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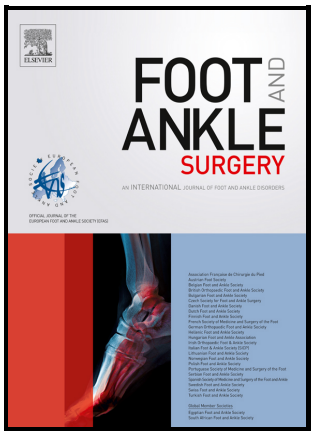
Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment



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PII: S1268-7731(22)00241-7

DOI: https://doi.org/10.1016/j.fas.2022.12.006

Reference: FAS1836

To appear in: *Foot and Ankle Surgery*

Received date: 11 April 2022
Revised date: 6 December 2022
Accepted date: 12 December 2022

Please cite this article as: Maria Swennergren Hansen, Jesper Bencke, Morten Tange Kristensen, Thomas Kallemose, Per Hölmich and Kristoffer Weisskirchner Barfod, Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment, *Foot and Ankle Surgery,* (2022) doi:https://doi.org/10.1016/j.fas.2022.12.006

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TITLE PAGE

Title: Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment

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Competing interests

The authors declare that they have no competing interests.

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TITLE: Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment

ABSTRACT

Background: Individual treatment selection has been proposed as the key to optimized treatment. The purpose was to investigate if treatment selection using the individualized treatment algorithm Copenhagen Achilles Rupture Treatment Algorithm (CARTA) differs between patients treated as usual regarding gait dynamics and tendon elongation.

Methods: The patients were randomized to one of three parallel groups: 1) intervention group: participants treated according to CARTA, 2) control group: participants treated non-operatively, 3) control group: participants treated operatively. The primary outcome was ankle peak power during push off during walking at 12 months.

Results: 156 patients were assessed for eligibility. 21 were allocated to the intervention group, and 20 and 19 to the control groups. The results indicated no statistically significant differences between the intervention group and the control groups.

Conclusions: Individualized treatment selection based on CARTA did not demonstrate less affected gait dynamics or less tendon elongation than patients treated as usual.

Key-words: Achilles tendon rupture, gait dynamics, tendon elongation, individualized treatment, ultrasound

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1. Introduction

The average patient sustaining an acute Achilles tendon rupture is male around 40 years of age [1] with a clear goal of returning to pre-injury sports and work [2]. The results are not satisfactory, with a low rate of patients returning to sports [2–4] and patients experience physical limitations for several years [5].

Fully recovered gait pattern is considered a basic goal for all patients. Unfortunately, gait dynamics is seen to be affected both short [6,7], and long term [8–10] after an Achilles tendon rupture. Two to five years after injury, biomechanical deficits during walking with increased ankle dorsiflexion and decreased plantar flexor power and work, are common [9,10]. This might be due to persistent tendon elongation resulting in reduced force production in the end range of plantar flexion during push off [11,12].

The differences between operative and non-operative treatment have been frequently discussed [13,14]. A systematic review and meta-analysis from 2019 concluded that operative treatment reduces the risk of re-rupture, but is associated with a higher risk of complications. [13]. The study proposed that decision of how to treat an acute Achilles tendon rupture should be based on patient specific factors [13].

Individual treatment selection algorithms, based on the morphology of the rupture, have also been proposed [15,16], but their efficacy have never been evaluated. In that view, the newly-developed Copenhagen Achilles Rupture Treatment Algorithm (CARTA) [17,18], an individualized treatment algorithm based on the validated ultrasonographic Copenhagen Achilles Length Measure (CALM) [19,20] might be of relevance. CARTA is based on a combination of tendon overlap inspired by Amlang's Classification system [15] and tendon elongation measured with CALM [19].

The hypothesis was that patients treated with CARTA would have less affected gait dynamics, less tendon elongation, and a higher score within the patient-reported outcome measures, than patients in the control groups.

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2. Methods

The trial was performed as a three-armed randomized controlled trial with the patients randomized in a 1:1:1 order to one of three parallel groups. The present study is a satellite study to an on-going multicenter trial planned to include 300 patients using heel-rise work test as the primary outcome [17]. The first 60 patients included at Hvidovre hospital were included in the present satellite study focusing on gait dynamics using peak ankle plantarflexor power during push off at 12 months as the primary outcome. The trial protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), and the Consolidated Standards of Reporting Trials (CONSORT) guidelines and checklists [21,22].

The protocol, as well as the patient information and declaration of consent, was approved by the National Committee on Health Research Ethics (journal number: 1-10-72-428-17). Informed consent was obtained, and the rights of participants were protected.

This trial was registered at ClinicalTrials.gov the 1st of June 2018 (NCT03543943) and the study protocol published in *TRIALS Journal* [17]. No changes to the study design have been made.

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2.1 Study participants

Patients treated for an acute Achilles tendon rupture at Copenhagen University Hospital Amager-Hvidovre were assed for eligibility. Inclusion criteria: 18-65 years, an appointment in the outpatient clinic within four days, a total Achilles tendon rupture, initial treatment with split plaster cast with the ankle in maximal plantar flexion started within 24 hours, possibility of attending post-examinations, ability to speak and understand Danish and to give informed consent. Exclusion criterion: a rupture of the Achilles tendon either at the insertion on the

calcaneus or at the musculotendinous junction, a previous Achilles tendon rupture, treatment with flourquinoles or corticosteroids within the last 6 months, in medical treatment for diabetes, other conditions resulting in reduced function in the legs, contraindication for surgery, inability to lie in prone position, terminal illness [17]. Patients were given written and verbal information. Those who did not want to participate were treated non-operatively according to the department's guidelines.

2.2 Treatment

The diagnosis was set in the emergency room based on the patient history and a clinical examination (calf-squeeze test [23], Matles test [24] and palpable defect in the Achilles tendon). A split plaster cast with the ankle in maximum plantar flexion was applied, no weightbearing allowed.

Within four days after rupture, the patients attended the outpatient clinic to conduct the randomization into one of three groups:

1. Intervention group: individualized treatment selection for operative vs non-operative treatment based on CARTA
2. Control group: participants treated non-operatively.
3. Control group: participants treated operatively.

2.2.1. The intervention

In the intervention group, the choice of operative or non-operative treatment was based on the individualized treatment algorithm CARTA which consists of two ultrasonographic examinations conducted within 4 days after injury (**Fig. 1**). A detailed description of CARTA is found in the protocol paper [17].

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Firstly, the degree of overlap of the ruptured tendon stumps was examined by looking at the cross-sectional area. If less than 25% tendon fibers at the rupture site, the overlap was considered minimal and the patient was recommended for operative treatment. If more than 25% fibers, the overlap was considered substantial and the patient was scanned for elongation.

Secondly, tendon elongation was measured using CALM [19]. Both legs were examined and the difference between the sides was calculated as the elongation and was given as a percentage of the length of the non-injured tendon. Patients with up to 7% elongation were treated non-operatively and patients with 7% or more were treated operatively.

2.2.2. Non-operative treatment

The patients randomized to the non-operative control group or to the intervention group with the decision to be treated non-operatively, were treated with a full below-the knee cast with the ankle in maximal plantar flexion and no weight-bearing. After three weeks the cast was replaced by a functional brace with three heel wedges, inducing 20 degrees of plantarflexion over the ankle. A wedge was removed after two and four weeks and the orthosis after six weeks. Partial weight bearing was allowed from week four to seven and full weight bearing from week eight onwards. Weight bearing was restricted based on studies arguing increased risk of tendon elongation with early loading of the tendon [3,25]. The brace was to be kept on at all times except during bathing if the patient was seated and did not bear weight on the foot [17].

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2.2.3. Operative treatment

Patients randomized to the operative control group or the intervention group with the decision to be treated operatively were operated on within 14 days after rupture. The procedure was performed under local anesthesia with an incision approximately 5 cm over the rupture site, medial to the midline. The peritendium was kept intact. Two modified Kessler sutures were used to fix the tendon (Fiber-wire®, Arthrex size 2). The ankle was placed in maximal, unforced plantarflexion and the sutures were tightened maximally [17]. After the operation, patients were treated exactly like the non-operatively treated patients with a circular below-the knee cast for three weeks and an orthosis for six weeks.

2.2.4 Rehabilitation

All patients followed the same rehabilitation plan. After removing the cast, they were instructed to use running shoes with a heel wedge (10 mm) and to use compression socks during daytime. Patients were instructed to avoid total dorsiflexion with weightbearing and use crutches as long as they were unable to walk without a limp evaluated by the physiotherapist.

At week 9-13 the patients were instructed to perform a home exercise program two times daily. For continuing physiotherapy after week 13, the patients were referred to rehabilitation in the municipality. A detailed description of the rehabilitation program is found in the protocol paper [17].

2.3. Outcomes

The primary outcome was peak ankle plantarflexor power during push off at 12 months; this was the maximal power produced by the plantar flexors during the push off phase. Gait

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analysis was performed as previously described by Speedtsberg et al [9] using a Vicon Motion Systems [26]. Data were subsequently calculated using the inherent software (Nexus 2.9.1; Vicon Motion Systems, Oxford, UK) and outcome parameters were extracted using custom-made Matlab scripts (MATLAB 9.0.0,R2016; MathWorks Inc.,Natick, MA).

Secondary outcomes were peak ankle plantarflexor power during push off at six months, peak ankle plantarflexor moment at six and 12 months, and peak ankle dorsiflexion during stance phase at six and 12 months.

Tendon elongation measured with ultrasound using the CALM at six and 12 months was also a secondary outcome [19,20].

The patient-reported outcome measure used was the Achilles tendon Total Rupture Score (ATRS, ranging from 0-100, where 100 indicates no symptoms), which was developed to assess symptoms and physical activity after treatment of an acute Achilles tendon rupture [27,28].

2.4 Randomization

Randomization was computer-based and conducted through a web-based database hosted by Procordo, Copenhagen, Denmark [17]. The allocation key was only accessible by Procordo.

2.5. Blinding

Due to the nature of the intervention, it was not possible to blind the patient. Inclusion, randomization, and follow-up were performed by the lead investigator. The surgeons performing the operative treatment were blinded to treatment arm (individualized or surgical). Follow-up was not fully blinded, as the lead investigator performed both randomization and

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follow up, but to blind the investigator for operative and non-operative treatment, the patients had a piece of tape placed over the Achilles region on the injured leg during the gait analysis. Data were blinded while performing the statistical analyses.

2.6. Statistics

As of the planning of this study, to our knowledge, no measurements were available for the primary outcome to make a reliable sample size calculation. Therefore, sample size was based on what was logistically possible to complete within the time plan. Hence, results of this study should be considered exploratory; that is, indicating but not confirmatory of any effect.

Demographic parameters were presented for each treatment group with mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables, depending on the distribution of data, and with frequencies and percentages for categorical variables.

The non-injured side was used as a reference for gait biomechanical outcomes as well as for tendon elongation. The difference between the injured and non-injured side for walking was used as an expression of affected gait. The outcomes expressed in power (watt/ body mass) and moment (Newton meter/body mass) were calculated as the percentual deficit (difference between injured and non-injured side/value for non-injured side*100).

The primary outcome, difference in peak ankle power during push-off at 12 months, was tested with use of ANCOVA. Tests were made for the comparison intervention group vs. operative control group, and intervention group vs. non-operative control group. Possible confounding variables (sex, age, BMI, ATRS pre-injury and pre-injury activity level, tendon elongation) were evaluated by comparison of intervention vs. control groups estimates from models with, and without, the specific confounder. If a relevant change was observed, the variable was included as a confounder.

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The secondary outcomes, gait analysis at six and 12 months as well as tendon elongation at six and 12 months, and ATRS, were analyzed with the similar ANCOVA model as for the primary outcome, with relevant confounders evaluated for each model. The analyses on ATRS were done both for the full score (range) and for items 6 to 10 separately since they represent different physical tasks.

All analysis was done as intention to treat (ITT). Additionally, the analysis for the primary outcome was also conducted as per protocol analysis.

Missing data was imputed by multiple imputation; 100 imputations were performed, with imputation models based on available variables.

Additionally, a sub-analysis for the primary outcome was done by only including patients measured within the time limit (plus/minus one month) in the model, to evaluate possible bias introduced from prolonged follow-up time.

Re-rupture rate was noted. The precise definition of a re-rupture versus a re-injury is somewhat subjective and up to the individual clinician. Therefore, all re-injuries that led to a change and a re-start of the treatment plan were considered a re-rupture.

Estimates were presented with 95% confidence intervals (CI). All analysis was done in R 3.6.0 [29] with the mice package [30] used for multiple imputation. A p-value of less than 0.05 was considered statistically significant.

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3. Results

One hundred and fifty-six patients were assessed for eligibility from June 2018 to September 2019 (**Fig. 2**). The baseline data of the population is shown in **Table 1**.

Table 1 Baseline data

	Randomization groups			The intervention group divided in selected treatments	
	Control group non-operative n= 20	Control group operative treatment n= 19	Intervention group n= 21	Operative treated patients n= 14	Non-operative treated patients n= 7
Age (years)	39.7 (10.1)	42.9 (8.3)	39.2 (8.8)	39.5 (8.7)	38.7 (9.8)
BMI (kg/m^2)	26.1 (2.5)	26.1 (3.6)	26.5 (3.9)	27.1 (3.0)	25.3 (3.0)
ATRS pre-injury	97.3 (4.9)	96.5 (9.4)	93.3 (13.8)	97.4 (5.3)	85.1 (21.3)
Tegner score	5.1 (2.0)	3.7 (2.2)	4.0 (1.8)	3.7 (1.7)	4.6 (2.1)
Elongation (mm)	17.2 (12.4)	24.7 (11.5)	16.4 (15.0)	23.9 (12.0)	1.6 (6.9)
Tendon overlap	15/20 (75)	13/19 (68)	10/21 (47)	3/14 (21)	7/7 (100)
Female	5/20 (25)	3/19 (16)	4/21 (19)	2/14 (14)	2/7 (28)
Injured side: left	7/20 (35)	13/19 (68)	8/21 (28)	7/14 (50)	1/7 (14)
Time to surgery (days)	-	5.1 (2.9)	5.5 (3.3)		-

Data are presented as 'mean (SD)' for continuous data and 'yea/total number (percentage)' for dichotomous data. BMI: Body mass index; ATRS: Achilles tendon Total Rupture Score.

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One patient was lost to follow-up and four patients were not able to perform the gait analysis, leaving 55 patients available for the 12-month follow-up for the primary outcome (**Fig. 2**). All 21 patients in the intervention group adhered to the assigned treatment. Of the 20 patients in the non-operative control group, 19 adhered to the assigned treatment; one patient fell on his bare foot when standing up without the walker and sustained a re-rupture treated operatively. Of the 19 patients in the operative control groups, 18 adhered to the assigned treatment; one patient started bicycling and sustained a re-rupture treated with a cast for two weeks and a functional brace for four weeks.

The use of the CARTA algorithm led to 14 of 21 patients in the intervention group being treated operatively and seven patients non-operatively. If the CARTA algorithm had been applied in the operative control group, 16 patients would have been treated operatively and three non-operatively. In the non-operative control group, 14 patients would have been treated operatively and six non-operatively.

3.1. Primary outcome

The average peak ankle plantarflexor power during push off deficit was 14% (CI=7.20:21.4) p=<0.001 at six months and reduced to 7% (CI=0.9:13.6) p= 0.027 at 12 months for the intervention group, with no statistically significant differences in comparison with the control groups (at 12 months: intervention group vs. operative control group -0.39% (-10.48:9.70) p=0.939, intervention group vs. non-operative control group 4.83% (-3.67:13.33) p=0.259) (**Fig. 3**).The intention to treat and per protocol analysis did not show any statistically significant differences. Neither did the sensitivity analysis.

The following variables were found to contribute confounding effect to the models: ATRS pre-injury, pre-injury activity level, age, BMI, sex, tendon elongation and time to follow-up. However, inclusion of these confounders did not lead to changes in the statistical or clinical

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interpretation of the models compared to the unadjusted models. Because of this, results are reported from the unadjusted models.

3.2. Secondary outcomes

Regarding the secondary outcomes (**Fig. 3-5**), no statistically significant or clinically relevant differences between the groups were found. The between group differences in peak ankle plantarflexor moment deficit at 12 months were: intervention group vs. operative control group 0.07% (-4.66:4.79) p=0.977, intervention group vs. non-operative control group 1.20% (-3.10:5.51) p=0.577. Corresponding values for the other secondary outcomes at 12 months were: peak ankle dorsiflexion angle during stance phase 0.97 degrees (-1.23:3.16) p=0.378, 0.34 degrees (-1.59:2.28) p= 0.724, tendon elongation 0.35 mm (-8.84:9.53) p= 0.940, -0.61 mm (-9.51:8.29) p=0.891 and ATRS score -5.64 point (-20.36:9.08) p= 0.445, -3.02 (-16.99: 10.95) p=0.666.

Regarding differences between injured and non-injured side for the intervention group, statistically significant differences among the secondary outcomes were found in peak ankle plantarflexor moment at 6 months (-5.72% (-11.12:-0.31) p=0.039), in tendon elongation both at 6 (17.71 mm (12.36:23.07) p=<0.001) and 12 months (19.41 mm (13.00:25.83) p=<0.001), and in ATRS at 12 months (73.57 points (63.81:83.33) p=<0.001)

In total, five patients experienced a re-rupture. None of them were enrolled in the intervention group; four were assigned to the non-operative group and one to the operative group. Within the four patients assigned to the non-operative group, three of them would have been treated operatively if treatment selection had been made using CARTA.

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4. Discussion

The most important finding of the study was that individualized treatment selection for operative vs non-operative treatment based on CARTA does not seem to result in less affected gait dynamics, less tendon elongation, or a higher ATRS score than treating patients operatively or non-operatively by default. This is the first study evaluating an individualized treatment algorithm in a randomized controlled set-up with functional outcomes. Other algorithms have been proposed by Amlang [15] and Hutchinson et al. [16] and shown promising results, but none of them have been assessed in a randomized trial.

A weakness of CARTA and potential reason for no between group differences in the present study could be that the first part of the ultrasonographic examination (tendon overlap) has not been validated. Although, the rationale of tendon overlap inspired by Amlang et al. [15] is clinically reasonable. The ultrasound finding used in the treatment algorithm by Hutchinson et al. [16] on the other hand, a gap of the tendon above 1 cm on passive plantar flexion is questionable since a gap is rarely present. More often, the fibers of the tendon rupture with a thinning of the tendon and a decrease of the cross-sectional area of the tendon fibers instead of a transection.

Additionally, gait dynamics may not be an optimal outcome for a 12-month follow-up after an Achilles tendon rupture. Dissecting the ATRS at 12 months showed high scores, meaning few problems, for activities involving walking (items 6 and 7), and lower scores when asking about the patients' ability to run and jump (items 8 and 9). Future studies should therefore consider using outcomes consisting of activities requiring higher levels of joint angular velocity and force development, such as running and jumping, as they might be better to reveal relevant functional deficits and between-group differences.

There were statistically significant differences between the injured and non-injured side concerning all gait analysis parameters for the intervention group. The ankle plantarflexor power during push off remained statistically significantly reduced at 12 months with a deficit

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of 7%. The deficits in moment and power at six months have previously been described by Aufwerber et al. [7] Its clinical relevance is unknown as a clinically relevant difference has not been determined.

There were no between-group differences in tendon elongation but a statistically significant difference between injured and non-injured sides at both six and 12 months after injury, with an elongation of 17.7 and 19.4 mm found, respectively. The degree of tendon elongation [19,31] and no substantial change from six to 12 months [25] are comparable with findings in previous studies. As for power, the knowledge of a clinically relevant difference is lacking. Tendon elongation is reported as a clinical problem among both operatively and non-operatively treated patients [3,32–34]. Severe elongation with impaired function might benefit from surgical shortening [35].

Time to surgery has been suggested to affect outcome with a proposed cut off for optimal outcome being 3 days after injury [36]. The mean time to surgery was 5 days, which might have affected the operatively treated patients.

Strengths within present study is the randomized controlled design following state of the art guidelines [21,22]. Furthermore, the gait analysis including 60 patients is larger than most previous study populations [8,9,37]. The study is limited by the exploratory design with no sample size calculation and therefore unable to give confirmatory conclusions. Also, using the ATRS as a pre-injury score might have introduced unknown bias, since the questionnaire was developed for people who had sustained a rupture and not for healthy people. Furthermore, the use of the pre-injury score introduces the risk of recall bias.

The multicenter study which present study's participants are included in is on-going. These future results will be able to confirm whether treatment selection based on CARTA will give a better limb symmetry index for heel-rise-work test compared to treating patients non-operatively or operatively per default [17].

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5. Conclusion

Individualized treatment selection for operative vs non-operative treatment based on CARTA did not seem to result in less affected gait dynamics or less tendon elongation than usual care. Our results suggest statistically significant deficits in ankle plantar flexor power during walking in the injured compared to the healthy leg at 12 months after injury together with a significant tendon elongation.

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Figure Captions

Fig. 1. The Copenhagen Achilles Rupture Treatment Algorithm (CARTA) which includes two ultrasonographic (US) investigations. A detailed description of CARTA is found in the protocol paper [17].

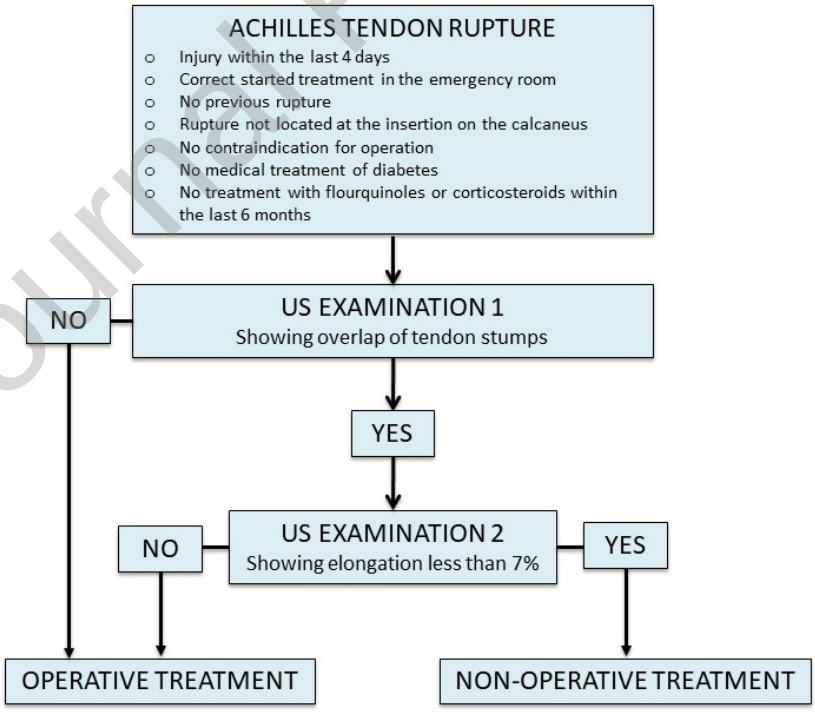

Fig. 2. CONSORT flow diagram. The reasons for exclusion could be more than one. Missing data (both if parts of follow-up were missing or lost to follow-up) were imputed to allow all 60 patients to be included in the intention to treat analysis. Patients that did not adhere to the assigned treatment are excluded in the per protocol analysis.

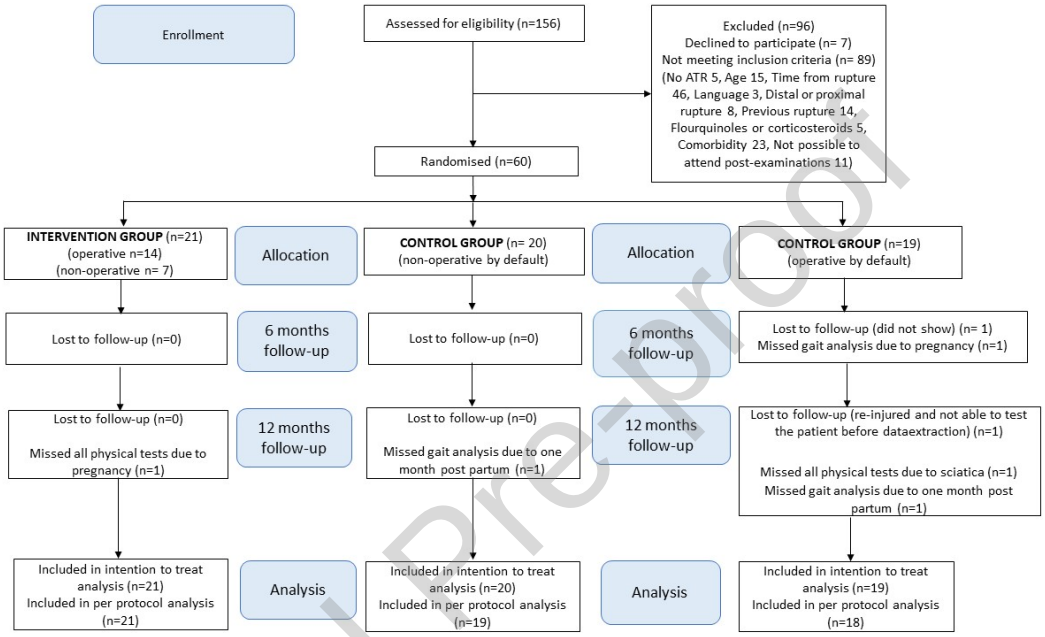

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Fig. 3. Results for peak ankle power and peak ankle plantarflexor moment at six and 12 months. Data are presented as percentual deficits (calculated as the difference between injured and non-injured side/value for non-injured side*100), 95% CI, confidence interval. Estimates are presented for the intervention group (treatment selection using CARTA) and the differences between the intervention group and the two control groups (treatment selection per default).

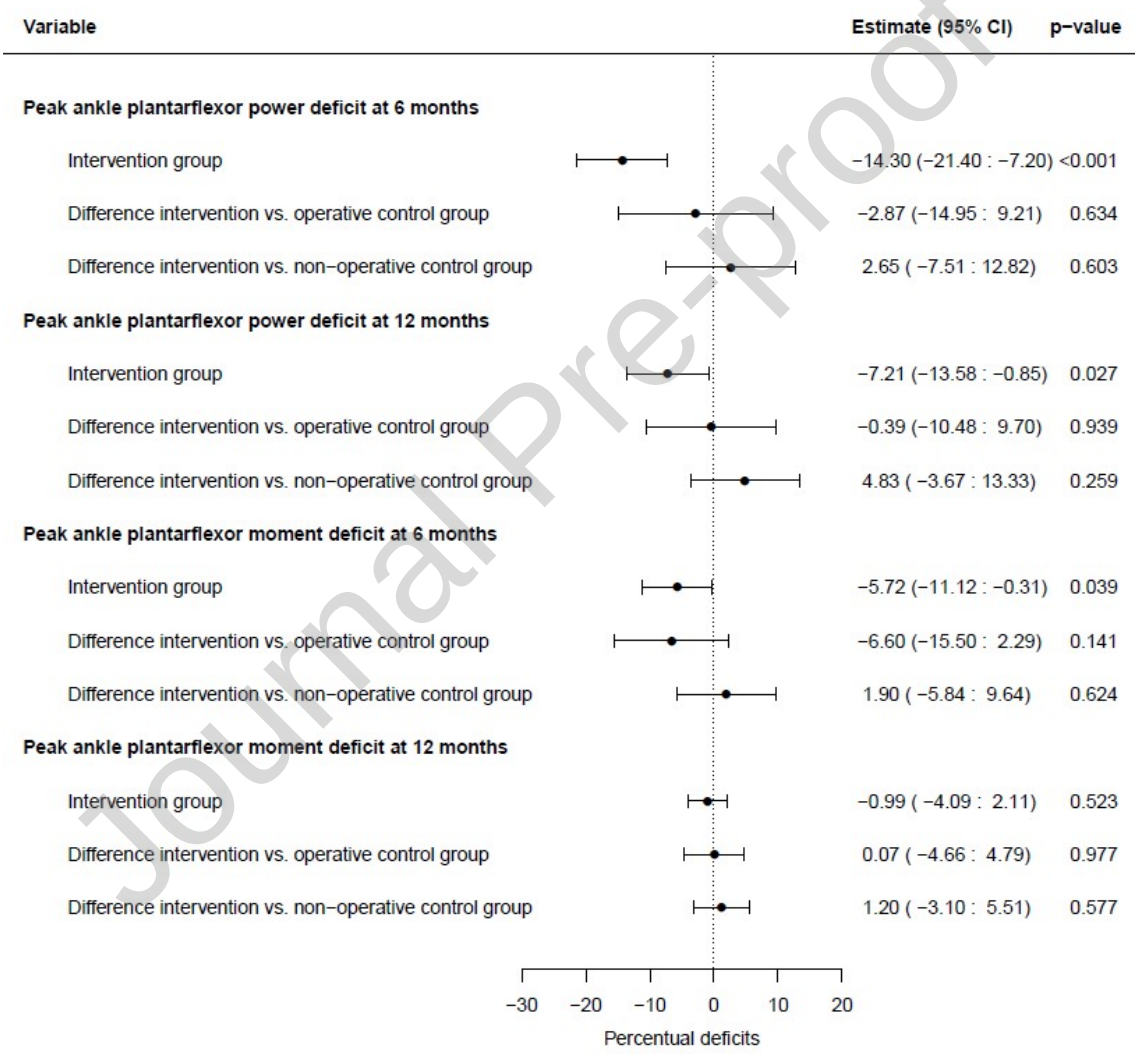

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Fig. 4. Results for peak ankle dorsiflexion during stance phase and for tendon elongation measure with CALM at six and 12 months. Data are presented as difference between injured and non-injured leg, 95% CI, confidence interval. Estimates are presented for the intervention group (treatment selection using CARTA) and the differences between the intervention group and the two control groups (treatment selection per default).

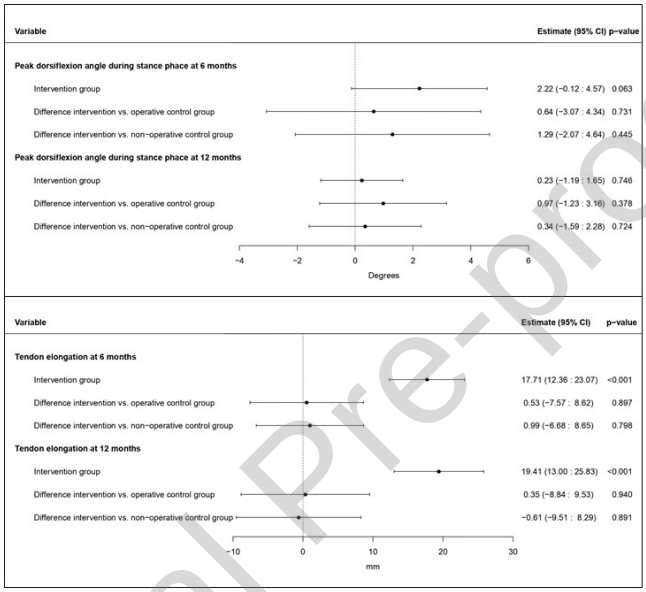

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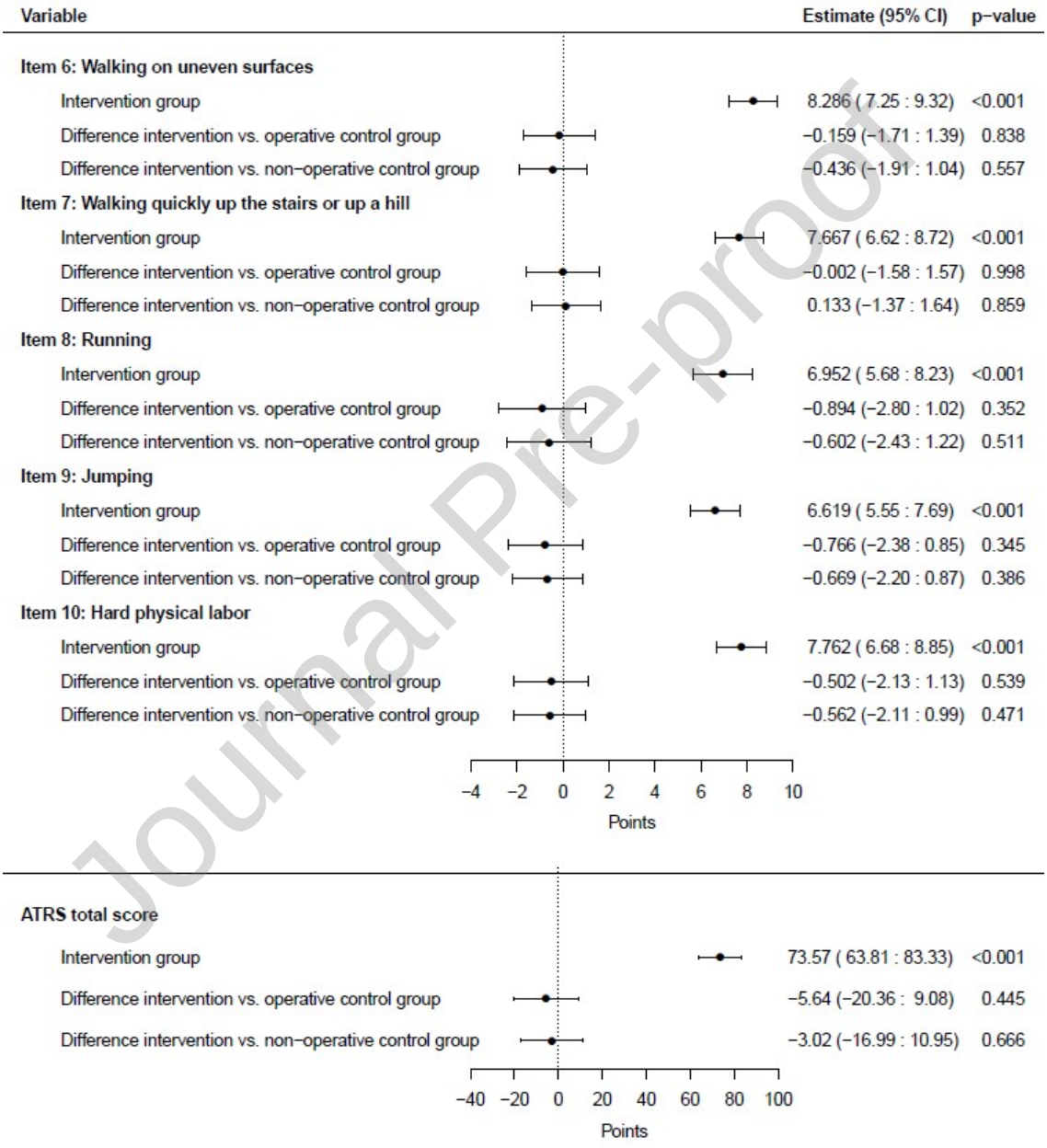
Fig. 5. Results for ATRS at 12 months, items 6-10 and total score. ATRS, Achilles tendon Total Rupture Score, 95% CI, confidence interval. Estimates are presented for the intervention group (treatment selection using CARTA) and the differences between the intervention group and the two control groups (treatment selection per default).



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Acknowledgements

Present study was supported by the Department of Orthopedic Surgery and Department of Physiotherapy and Occupational Therapy at Copenhagen University Hospital Amager. The authors also want to give a special thanks physiotherapist Julie Jenlar and to the staff in the Orthopedic Department contributing to the data collection – the study would not be possible without your contribution and interest for the study. Finally, the authors want to give the biggest thank to all participants for their involvement in the study.

Funding source

This study was funded by the Department of Orthopedic Surgery and Department of Physiotherapy and Occupational Therapy at Copenhagen University Hospital Amager. Further support has been given by DJO Global (100.000€). The Hospitals Research Foundation of Amager-Hvidovre Hospital have contributed with 32.000€ and Fysioterapipraksisfonden 33.500€. The project group has independently initiated the study. Funders have not had any role or authority concerning study design, data collection/analysis or interpretation of data.

Competing interests

The authors declare that they have no competing interests.

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