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SECTION 1: ADMINISTATIVE INFORMATION

Statistical analysis plan (SAP)

tREatment of triangular FibrOcaRtilage ComplEx Ruptures (REINFORCER): Protocol for Randomised, Controlled, Blinded, Efficacy Trial of Triangular Fibrocartilage Complex Tears

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Trial registration:

The trial is registered at www.clinicaltrials.gov with the number NCT04845074.

Protocol version:

This document has been written based on the information contained in the trial protocol of REINFORCER 2.0.

Statistical Analysis Plan (SAP) revision history:

SAP version	Section changed	Description and reason for change	Date changed
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Roles and responsibilities:

Role	**Name**
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Signatures:

Role	**Name**	**Date**	**Signature**
SAP author	Mikko Petteri Räisänen		
Senior statistician	Aleksi Reito		
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SECTION 2: INTRODUCTION

Background and rationale

The wrist joint is a complex structure comprising the distal radioulnar (DRUJ), radio-, 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 injuries is non-operative and may include immobilisation, activity modification, analgesics, cortisone injections and physiotherapy.[4] Immobilization has been reported to yield good results in TFCC injuries.[5] Although physiotherapy is commonly utilized, there is currently no high-quality evidence supporting its efficacy in treating TFCC injuries. Most publications on this topic are either retrospective comparative studies, case studies, or presentations of physiotherapy techniques.[6–8]

Operative treatment options for TFCC injuries 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 injuries, often found in the cartilage, which lacks healing capacity.[13–15] Debridement is less invasive than TFCC repair and immobilisation is notable shorter.[16]

After debridement for central- or radial-side TFCC tear, up to 85% of patients reported pain relief, with a mean grip strength and mean arc of motion restored to 94% compared to unaffected side, in non-controlled studies.[17–20] However, it's 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 utilized for peripheral tears, because its integrity is crucial to the stability of DRUJ and the tear is capable of healing.[22]

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A systematic review conducted by McNamara et al. showed that none of the techniques – either debridement or repair –has been compared with non-operative treatment or no treatment in a RCT.[23] Actually, these kinds of trials are rare in the entire hand surgical field.[24] 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.[25,26] To date, no evidence of the efficacy of TFCC injury treatment with debridement or repair exists. This underscores the need for a 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 (Table 1) in two randomised cohorts using Patient-Rated Wrist Evaluation (PRWE) at one year post randomisation 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 six-months, one-, two-, five- and 10-year follow-ups.

Table 1. Palmer's classification for TFCC ruptures

Palmer[3] **Class 1: Traumatic**		**Palmer Class 2: Degenerative**	
1A	Central perforation	2A	TFCC wear
1B	Ulnar tear	2B	2A + chondromalacia
1C	Distal tear	2C	2B + central perforation
1D	Radial tear	2D	2C + lunotriquetral ligament tear
		2E	2D + ulnocarpal arthritis

TFCC, triangular fibrocartilage complex

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SECTION 3: STUDY METHODS

Trial Design

The trial design of tREatment of triangular FibrOcaRtilage ComplEx Ruptures (REINFORCER) is a multicentre, randomised, superiority, controlled, participant (only debridement versus placebo surgery randomisation cohort) and outcome assessor 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 tear), participants will be randomised to arthroscopic/open TFCC repair or physiotherapy. The reporting of the trial will follow the "*Consolidated Standards of Reporting Trials*" (CONSORT) statement.[27]

The Reinforcer is a multicentre and -national randomised controlled and blinded trial. The participants will be recruited from secondary and tertiary referral hospitals in Denmark, Finland, and Sweden that have at least two practicing specialists of hand surgery.

The Statistical Analysis Plan (SAP) are reported in accordance with the "*Guidelines for the Content of Statistical Analysis Plan in Clinical Trials*".[28]

The REINFORCER trial is registered at www.clinicaltrials.gov with the number NCT04576169. The Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital (ref ETL R19076) has approved the trial.

Randomisation

The included patients will be randomised with a 1:1 allocation using a random block size to either debridement or diagnostic arthroscopy in the radial or central tear group, and to repair or physiotherapy in the ulnar tear group after their diagnostic arthroscopy. A centralised allocation system will be utilised (www.randomizer.at). The concealment of allocation is ensured, as the randomisation code will be released only after the diagnosis is confirmed during arthroscopy. Dominant/non-dominant hand will be used as a stratification criterion.

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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 standard deviations (SD) of 20. Considering the attrition rate of 15% the final number of participants per randomisation cohort arm is 51 totalling 204 participants for the whole trial.

Framework

The overall objective of the trial is to determine whether surgical interventions result in a clinically and statistically significant greater improvement compared to placebo surgery and physiotherapy on PRWE (primary outcome).

Statistical interim analysis and stopping guidance

No formal statistical interim analysis has been planned for the REINFORCER trial. The estimated final deadline for patient recruitment has been set for December 2025, but recruitment will continue until the planned sample size has been achieved.

Timing of final analysis

The final analysis for the primary outcome, the end scores on PRWE at one-year, will be performed after the last follow-up assessment. The main publication of the trial will be prepared when these data are available. In addition, papers on five- and 10-years follow-up will be performed, when these follow-up assessments are available.

Timing of outcome assessments

The trial consists of six-time points; baseline, six-months, one-, two-, five-, and 10-years (Table 2).

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Table 2. Outcomes and assessment time points

Outcome	Preoperatively	Six-months*	One-year*	Two-years*	Five-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 six-months, one-, two-, five-, and 10-years from primary intervention
† Primary (one-year) and secondary outcome (six-months, two-,five-, and 10-years)

PRWE, Patient-Rated Wrist Evaluation; EQ-5D-3L, three-level EuroQol five-dimensional questionnaire; VAS, Visual Analogue Scale; ROM, range of motion

SECTION 4: STATISTICAL PRINCIPLES

Confidence intervals and P values

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

Adherence and protocol deviations

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 have access to 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 follow-up schedule, they are contacted, and patient reported outcomes are collected via phone if the participant agrees.

During recruitment, the Co-principal investigator (Co-PI) informs participants that if they do not achieve adequate symptom improvement at the one-year postoperative evaluation or thereafter, participants in the central or radial tear cohort may be unblinded and undergo debridement if the initial treatment was 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 repair, the surgeon will determine the appropriate treatment with the participant. Unblinding will be conducted by Co-PI of the centre and CRA. The randomisation code for unblinding will be retrieved from the centre where the participant was treated. Unblinded participants will continue in the trial but will be marked as 'unblinded' in the results.

Analysis populations

The primary analysis will be based on the Intention to Treat (ITT) principle. Patients 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 analysis will be conducted as sensitivity analysis per the actual treatment received by the patients.

SECTION 5: TRIAL POPULATION

Screening data

The coordinating principal investigators or deputy investigator at each centre will screen all patients referred to the trial centre for ulnar sided wrist pain and record their details in the screening log. The number of patients who do not meet the criteria and the reason for ineligibility will be reported in a CONSORT flow chart.

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Eligibility

Patients fulfilling the inclusion and exclusion criteria and are willing to participate are eligible for the REINFORCER trial (Table 3).

Table 3. 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 three 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 radio- 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.
† Will be defined as "obvious instability in clinical examination in each forearm and wrist position"

TFCC, triangular fibrocartilage complex; DRUJ, distal radioulnar joint; RA, rheumatoid arthritis, LT, lunotriquetral, ECU, extensor carpi ulnaris

Recruitment

The CONSORT flowchart will present the number of patients screened, excluded (with reasons), eligible for inclusion, randomised, receiving allocated treatment, withdrawals (with reasons), lost to follow-up (with reasons), included in the ITT analysis, included in the per protocol analysis.

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Withdrawal/follow-up

Throughout the trial period the participants are allowed to withdraw from the study at any time. Participants who decide to withdraw will be encouraged to continue in the study as if they have received the intervention. The number of withdrawals and the timing of withdrawal will be presented in the CONSORT flowchart (with reasons).

Baseline patient characteristics

The baseline assessment encompasses typical demographics, duration of symptoms, involved hand, questionnaires, ulnar variance, ROM, and previous injuries or treatments in symptomatic wrist (Table 4). Categorical variables will be presented as numbers and percentages. Continuous variables will be presented as mean with SD, if normally distributed and ad median with interquartile range (IQR) if not normally distributed. No tests of significance will be conducted for the baseline characteristics, imbalances of importance will be noted. Baseline and follow-up values for the primary and secondary outcomes will be presented as part of the analysis.

Table 4. Baseline assessment

Characteristic	Variable
Sex	male/female
Age	years (from 18 to 65 y)
Hand dominance	left/right
Education	first/second/third level
Occupation	never worked/blue-collar/white-collar
History of smoking	no/yes
Duration of symptoms	years
Involved hand	left/right
PRWE	questionnaire
EQ-5D-3L	questionnaire
pain (VAS) in use	questionnaire
ulnar variance	+/- mm, determined from x-ray
passive ROM of the wrist and forearm	degrees

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previous injuries in symptomatic wrist	no/yes*
previous surgeries to symptomatic wrist	no/yes†

* When the injury occurred and the mechanism behind it
† when the operation occurred and details about which procedure was performed

Y, years; PRWE, Patient-Rated Wrist Evaluation; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; VAS, visual analogue scale; ROM, range of motion

SECTION 6: ANALYSIS

Outcome definitions

The Patient Rated Wrist Evaluation (PRWE)

The Primary outcome, PRWE, will be evaluated at one year time point. 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 specific wrist instrument with good reliability, validity, and responsiveness.[29,30] The 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.[31]

Secondary outcomes

The secondary outcomes include quality of life, adverse events, patient satisfaction, pain during activity, grip strength, and range of motion (ROM) of the forearm and wrist (Table 5).

Table 5. Secondary outcomes

Outcome	Definition
PRWE	The PRWE questionnaire is a wrist-specific instrument comprising a 15-item questionnaire assessing pain and disability in daily living. PRWE provides a score ranging from 0 (best) to 100 (worst). This wrist-specific tool demonstrates good reliability, validity, and responsiveness.[29,30] Translation and validation have been conducted for Danish, Finnish, and Swedish languages. In interpreting the results, we will employ the Minimally Important Difference (MID) value of 14.[31] PRWE as secondary outcome will be measured at all the other time points (6-months, 2-, 5- and 10-years) than primary outcome.
Quality of life	The generic health-related quality of life questionnaire utilised in this trial is the EQ-5D-3L[32], a widely employed instrument comprising five dimensions and a visual VAS for health level. The five dimensions assessed by EQ-5D-3L include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, patients rate their current state on each dimension using a 3-point scale, and the VAS scale ranges from 0 (worst) to 100 (best). Utility or preference weights, applied with an aggregation

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	formula, yield a single index number used to evaluate overall health-related quality of life. The EQ-5D-3L has been proven to be a reliable[33] and validated tool, and it is widely used in healthcare research. The EQ-5D-3L has demonstrated good responsiveness in upper extremity conditions, such as distal radius fractures[34], its responsiveness in hand surgery has not been measured previously. The MID for the index is 0.085 and for the VAS 6.41.[35] Translation and validation for Danish, Finnish, and Swedish languages have been conducted.
AE	All wrist-related AEs will be documented: ligament, nerve, tendon, or vascular injury; fracture; CRPS; infection; chondral lesion; hematoma; or any other condition that can be attributed to the intervention. Participants are instructed to promptly notify the outpatient clinic at their centre if they detect a potential AE. Additionally, AEs will be assessed during each follow-up visit. Any events resulting in hospitalisation or death will be classified as SAE.
Global improvement	Patient-rated global improvement will be assessed using the question: "How would you rate the function and pain of your wrist compared to the situation before the treatment?" Participants will provide responses on a 7-step Likert scale, ranging from "Much worse" to "Much better.". This global rating of the treatment effect offers a subjective evaluation of the participant's perception of the treatment's impact on their wrist condition. It enables participants to offer feedback on their overall experience and evaluate the practical significance of the treatment's effect on their wrist. The Likert scale, a simple and effective tool for assessing participant-evaluated global ratings, is widely used in clinical research.
Pain in activity	Pain in use will be evaluated using the VAS, a validated and reliable tool for pain assessment.[36] It is widely employed in pain assessments, the VAS scale ranges from 0 to 100 mm, with higher values indicating more severe pain. The MID for VAS-pain is reported to fall between 16-19 mm.[37]
Grip strength	Grip strength will be assessed using the Jamar dynamometer, known for its good within-instrument reliability (Spearman Rho correlation coefficient test 0.82).[38] The strength measurement will be performed with the handle in 2-position: with the elbow in 90° flexion and the arm in adduction. Results will be reported in kilograms. The MID of grip strength is reported to be 5.5 kg.[39]
ROM of forearm and wrist	Passive ROM of the forearm and wrist are commonly employed as outcomes in studies addressing the treatment of wrist pathologies. Prosupination, recorded as forearm ROM, will be measured with the elbow at 90° flexion. Wrist ROM measurements will include extension, flexion, ulnar deviation, and radial deviation. MID of forearm and wrist ROM have not been determined.

PRWE, Patient-Rated Wrist Evaluation; MID, minimal important difference; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; VAS, visual analogue scale; AE, adverse event; SAE, serious adverse event; ROM, range of motion; CRPS, Complex regional pain syndrome; CRPS, complex regional pain syndrome

Analysis methods

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

The primary comparison in PRWE between groups will be done using a linear mixed model allowing for repeated measures. Group allocation and time (six-months and one-year) will be

included as fixed effects and patient as random. Baseline score and hand-dominance (in regards with the repaired side) will also be included as fixed covariates. Group*time interaction between will be also included in the model. Mean marginal difference at each time-point will be interpreted a treatment effect. Satterwaithes method is used to estimate degrees of freedom for this. 95% confidence intervals 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).

Number of adverse events is a binary secondary outcome variable. A generalized 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 patient rating, we will employ ordinal logistic regression separately for each timepoint. If patient ratings show skewed distribution to higher categories, we will dichotomies the global improvement variable between no change and little better and use a generalised repeated measures mixed logistic model analysis.

To minimise any bias in interpreting the findings, the statistician will be blinded for the treatment allocation. Blinded results (group A and B in the central/radial tear cohort, and group C and D in the ulnar tear cohort) will be presented to the writing committee, who will reach a consensus on the interpretation of the findings before the code is broken.[40]

Missing data

As stated above, imputations will not be applied in this study due to the repeated mixed model analysis. Each randomised patient will be included in the intention-to-treat analysis with the collected data. If patient withdraw from the study, data collected so far will be included.

Harms

Adverse and serious adverse events will be presented as number and percentage for each event.

Sensitivity analysis

Per protocol analysis will be done as a sensitivity analysis. In per protocol analysis patients will be analysed according to the treatment groups patients actually received.

Statistical software

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

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