www.tandfonline.com/doi/abs/10.1080/1364557032000119616

3) The current scoping review will be developed upon a protocol table following the study published by Levac et al. (2010): https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-5-69

4) The current scoping review will be modeled on the following review published by Reiman et al. (2002): **https://pubmed.ncbi.nlm.nih.gov/32272028/**

Protocol and Registration

1   The authors developed the protocol and made it public by registering it on protocols.io.

Methods

2   Our study protocol is prepared in accordance with the PRISMA Extension for systematic reviews. Additionally, we drafted this article according to the 5-stage methodological framework for scoping reviews described by Arksey & O'Malley.

1. Stage #1: Identifying the question
2. Stage #2: Identifying the relevant literature
3. Stage #3: Study selection and data collection processes
4. Stage #4: Data charting
5. Stage #5: Collating, summarizing, and reporting results

Research Question

3   Our scoping review aims to evaluate the reproducibility of reporting of post-operative physical therapy rehabilitation programmes in published studies describing surgical interventions (anterior cruciate ligament reconstruction surgery) for patients with a primary anterior cruciate ligament rupture.

The research question is: what is the reproducibility of reporting of ACL-R post-operative rehabilitation programmes in published studies describing ACL-R for patients with a primary ACL rupture?

The PICO elements of the title are outlined as follows:

Participants: *"patients with a primary anterior cruciate ligament rupture"*.

Interventions: *"anterior cruciate ligament reconstruction surgery"*.

Comparators: Not applicable.

Outcomes: *"the* reproducibility *of reporting of post-operative physical therapy rehabilitation programmes"*.

Identifying Relevant Literature

4   Studies will be imported from the MEDLINE, Web of Science, the Cochrane Library, and Scopus databases
into EndNote (New Jersey Institute of Technology University Heights, Newark, NJ). All duplicates will be removed with the automatic EndNote function and then through an additional manual check performed by one author (SN). All studies will then be imported from EndNote into the systematic review software,
'Rayyan'. Further duplicates will be discarded, and the remaining studies will be classified as "potentially eligible". One author will perform the selection of studies for inclusion. He will screen the titles and abstracts of the "potentially eligible" studies to assess their eligibility for inclusion. Studies are considered for inclusion based on their fulfillment of the pre-specified eligibility criteria (see eligibility criteria). Full-length texts of remaining peer-reviewed articles will be sought and reviewed to determine their eligibility if there is uncertainty about their eligibility from title and abstract screening.

The eligibility criteria are detailed as follows:

- *Study design:* either prospective or retrospective intervention studies such as case series, clinical studies, clinical trials, comparative studies, controlled clinical trials, observational studies, pragmatic clinical trials, and randomized controlled trials;
- *Language:* only articles published in English were considered;
- *Publication status:* full-text article published in peer-reviewed journals;
- *Sample size:* minimum of 20 patients;
- *Clinical question* (studies fulfilling the following criteria framed according to PICO): studies reporting post-operative rehabilitation following ACL-R (rehabilitation included) for patients with a primary ACL rupture.

To be deemed eligible for inclusion, studies will be required to fulfil the following criteria (framed according to **PICO**):

- **P**articipants: *"patients with a primary anterior cruciate ligament rupture"*.
- **I**nterventions: *"anterior cruciate ligament reconstruction surgery"*.
- **C**omparators: Not applicable.
- **O**utcomes: *"the reproducibility of reporting of post-operative physical therapy rehabilitation programmes"*.

Study Selection

5   The search strategy will be applied across electronic bibliographic databases (PubMed, Web of Science, the Cochrane Library, and Scopus). The search terms will be mapped to Medical Subject Headings (MeSH) terms where possible. Search terms will be applied from conception of each database to July 2022. The reference lists of included articles will be hand searched to identify other potentially relevant articles.

The following is an example of the search to be conducted on the PubMed database:

The following string has been filtered in PubMed including (Case Reports, Classical Article, Clinical Study, Clinical Trial, Comparative Study, Controlled Clinical Trial, Multicenter Study, Observational Study, Pragmatic Clinical Trial, Preprint and Randomized Controlled Trial) and articles written in English only.

STRING

("Anterior Cruciate Ligament" OR "ACL" OR "Anterior Cruciate Ligament Reconstruction" OR "ACL Reconstruction" OR "Anterior Cruciate Ligament surger*" OR "ACL surger*" OR "Anterior Cruciate Ligament
injur*" OR "ACL injur*") AND ("physical therapy" OR physiotherapy OR rehabilitation OR exercise OR "exercise therapy" OR recovery)

Study selection will be performed by two reviewers (SN and ED) independently. A third reviewer (CC) will
be consulted to resolve disagreements amongst these reviewers and to facilitate consensus. The two reviewers will independently screen the titles and abstracts of the identified peer-reviewed articles to assess eligibility for inclusion in this review. Studies will be considered for inclusion based on their fulfilment of pre-specified eligibility criteria. Full-length texts of remaining peer-reviewed articles will be sought and reviewed in full to determine eligibility if reviewers are uncertain about their eligibility from title and abstract screening.

Data Extraction (Data Charting Process)

6 A standardized data extraction sheet (created in Microsoft Excel) will be used to extract data. Data extraction will be performed by one reviewer (SN). A second reviewer (ED) will perform data extraction for a proportion of the included studies (10%), as part of a quality assurance process.

Prior to data extraction, two authors (SN, ED) will develop the preliminary domains used to categorize the descriptions of the post-operative rehabilitation programmes. One author (SN) will adapt these domains based on the emerging characteristics of the extracted data observed during the data charting process.

Data will be organized in the following manner:

Study Characteristics:
1. study lead author
2. study title
3. journal

4. year of publication
5. study design
6. level of evidence (using the Oxford, UK CEBM Levels of Evidence)

Participant Characteristics:
1. country in which the study was originally conducted
2. sample size (total included participants, n = …)
3. age of participants (mean age in years, standard deviation of age in years, standard error of age in years)
4. sex of participants (male OR female OR mixed (male and female); n-male (%); n-female (%))
5. level of physical activity (method of quantification; levels)
6. surgical access type
7. graft type (bone-patellar tendon-bone - BPTB, hamstrings - HS, allograft, quadriceps tendon - QT)
8. coexisting lesions at the time of surgery (meniscus tear, cartilage lesions, bone edema, medial/lateral collateral ligament tear, postero-lateral corner injuries)

The reviewers will pilot the above-described charting form on ten studies to determine whether this approach to data extraction is consistent with the research question and purpose.

The outcomes for which data will be sought, including prioritization of main and additional outcomes, will be:

- Prehabilitation (Y/N - if yes what they've done)
- Time to start PT following ACL-R
- Weight-bearing restrictions
- CPM use
- Brace/Orthosis use
- Pain
- Swelling
- Range of motion restrictions
- Range of motion specific regain rehab
- Manual therapy
- Neuromuscular inhibition
- Muscle weakness/strengthening
- Static postural balance
- Dynamic postural balance
- Altered movement patterns
- Walking
- Cycling
- Jogging
- Hopping

- Agility
- Psychological aspects/criteria
- Criteria to be cleared for return to run (RTR)
- Criteria to be cleared for return to restricted training (RTT)
- Criteria to be cleared for return to sport (RTS)

Collating, Summarizing, and Reporting Results

7   All analyses will be conducted in Excel 2016 (Microsoft Corporation, Redmond, WA). Median and ranges or mean ± SD values for continuous variables will be calculated where possible. Demographic information, post-operative restrictions (e.g., weight-bearing, range of motion, bracing and associated prescribed time frames, time to start rehabilitation since surgery, etc.), and rehabilitation indications regarding continuous passive motion, range of motion, time to introduce close vs. open kinetic chain exercises, strengthening progressions, resumption of specific physical activities (e.g., walking, biking, swimming, jumping, hopping, etc.), and criteria for returning to running and sport will be collated and recorded in an Excel spreadsheet. To report the results in an easily accessible format, the elements of the post-operative rehabilitation programmes will be classified under the domains generated through the data-charting process. We will use the template for the intervention description and replication (TIDieR) checklist to evaluate the clinical reproducibility of all included studies. Additionally, the median of the TIDieR scores of the studies specific to each domain (mcTIDieR) will be calculated (TIDieR score of the single studies / the number of studies included per domain) to characterize the final reproducibility of each domain in clinical practice. We will use a "traffic light system" (mcTIDieR score from 0 to 4 = red light/not clear, mcTIDieR 5-8 = yellow light/unclear, mcTIDieR 9-12 = green light/clear) to represent the reproducibility of studies for each of the domains of the post-operative rehabilitation programmes.

Funding

8   There is no funder or sponsor associated with this scoping review.

Protocol references

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