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tREatment of trIaNgular FibrOcaRtilage ComplEx Ruptures (REINFORCER): protocol for randomised, controlled, blinded, efficacy trial of triangular fibrocartilage complex tears

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ABSTRACT

Introduction Triangular fibrocartilage complex (TFCC) tear is often considered to be the cause of ulnar wrist pain. The primary treatment typically involves non-operative methods; however, in cases of persistent symptoms, operative intervention has been proposed as a viable option. Depending on the tear's morphology, treatment may involve debridement (central or radial tear) or repair (peripheral tear). Efficacy of operative treatment has not been studied in a randomised controlled trial.

Methods and analysis This is a prospective, randomised, controlled, blinded multicentre trial, with two randomisation stratums. The first stratum includes central or radial TFCC tears, while the second stratum comprises peripheral TFCC tears. Each stratum consists of two parallel 1:1 arms, comparing the efficacy of (1) debridement of central or radial tear with placebo surgery and (2) repair of peripheral tear with physiotherapy. Participants are recruited from secondary and tertiary referral hospitals in Denmark, Finland and Sweden. Primary outcome is the Patient-Rated Wrist Evaluation (PRWE) at 1 year. Secondary outcomes include subjective and objective outcome measures at 6 months, 1, 2, 5 and 10 years follow-ups.

Ethics and dissemination The trial was approved by the Pirkanmaa Hospital District Institutional Review Board in March 2020. All participants will be asked to give a written informed consent. The results of the trial will be disseminated as published articles in peer-reviewed journals.

Trial registration number NCT04576169.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Rigorous placebo surgery controlled randomised trial.
⇒ Efficacy trial design.
⇒ Wide catchment area for participants.
⇒ Participants in the peripheral tear stratum are not blinded to treatment allocation, which may bias the outcomes.

INTRODUCTION

Background and rationale

The wrist joint is a complex structure comprising the distal radioulnar (DRUJ), radiocarpal and ulnocarpal joints. The stability of the DRUJ is crucial for normal forearm and wrist function, and it is primarily provided by the triangular fibrocartilage complex (TFCC), which also transmits axial ulnocarpal load.[1] The TFCC consists of a triangular articular disc over the distal head and ligaments spanning from the radius or carpal bones to the fovea or styloid of the ulna.[2] These components are susceptible to injuries and degeneration, leading to pain and disability. Tears of the TFCC can be classified as traumatic or degenerative, following the classification suggested by Palmer.[3]

Primary treatment of traumatic TFCC tears is non-operative and may include immobilisation, activity modification, analgesics, cortisone injections and physiotherapy.[4] Immobilisation has been reported to yield good results in TFCC tears.[5] Although physiotherapy is commonly used, there is currently no high-quality research to determine its efficacy in treating TFCC tears. Most publications on this topic are either retrospective comparative studies, case studies or presentations of physiotherapy techniques.[6–8]

Operative treatment options for TFCC tears include debridement,[9] repair[10] or reconstruction,[11] depending on the morphology and healing capacity of the tear.[12] Arthroscopic debridement is commonly employed for stable central TFCC tears, often found in the

fibrocartilage disc lacking healing capacity.[13–15] Debridement is less invasive than TFCC repair, and immobilisation is notably shorter.[16]

After debridement for central-side or radial-side TFCC tear, up to 85% of patients reported pain relief, with mean grip strength and mean arc of motion restored to 94% compared with the unaffected side in non-controlled studies.[17–20] However, it is important to note that the natural course of TFCC tears[21] could explain the findings. There is also controversial evidence that debridement is not an efficient treatment for stable central tears of TFCC.[19] Arthroscopic or open repair is used for peripheral tears because its integrity is thought to be crucial to the stability of DRUJ and the tear is capable of healing.[22 23]

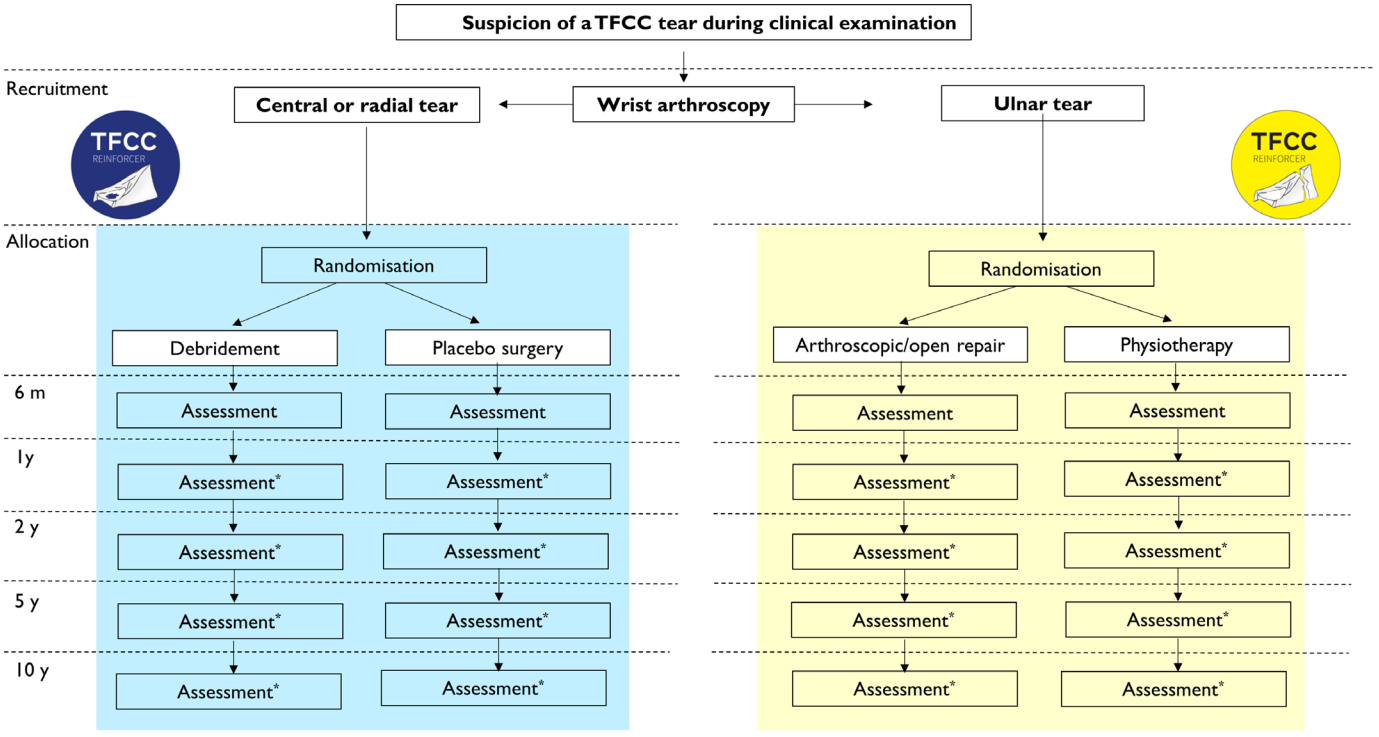
A systematic review conducted by McNamara *et al* showed that none of the techniques—debridement or repair—has been compared with non-operative or no treatment in a randomised controlled trial (RCT).[24] Such trials are rare in the entire field of hand surgery.[25] It is important to note that improvement after surgery without a control group does not provide evidence of efficacy, as is observed in several commonly performed musculoskeletal procedures.[26 27] No evidence of the efficacy of TFCC tear treatment with debridement or repair exists. This emphasises the necessity for an RCT to thoroughly investigate the efficacy of debridement and repair in the treatment of TFCC tears.

Objectives

Our primary objective is to investigate the superiority of (1) debridement over placebo surgery for central (Palmer 1A)[3] and radial (Palmer 1D) TFCC tears and (2) repair over non-operative treatment (physiotherapy) for ulnar (Palmer 1B) TFCC tears (online supplemental material I, table S1) in two randomised cohorts using Patient-Rated Wrist Evaluation (PRWE) at 1-year postrandomisation as the primary outcome. The secondary objectives are to determine if debridement is superior to placebo surgery, and repair to non-operative treatment (physiotherapy), in (1) quality of life, (2) safety, (3) patient satisfaction, (4) pain in activity, (5) grip strength and (6) forearm and wrist range of motion (ROM) at 6 months, 1, 2, 5 and 10 years follow-ups.

Trial design

The trial design of tREatment of trIaNgular FibrOcaRtilage ComplEx Ruptures (REINFORCER) is a multicentre, randomised, superiority, controlled, participant and outcome assessor (debridement vs placebo surgery randomisation cohort) and trialist blinded (both arms) superiority, umbrella trial with two randomised cohorts which both include two 1:1 parallel arms. Participants in the first cohort (central or radial TFCC tear) will undergo randomisation to either arthroscopic debridement or placebo surgery. In the second cohort (peripheral TFCC



*Possibility to cross-over

TFCC, Triangular Fibrocartilage Complex; m, months; y, years

Figure 1 Assessment and treatment plan.*Possibility to cross-over. TFCC, Triangular Fibrocartilage Complex; m, months; y, years.

tear), participants will be randomised to arthroscopic/open TFCC repair or physiotherapy (figure 1).

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials guidelines (online supplemental material I, table S2).[28 29]

Study setting

The participants will be recruited from secondary and tertiary referral hospitals in Denmark, Finland and Sweden with at least two practising specialists in hand surgery (online supplemental material I, table S3). To be eligible, investigators must hold a specialist degree in hand surgery or orthopaedics and have performed a minimum of 30 wrist arthroscopies before the trial commencement. One of the hand surgeons will serve as the centre's co-principal investigator (Co-PI). Each trial centre will be responsible for screening all patients referred under the diagnosis of ulnar wrist pain.

Participants

The Co-PI or deputy investigator (DI) at each centre will screen all patients referred to the trial centre for ulnar wrist pain and record their details in the screening log (figure 2). The inclusion and exclusion criteria have been designed to enable the best possible generalisability of the trial, but exclusion criteria are planned to exclude significant possible sources of invalid data (table 1).

Patients should present with symptoms and clinical examination findings consistent with a TFCC tear. They must be of working age, willing to participate and able to provide and complete all required information. The TFCC tear, confirmed via arthroscopy, should account for the patient's symptoms, with ulnocarpal ligament tears being excluded. Patients with remarkable gross instability of the DRUJ, osteoarthritis on the ulnar side of the wrist,

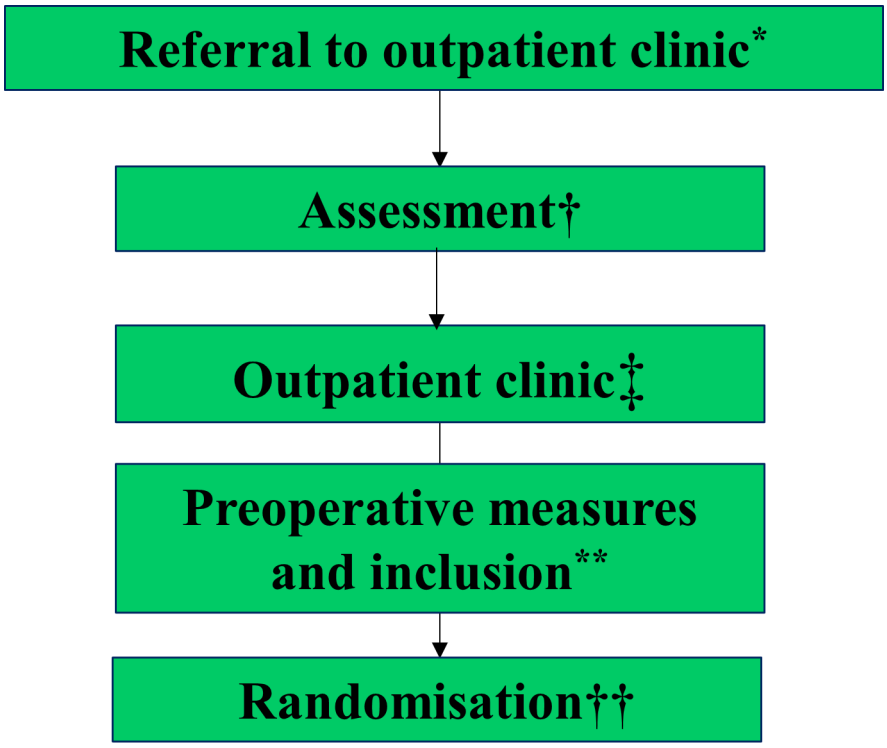


Figure 2 Recruitment, data collection and randomisation.*Based on the referral, an appointment at the outpatient clinic is scheduled for the patient. The cover letter, along with patient information and consent forms, can be sent to the participant along with the details of the outpatient clinic visit.†If a TFCC rupture is suspected, an MRI can be optionally conducted before the outpatient clinic visit.‡If suspicion of a TFCC rupture arises during the outpatient clinic visit, the participant will be informed about the trial. If the patient is considered potentially eligible, consent for participation may be obtained. The Co-PI or DI will gather information on grip strength, ROM of the wrist and forearm, and ulnar variance. Additionally, the participant will be given EQ-5D-3L, PRWE, and VAS questionnaires to complete and return before the scheduled arthroscopy.**Preoperatively, RN, or optionally the Co-PI, or DI, will gather information on sex, age, duration of symptoms, history of smoking, occupation, job, involved hand, hand dominance, and any previous injuries or treatments related to the symptomatic hand. The RN, or optionally the Co-PI or DI, will also ensure that EQ-5D-3L, PRWE, and VAS questionnaires are correctly completed and collect the forms. If a TFCC tear is identified as 1A, 1B, or 1D[3] during arthroscopy, and there are no exclusion criteria, the participant's recruitment is considered finalized.††Randomisation will be conducted during the arthroscopy using the online randomisation software available at https://www.randomizer.at.Co-PI, Co-principal investigators;DI, deputy investigator; EQ-5D-3L, European quality of life 5 dimensions 3 level version; MRI, magnetic resonance image; PRWE, Patient rated wrist evaluation; RN, research nurse; ROM, range of motion; TFCC, triangular fibrocartilage complex; VAS, visual analogue scale.

Table 1 Inclusion and exclusion criteria

Inclusion
Ulnar-sided wrist pain
Age ≥18 years
Suspicion of TFCC tear in clinical examination
Provision of informed consent
Ability to fill the Danish, Finnish or Swedish versions of questionnaires
Symptom duration more than 3 months and unsuccessful non-operative treatment
1A, 1B or 1D* tear explaining the pain in arthroscopy
Exclusion
Gross instability of DRUJ†
1C* TFCC tear in arthroscopy
Ulnocarpal or DRUJ arthrosis (Atzei class 5)[12]
Ulnar variance ≥+2 mm in X-ray
Age >65 years
RA or other inflammatory disease effecting radiocarpal or ulnocarpal or DRUJ
LT instability diagnosed in arthroscopy
ECU instability
Massive tear and degenerated edges or frayed tear which fails suture (Atzei class 4A–4B)[12]

*Palmer classification[3]: 1A, central; 1B, ulnar; 1C, distal and 1D, radial. In combined tears, treatment will be determined by the tear most likely to cause the symptoms (online supplemental material I, table S4).
†Will be defined as 'obvious instability in clinical examination in each forearm and wrist position'.
DRUJ, distal radioulnar; ECU, extensor carpi ulnaris; LT, lunotriquetral; RA, rheumatoid arthritis; TFCC, triangular fibrocartilage complex.

inflammatory diseases affecting the wrist or notable ulnar-side instability in structures other than the TFCC will also be excluded.

The aim of the inclusion and exclusion criteria is to identify patients most likely to benefit from surgical treatment of a TFCC tear. Paediatric patients are also excluded because their treatment differs from that of the adult population. Patients with gross instability are excluded because, in the authors opinion of this protocol, they should be evaluated in a separate trial, as the present trial does not have sufficient power to allow for adequate subgroup analysis. Ulnocarpal ligament tears are excluded due to their extreme rarity and the lack of consensus on their treatment.

Patients eligible for the trial must have a suspected TFCC tear based on their medical history and clinical examination, with an optional MRI showing a possible TFCC tear. If they meet the inclusion criteria and none of the exclusion criteria, diagnostic arthroscopy is indicated. Decision of diagnostic arthroscopy will be made by the recruiting hand surgeon.

Interventions and adherence

All eligible patients are provided with a written information form about the trial, and the Co-PI or DI (recruiter) is responsible for obtaining consent from potential participants. The final inclusion or exclusion of participants occurs during an arthroscopic evaluation of the wrist, when a TFCC tear is identified as either (1) central or radial tear or (2) ulnar tear, confirming adherence to the trial's inclusion criteria. After the diagnostic part of the arthroscopy, the surgeon retrieves the randomisation code from the internet-based programme at https://www.randomizer.at.

In both randomisation cohorts, arthroscopy will be conducted with or without irrigation, and the treatment will be conducted based on the randomisation. For ulnar tears, those undergoing repair will undergo postoperatively 6 weeks of immobilisation with cast, splint or orthosis, which immobilises the forearm and wrist, while those in the non-operative (physiotherapy) group will have a 2-week immobilisation period with dorsal cast, splint or orthosis immobilising the wrist (online supplemental material I, table S5 and online supplemental material II).

The investigated treatments are widely used and demonstrated to be safe.[9 10] We see no reason to discontinue or modify the interventions randomly assigned to the participants.

Full adherence to the allocated treatment is anticipated, as arthroscopic debridement and repair of TFCC ulnar tear are performed immediately after randomisation during the same operation. In the central or radial tear randomisation cohort, participants, caregivers and all trial personnel, excluding operating theatre staff, remain blinded to the treatment allocation. To enhance adherence to follow-up, participants receive comprehensive information about the trial and treatments during the initial contact. Participants receive contact details for the coordinating research assistant (CRA) and outpatient clinic at each centre, allowing them to reach out at any point during the trial. Active monitoring of participant controls occurs at specified intervals by junior investigators (JI), research nurses and the CRA. If the participants do not adhere to the follow-up schedule, they are contacted, and patient-reported outcomes are collected via phone if the participant agrees.

Study outcomes

Follow-up time points and collected data in each point are planned so that all the needed data can be gathered while the participants are not overburdened with data collection (table 2).

Primary outcome variable

The PRWE questionnaire is a wrist-specific instrument comprising a 15-item questionnaire addressing pain and disability in daily living. PRWE gives a value between 0 (best) and 100 (worst). It is a wrist-specific instrument with good reliability, validity and responsiveness.[30 31] The

Table 2 The assessment time points and outcomes collected

Outcome	Preoperatively	6 months*	1 year*	2 years*	5 years*	10 years*
PRWE†	X	X	X	X	X	X
EQ-5D-3L	X	X	X	X	X	X
Adverse events		X	X	X		
Global improvement		X	X	X	X	X
VAS pain in activity	X	X	X	X	X	X
Grip strength	X	X	X	X		
Passive ROM of the wrist and forearm	X	X	X	X		

*Follow-up visits will be at 6 months, 1, 2, 5 and 10 years from primary intervention.
†Primary (1 year) and secondary outcome (6 months, 2, 5 and 10 years).
EQ-5D-3L, three-level EuroQol five-dimensional questionnaire; PRWE, Patient-Rated Wrist Evaluation; ROM, range of motion; VAS, Visual Analogue Scale.

PRWE has been translated and validated for the Danish, Finnish and Swedish languages. In interpreting the results, a minimal important difference (MID) value of 14 will be employed.[32]

Secondary outcomes

The secondary outcomes include health-related quality of life, adverse events, patient satisfaction, pain during activity, grip strength and ROM of the forearm and wrist (online supplemental material I, table S6). The Visual Analogue Scale (VAS) pain form is available as a supplementary document to this article.

Sample size

This trial is designed as a superiority trial, aiming to detect a mean difference of 14 points. With type I error rate of 0.05 and a power of 80%, we need 44 participants per arm to detect a difference of >14 points in PRWE assuming SD of 20. Considering attrition rate of 15%, the final number of participants per randomisation cohort arm is 51, totalling 204 participants for the whole trial.

Participant recruitment

The multinational and multicentre setup of this trial is designed to facilitate the recruitment of the required number of participants. CRA will actively monitor the recruitment progress from each centre. If any centre encounters challenges in recruitment, the CRA will promptly contact the JI and PI. Together with the Co-PI, they will engage in discussions to devise strategies for improving recruitment.

The first participant in the trial was recruited on 27 October 2020, and the last is expected to be recruited by the end of 2025. Therefore, the 10-year follow-up period is projected to conclude by the end of 2035. However, if the planned sample size has not been reached by the end of 2025, recruitment will continue until the required number of participants is enrolled, and the end date for the 10-year follow-up will be adjusted accordingly.

METHODS: ASSIGNMENT OF INTERVENTIONS

Randomisation and blinding

In this trial, a centralised allocation system will be employed. The concealment of allocation is ensured, as the randomisation code will be released only after the diagnosis is confirmed during the arthroscopy. The participants within randomisation cohorts are allocated 1:1 with a random block size. Dominant/non-dominant hand will be used as a stratification criterion.

The operating surgeon and operating theatre staff will not be blinded to the allocation due to the nature of the interventions. However, outcome assessors measuring grip strength and ROMs will be blinded in central or radial tear randomisation cohort and they will not participate in the care at any other point in the trial, except during follow-up visits. For central and radial tears, participants are also blinded, resulting in a triple-blinded randomisation cohort since investigators are also blinded in the data analysis phase as in foveal tear randomisation cohort.

In the central or radial tear cohort, to ensure blinding of the participants, the participants are not able to see the operation area or the monitor. They will listen to music with noise-cancelling headphones throughout the operation. In the placebo group, the operative time will be matched, with the surgeon simulating a debridement procedure. The postoperative protocol is identical in both arms. The staff in the operation theatre will not communicate with the participant after the operation, and they will inform the staff responsible for follow-up in a similar way irrespective of the allocation.

In the ulnar tear cohort, the randomisation between repair and physiotherapy cannot be blinded due to differing postoperative treatments: a 6-week immobilisation in the repair group and a 2-week immobilisation in the physiotherapy group. Maintaining similar postoperative protocols might compromise the distinct outcomes associated with each intervention.

The success of blinding with the participant and the outcome assessor

In the central or radial tear randomisation cohort, during the 1-year follow-up visit, participants and outcome assessors will be asked to indicate which treatment group they believe the participant belongs to (debridement or placebo surgery). The success of blinding will be reported as a percentage of correct responses in both arms.

Cross-over and unblinding

During recruitment, the Co-PI informs participants that if they do not achieve adequate symptom improvement at the 1-year postoperative evaluation or thereafter, participants in the central or radial tear cohort may be unblinded and undergo debridement if the initial treatment is placebo surgery. In the ulnar tear cohort, the participant may undergo TFCC repair if the initial treatment was physiotherapy. If the initial treatment in the central or radial tear cohort was debridement, or in the ulnar tear cohort it was repaired, the surgeon will determine the appropriate treatment with the participant. Unblinding will be conducted by Co-PI of the centre and CRA. Unblinded participants will continue in the trial but will be marked as 'unblinded' in the results.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Baseline assessment

The baseline assessment encompasses typical demographics, duration of symptoms, involved hand, questionnaires, ulnar variance, ROM, and previous injuries or treatments in symptomatic wrist (online supplemental material I, table S7).

Data collection

Trial data will be collected with an electronic data capture platform, REDCap (Vanderbilt University, Nashville, Tennessee, USA). Assessors will undergo training for platform usage, and the REDCap forms include pictorial instructions for various measurements. If needed, individualised training will be organised for specific measurements, such as wrist and forearm ROM with a goniometer and grip strength with Jamar.

Participants have the option to withdraw from the trial at any point. In the event of participant withdrawal, data collection is discontinued, and the data collected up to the point of withdrawal will be used.

Data management

At each centre, data are collected in a password-protected electronic database (REDCap) using the participant's trial ID number. All data are stored on servers at the coordinating centre. Only investigators and the Data Safety and Monitoring Committee (DSMC) have access to the final dataset, and no contractual agreements limit such access.

During the analysis phase, data will be verified. The magnitude of all results will be reviewed to ensure they fall within a plausible range, and checks will be performed to avoid double data entries.

Statistical plan

Descriptive statistics will be presented as means with standard deviations (SD) for all approximately normally generated continuous variables. Continuous variables that do not follow a normal distribution but show a highly skewed distribution will be presented as median with interquartile ranges (IQR). Categorical outcomes will be presented as numbers with percentages.

For the primary outcome, the statistical tests will be two sided and a $p<0.05$ will be considered statistically significant. Confidence interval (CI) will be 95% CI and two sided. For the secondary outcomes and time points, we do not intend to adjust the p value for multiple comparisons, and the analyses are considered exploratory. The use of p-values will be toned down when interpreting the results.

The primary analysis will be based on the intention to treat (ITT) principle. Participants allocated to a treatment group (repair or debridement) should be followed up, assessed and analysed as members of that group, regardless of their adherence to the planned course of treatment. A per-protocol (PP) analysis will be conducted as a sensitivity analysis per the actual treatment received by the participants.

The primary comparison in PRWE between groups will be done using a linear mixed model allowing for repeated measures. Group allocation and time points (6 months and 1 year) will be included as fixed effects and participants as random. Baseline score and hand-dominance (in regard to the repaired side) will also be included as fixed covariates. Group×time interaction will also be included in the model. The mean marginal difference at each time point will be interpreted as a treatment effect. Satterwaithes method is used to estimate df for this. 95% CI are reported for each treatment estimate. Due to the repeated measures mixed model analysis, no missing data imputation will be done. The same analytical approach will be used for all continuous secondary outcomes (VAS pain, QoL, ROM and grip strength).

The number of adverse events is a binary secondary outcome variable. A generalised repeated logistic mixed model analysis will be employed, and the difference in the proportion of the outcome events will be reported based on marginal mean effects for each time point. Global rating is an ordinal variable with seven possible categories. Depending on the final distribution of participant ratings, we will employ ordinal logistic regression separately for each time point. If participant ratings show a skewed distribution to higher categories, we will dichotomise the global improvement variable between no change and little better and use a generalised repeated measure mixed logistic model analysis.

All statistical analyses will be made using the latest Rstudio (R core team, Vienna, Austria) with appropriate packages such as lme4, emmeans and margins. The whole

statistical plan is presented in attachment of this protocol (statistical analysis plan, SAP).

Analysis

To minimise any bias in interpreting the findings, the trialist, who will be blinded to the treatment allocation, will perform data analysis. Blinded results (groups A and B in the central/radial tear cohort, and groups C and D in the ulnar tear cohort) will be presented to the writing committee, who will collectively reach a consensus on the interpretation of the findings. Once a consensus is reached, the groups will be unblinded.[33]

Data safety

We will establish a DSMC comprising one statistician, one clinician experienced in clinical trials, and another with expertise in TFCC tears. The DSMC is independent of any competing interest and will be tasked with safeguarding the interests of trial participants. Responsibilities include assessing the safety and efficacy of interventions, reviewing external evidence affecting risk/benefit balance and monitoring overall trial conduct. The DSMC has the authority to evaluate protocol amendments and recommend permission to continue the trial.

Interim analyses and stopping guidelines

Interim analyses outside the planned follow-up points will not be conducted. All the treatments, except placebo surgery, which likely has fewer risks than the treatments of usual care, are used widely for treating TFCC tears and they are considered equally safe.[9 10] As there is no expectation of major differences in the incidence of serious adverse events (SAEs) between the trial groups, no priori stopping rules will be applied.

SAEs and safety

All SAEs will be documented and promptly reported to the DSMC. Additionally, annual reports on SAE will be submitted to the Institutional Review Board (IRB) of Pirkanmaa Hospital District. In this trial, SAE is defined as any event leading to participant hospitalisation or death, directly attributable to the treatment. Other conditions linked to the intervention will be considered adverse events.

Centres are instructed to report SAE immediately to the CRA who notifies the JI, PI, Co-PI and DSMC within 48 hours. Participants are informed to contact their centre's outpatient clinic if they suspect a possible adverse event. Adverse events are also assessed during follow-up visits.

Centres are equipped to handle emergencies, being on-call units of hand surgery, or participants can be directed to a hand surgeon promptly. Adverse events are documented and reported in the results. There is no need for unblinding in the radial or central tear groups, even if the participant is hospitalised, for example, septic arthritis, as no foreign material is left in either treatment to the wrist joint.

Adverse events are treated similarly to any patient, regardless of trial participation. As the investigated treatments are widely used and considered safe, the anticipated risk of significant SAE is low, equivalent to standard treatment. Since the trial serves routine treatment methods, possible treatment injuries will be compensated by the local patient insurance centre.

The investigators hold the responsibility to make the final decision to end the trial based on the DSMC's recommendation.

Monitoring

The study will undergo monitoring by an external monitor. Initial monitoring of all centres is scheduled for 2023–2024, with a total of three monitoring visits in each centre throughout the trial. The full monitoring plan will be published as a supplementary document to this article.

ETHICS AND DISSEMINATION

Ethical considerations

Placebo surgery-controlled trials often raise ethical questions. However, multiple musculoskeletal trials have shown that the surgical treatment in question lacked efficacy,[26 27] despite common assumptions to the contrary. Following groundbreaking placebo-controlled trials in musculoskeletal surgery, it can be argued that comparing surgical treatments to placebo surgery is ethically more justifiable than continuing to use procedures that have not been proven adequately effective. Surgeons often believe that without surgical intervention, certain conditions may progress or worsen, but the reality can be quite different, for example, conservative treatment of a scaphoid fracture may not generate osteoarthritis of the scaphotrapeziotrapezoid joint, but the risk is significantly higher with surgically treated.[34] In many cases, the natural history of diseases remains unclear.

The trial protocol received approval from the IRB of Pirkanmaa Hospital District in March 2020 and was subsequently registered on ClinicalTrials.gov with the trial identifier NCT04576169 in September 2020. This trial will be conducted in accordance with the Declaration of Helsinki.

Eligible participants receive comprehensive information about the trial's risks and benefits before providing informed consent. The participants can discontinue the trial at any time they wish without any obligation to report a reason for their decision.

Any protocol amendments are communicated to the Co-PI and DSMC. IRB approval is sought before implementing amendments, and all changes are documented in the ClinicalTrials.gov registry and published results.

Electronic files are secured with passwords, and participant data are stored anonymously in the trial's electronic database. Files containing participant names or personal identification numbers are stored separately from the trial data records. All files will be retained for 15 years following the trial's completion.

Information of the trial and approval of the participant

Participants will receive information about the trial at an outpatient clinic from the recruiter. A written information

form about the trial will be provided to the participant, allowing sufficient time to read and consider participation. The recruiter will obtain consent for the trial and collect baseline data. No additional consent provisions are required for the collection or use of participant data.

Confidentiality

All participants' personal data are pseudonymised, preventing any connection to an individual without additional information. The participant's study ID is retrieved from the identification log, which is securely stored in a locked cabinet at each centre.

The pseudonymised participant-level dataset and statistical code will be made available for researchers who provide a methodologically sound proposal after the trial concludes, following the General Data Protection Regulation (online supplemental material I, table S8).

Patient involvement

At the planning stage of the trial, trialist AK discussed with patients with TFCC pathology about their symptoms, wrist function, and stability. AK also presented the REINFORCER trial setting plan to patients, seeking their feedback and thoughts. These discussions led to changes in the research team's planned protocol, including introducing a 1-year time point for cross-over and including grip strength as an outcome measure. It is important to note that these patients were not involved in the recruitment or conduction of the trial. They did not report issues with the intervention's burden or the time required for trial participation.

Communication of results, authorship and access to data

The results will be published in peer-reviewed journals. Authorship eligibility criteria in REINFORCER trial are based on The International Committee of Medical Journal Editors recommendations[35] basing authorship on the following four criteria: (1) substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; (2) drafting the work or reviewing it critically for important intellectual content; (3) final approval of the version to be published; and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Professional writers will not be employed.

Data will be stored in REDCap, managed by the coordinating centre. All centres have access to their respective data. If Co-PI requires access to the entire database, they can apply through the PI, who will organise the pseudonymised data disclosure.

DISCUSSION

This protocol outlines a trial comparing the efficacy of two commonly used operative treatments for TFCC tears: debridement compared with placebo surgery in central and radial tears, and repair with physiotherapy in ulnar tears. The existing literature lacks robust evidence to support operative treatments for TFCC tears, which carry potential risks. These tears are commonly managed both non-operatively and operatively suggesting there is clinical equipoise between the options. The use of placebo surgery and physiotherapy as comparators is justified due to the lack of adequate evidence of the efficacy of debridement or surgical repair. Only a few RCTs have been published in TFCC tear treatments[36–39] and they do not inform whether people with TFCC tears benefit from surgery.

Afifi *et al* compared the repair of foveal tear with anchor or transosseus repair, finding similar results with fewer complications in the anchor repair group.[36] Lee *et al* published a report comparing conservative and operative treatment of DRUJ instability related to distal radius fracture, concluding that conservative treatment is as effective as operative treatment for TFCC tears related to distal radius fracture.[40] Most existing studies are observational[9 10] and although people improve after surgery, this may not be due to surgery.

We measure the effect with PRWE, that combines self-reported disability and pain. The cut-off for meaningful improvement (14 points) was based on the MID for PRWE.[32] This decision prioritises self-reported, patient-important outcomes over objective measures, enhancing the interpretability of results and providing a true understanding of treatment impact from the patient's perspective. It aligns with the principle that surgeries are performed for the benefit of patients rather than for surgeons.

There are some limitations in this trial. While we have defined a minimum experience level for surgeons, variations in their expertise may exist. On the other hand, several surgeons with differences in experiences, and preferences, improves the generalisability of the results. Additionally, the open-label nature of the randomisation cohort comparing TFCC repair to physiotherapy may introduce performance and detection bias.[41] Despite recognising this limitation, blinding was deemed unfeasible due to the distinctly difference postoperative care. Moreover, blinding may not be imperative, as shown by a recent study.[42]

The trial's strengths include a multicentre setting with a large population allowing a sufficiently powered trial and good generalisability. Placebo controls in central/radial tears ensure a robust, unbiased estimate of treatment effect. The pragmatic efficacy trial design is an additional strength, emphasising the generalisability of the demonstration of the surgical treatment's effectiveness if it exists.

In conclusion, TFCC tears represent a common wrist pathology frequently addressed through surgical interventions. The existing literature, however, lacks sufficient evidence regarding the efficacy of TFCC tear treatments. The REINFORCER trial aims to bridge this knowledge gap and contribute valuable insights to the field.

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