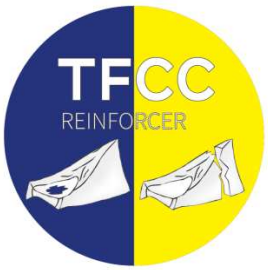
SUPPLEMENTAL MATERIAL



This appendix provides readers with additional information about the authors' work.

Supplement to:

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

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Kaivorinne A, *et al. BMJ Open* 2024; 14:e086102. doi: 10.1136/bmjopen-2024-086102

Table of Contents

38 # Table S1. Palmer's classification for TFCC ruptures
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Palmer[1] **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

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42 TFCC, triangular fibrocartilage complex
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Table S2. Spirit Checklist

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4&16
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	SM I 15-16
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1&23
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	3
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6-7
Objectives	#7	Specific objectives or hypotheses	7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8&SM I T3
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10&SA T5
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	10
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9-10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9-10&SM I T5
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11&SM I T6
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7-8, 12&Figure 1- 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12-13
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12-13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13-14
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9-10
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15&SAP
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16&SAP
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-15&SAP
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent	16-17

		from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17&SI T6
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	18
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not needed
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18-20
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	22-23
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19-20
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	17&SM I T6
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18-20
Dissemination	#31b	Authorship eligibility guidelines and any intended	19-20

policy: authorship		use of professional writers	
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18-20&SM I T8
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Please see the notes
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not needed

Notes:

- The patient information and consent form, visual analogue scale of wrist pain, and monitoring plan will be included in the protocol and uploaded to clinicaltrials.gov.
- This checklist was completed on 30. October 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

SM, supplementary material

Table S3. Trial centres and investigators

Name	Role	Center
Turkka Anttila	Co-PI	Helsinki University Hospital, Helsinki, Finland
Robert Gvozdenovic	Co-PI	Herlev/Gentofte University Hospital of Copenhagen, Copenhagen, Denmark
Matti Juntunen	DI	Kuopio University Hospital, Kuopio, Finland
Antti Kaivorinne	Co-PI	Tampere University Hospital, Tampere, Finland
Olli-Pekka Kangasniemi	DI	Hospital Nova of Central Finland, Jyväskylä, Finland
Teemu Karjalainen	Co-PI	Hospital Nova of Central Finland, Jyväskylä, Finland
Morten Kjaer	DI	Herlev/Gentofte University Hospital of Copenhagen, Copenhagen, Denmark
Toni Luokkala	DI	Hospital Nova of Central Finland, Jyväskylä, Finland
Patrick Luukinen	DI	Tampere University Hospital, Tampere, Finland
Heli Lähdeniemi	DI	Turku University Hospital, Turku, Finland
Panu Nordback	DI	Helsinki University Hospital, Helsinki, Finland
Annele Pönkkö	Co-PI	Oulu University Hospital, Oulu, Finland
Shabir Rashidi	DI	Hospital Sønderjylland, Sønderborg, Denmark
Mikko Räisänen	Co-PI	Kuopio University Hospital, Kuopio, Finland
Janne Soikkeli	DI	Oulu University Hospital, Oulu, Finland
Jerzy Stiasny	Co-PI	Hospital Sønderjylland, Sønderborg, Denmark
Elin Sward	DI	Karolinska Institute, Stockholm, Sweden
Tuukka Tanskanen	Co-PI	Turku University Hospital, Turku, Finland
Lars Vadstrup	DI	Herlev/Gentofte University Hospital of Copenhagen, Copenhagen, Denmark
Johanna Vonkieseritzky	DI	Karolinska Institute, Stockholm, Sweden
Maria Wilcke	Co-PI	Karolinska Institute, Stockholm, Sweden

Co-PI, Co-principal investigators; DI, deputy investigator

Table S4. Combination tears

Primary tear*	Secondary tear†	Action
Central (1A) or radial (1D)	Ulnar (1B)	Will be randomised as central (1A) or radial (1D) tear
Ulnar (1B)	Central (1A) or radial (1D)	Will be randomised as ulnar (1B) tear
Distal (1C)	Ulnar (1B)	Excluded
Distal (1C)	Central (1A) or radial (1D)	Excluded
Central (1A) or radial (1D)	Distal (1C)	Will be randomised as central (1A) or radial (1D) tear
Ulnar (1B)	Distal (1C)	Will be randomised as ulnar (1B) tear

* The surgeon estimates that the tear in question is primarily responsible for the patient's symptoms.
† The surgeon estimates that the tear in question does not remarkable contribute to the patient's symptoms.

Table S5. Interventions

TFCC Tear	Intervention	
Central (1A)* or radial (1D)*	Wrist arthroscopy can be performed dry or wet, at the surgeon's discretion. In the debridement arm, the TFCC tear is debrided with a shaver. Portals are closed either with sutures or with medical tape. Immediate mobilisation of the wrist is allowed after the operation. Participants are provided with instructions for home exercises, and they are advised to commence the exercises two weeks post-operation. In the placebo surgery arm, the TFCC tear is left untouched, and no further interventions are performed. Portals are closed in a similar fashion to the debridement arm. The postoperative treatment is identical to that of the debridement arm group. If the patient requires treatment after the trial has concluded, they will receive care according to the standard healthcare procedures of their respective countries.	
Ulnar tear (1B)*	Wrist arthroscopy can be performed dry or wet, at the surgeon's discretion. In the repair arm, the TFCC is sutured to the capsule or fovea with a method chosen by the surgeon (arthroscopic or open). Acceptable methods include TFCC fixation through the capsule, bone tunnel, or via a suture anchor. Wounds are closed, followed by the application of an above-elbow cast or orthosis. Standardized post-operative treatment (physiotherapy) will commence after six-weeks. In physiotherapy arm, only diagnostic arthroscopy is performed: the tear is left untouched, and no further interventions are done. Portals are closed. Participant will wear a below-elbow cast or orthosis for two-weeks, followed by standardised protocol of physiotherapy exercises for the wrist and DRUJ stabilisers starting after two weeks. If the patient requires treatment after the trial has concluded, they will receive care according to the standard healthcare procedures of their respective countries.	

* Palmer classification[1]: 1A, central; 1B, ulnar; and 1D, radial

TFCC, triangular fibrocartilage complex; DRUJ; distal radioulnar joint

Table S6. 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.[2,3] 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.[4] 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[5], 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 three-point scale, and the VAS scale ranges from 0 (worst) to 100 (best). Utility or preference weights, applied with an aggregation 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[6] 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[7], its responsiveness in hand surgery has not been measured previously. The MID for the index is 0.085 and for the VAS 6.41.[8] 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.[9] It is widely employed in pain assessments, with the VAS scale ranging 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.[10]
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).[11] 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.[12]
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. The MID for 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

Table S7. 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	no/yes
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
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

Table S8. Data Sharing Statement

Data Sharing Statement	
Will individual data be available (including data dictionaries)?	Not before the trial has been finished
What data in particular will be shared?	Pseudonymised raw data
What other documents will be available?	Trial Protocol*, Statistical Analysis Plan*, Informed Consent Form*, Analytic Code
When will data be available (start and end dates?)	Anonymous patient level data will be available if the European Union regulations permit after the trial has been finished. The end date is estimated to be January 1, 2037.
With whom?	Researchers who provide a methodologically sound proposal, and viewers of the journal where article will be published.
For what types of analyses?	To achieve aims in the approved proposal.
By what mechanism will data be made available?	Proposals should be directed to ville.mattila@tuni.fi. To gain access, data requestors will need to sign a data access agreement.

* Will be published

World Health Organization Trial Registration Data Set

Item	Description
1. Primary registry and trial-identifying number	Clinicaltrials.gov, NCT04576169
2. Date of registration in primary registry	29 September, 2020
3. Secondary identifying numbers	None
4. Sources of monetary or material support	This trial was funded by The Finnish Society for Surgery of the Hand, The Finnish Medical Foundation, Foundation of Vappu Uuspää, Finance Finland and Government's research funding. All funders are foundations, societies, or research funds.
5. Primary sponsor	Tampere University Hospital, Elämänaukio, Kuntokatu 2, 33520 Tampere, Finland
6. Secondary sponsor(s)	University of Tampere, Kalevantie 4, 33100 Tampere, Finland
7. Contact for public queries	Antti Kaivorinne (MD), +3583311611, antti.kaivorinne@pirha.fi, Elämänaukio, Kuntokatu 2, 33520 Tampere, Finland
8. Contact for scientific queries	Ville Mattila (MD, Professor), +3583311611, ville.mattila@tuni.fi, Elämänaukio, Kuntokatu 2, 33520 Tampere, Finland
9. Public title	Protocol for trial comparing treatment of triangular fibrocartilage complex tears
10. Scientific title	tREatment of triangular FibrOcaRtilage ComplEx Ruptures (REINFORCER): Protocol for Randomised, Controlled, Blinded, Efficacy Trial of Triangular Fibrocartilage Complex Tears
11. Countries of recruitment	Denmark, Finland, and Sweden
12. Health condition(s) or problem(s) studied	TFCC Tears
13. Intervention(s)	*Central or Radial Tear:* Experimental comparator: Arthroscopic debridement Placebo Comparator: Placebo surgery *Ulnar Tear:* Experimental Comparator: Arthroscopic or open repair Active Comparator: Physiotherapy
14. Key inclusion and exclusion criteria	*Inclusion criteria:* ulnar sided wrist pain; age ≥ 18 years; suspicion of TFCC tear in clinical examination (MRI optional); ability to fill the Danish, Finnish, or Swedish versions of questionnaires; symptom duration more than three months and unsuccessful non-operative treatment; and central, radial or ulnar tear explaining the ulnar wrist pain in arthroscopy *Exclusion criteria:* age > 65 years; gross instability of DRUJ*; distal TFCC tear (Palmer 1C)[1] in arthroscopy; ulnocarpal or DRUJ arthrosis; ulnar variance ≥ +2 mm in native x-rays; RA or other inflammatory disease effecting radio- or ulnocarpal or DRUJ; lunotriquetral instability diagnosed in arthroscopy; ECU instability; or massive tear or degeneration that requires reconstruction of the TFCC
15. Study type	Interventional *Allocation:* Randomised

	Masking: Triple (participant, outcome assessors, and investigator) in central or radial tear, and single (investigator) in ulnar tear *Interventional Study Model:* Parallel Assignment *Primary Purpose:* Treatment efficacy *Method of sequence generation and allocation concealment:* Internet based centralised allocation system (https://www.randomizer.at). The concealment of allocation is ensured, as the randomisation code will be released only after the diagnosis, and the investigators, care providers, and patients are not aware of the code
16. Date of first enrolment	27 October 2020
17. Target sample size	204
18. Recruitment status	Recruiting
19. Primary outcome(s)	PRWE at one year follow-up
20. Key secondary outcome(s)	PRWE at other time points[†], EQ-5D-3L, AEs, patient-rated global improvement, pain with VAS in stress grip strength, and ROM of forearm and wrist[‡]

[*] Will be defined as "obvious instability in clinical examination in each forearm and wrist position"
[†] six-months, two-, five- and 10-years follow-ups
[‡] six-months, one-, two-, five- and 10-years follow-ups

MD, Medical doctor; TFCC, Triangular fibrocartilage complex; MRI, magnetic resonance image; DRUJ, Distal radioulnar joint; mm, millimetres; RA, rheumatoid arthritis; ECU, Extensor carpi ulnaris; PRWE, Patient-Rated Wrist Evaluation; EQ-5D-3L, Euroqol Five Dimensions Three Level Questionnaire; AE, adverse event; VAS, Visual analogue scale; ROM, range of motion

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