Physiotherapy 126 (2025) 101428

A cardiac rehabilitation programme based on neuromuscular training improves the functional capacity of patients with acute coronary syndrome: a preliminary randomised controlled trial

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Abstract

Objectives To evaluate the effects of a cardiac rehabilitation programme based on neuromuscular training (NMT) compared with classic rehabilitation strength training (CRST) in patients diagnosed with acute coronary syndrome (ACS).
Design Preliminary randomised, double-blinded, parallel clinical trial.
Setting University health clinic in Valencia, Spain.
Participants Thirty patients with ACS.
Interventions Patients were assigned to one of two groups at random: the NMT group ($n = 15$) and the CRST group ($n = 15$). All patients attended the 20 sessions of the exercise programme.
Main outcome measures The primary outcome was the Incremental Shuttle Walk Test (ISWT). The secondary outcomes were the Chester Step Test (CST), the 30-Second Chair Stand Test (30CST), and hip flexor dynamometry. Assessments were made at baseline, immediately post-treatment, and at 6-month follow-up.
Results The NMT group showed a greater improvement in the ISWT than the CRST group, both at post-treatment {mean 648 [standard deviation (SD) 197] vs 493 (SD 219), mean difference 155, 95% confidence interval (CI) −1 to 310} and at follow-up [732 (SD 183) vs 518 (SD 222), mean difference 214, 95% CI 61 to 367]. The secondary outcomes showed significant between-group differences in favour of the NMT group at 6-month follow-up, except for the 30CST.
Conclusions These preliminary findings indicate that a cardiac rehabilitation programme based on NMT may improve functional capacity in terms of patient performance, cardiorespiratory fitness and muscle strength. Moreover, the improvements were maintained at medium-term follow-up. This could help improve the design of rehabilitation sessions, considering factors associated with performing everyday activities in patients affected by ACS.

Clinical Trial Registration number NCT04246008.

Contribution of the Paper

- This study provides insight into new modalities of strength interventions in patients with acute coronary syndrome.
- Neuromuscular training is a novel exercise modality in cardiac rehabilitation patients that has been shown to improve functional capacity.

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https://doi.org/10.1016/j.physio.2024.101428

Keywords: Cardiac rehabilitation; Neuromuscular training; Strength training; Functional capacity

Introduction

Acute coronary syndrome (ACS) is considered to be the adult pathology with the highest morbidity and mortality rates worldwide [1], accounting for an estimated 17.9 million deaths in 2019 [2].

There is evidence for the importance of a heart-healthy lifestyle that includes physical exercise in populations with cardiovascular pathologies [3].

Cardiac rehabilitation programmes (CRPs) are multifactorial interventions recommended by the World Health Organization, and are defined as 'the set of activities necessary to favourably influence the process of the clinical evolution of the disease, as well as to ensure patients the best physical, mental, and social condition possible so that they can, through their efforts, preserve or recover as normal a position as possible in community life'.

One of the main challenges in the field of cardiovascular rehabilitation is identifying the optimal type of training. The importance of strength/resistance training in conditioning patients with cardiovascular disease (CVD) has been confirmed, and its use has been endorsed by the National Strength and Conditioning Association [4] and the American College of Sports Medicine (ACSM) [5].

However, in recent years, new modalities of strength/resistance training have been studied, comparing their efficacy with classic strength interventions in cardiac rehabilitation programmes [6]. Neuromuscular training (NMT) is described as a multi-intervention programme that combines sport-specific and fundamental movements, including resistance, balance, core strength, dynamic stability and agility exercises, and plyometrics, to improve skills and health-related fitness [7–9]. Training in these neuromuscular skills for adequate movement control has been shown to have beneficial effects on cardiopulmonary and muscle strength outcomes in athletes [10], adult patients with chronic conditions [11,12], and young people [13,14].

However, the benefits of NMT-type interventions in patients with CVD, specifically in patients with ischaemic heart disease, and the inclusion of exercises in CRPs to improve both their aerobic and strength/resistance functional capacities have not been investigated to date. Thus, the objective of this study was to evaluate the effects of a CRP based on NMT compared with classic rehabilitation strength training (CRST) in terms of functional capacity in patients with ACS.

Methods

Study design

This was a randomised, double-blinded, parallel clinical trial with balanced randomisation (1:1); the study protocol has been published previously [15]. This study adhered to the recommendations of the Consolidated Standards of Reporting Trial statement [16]. The design of this study was approved by the Research Ethics Committee at the University of CEU Cardenal Herrera (Ref. No. CEI18/111), and followed the ethical guidelines set out in the Declaration of Helsinki. Eligible participants were informed about all the relevant aspects of this study, and signed an informed consent statement.

An investigator from the cardiology service at a private tertiary hospital was responsible for enrolling the participants, and a statistician from outside the research team generated the random number sequence using random number allocation software [17]. The random sequence was concealed from all the other investigators throughout the study period. A block size of six participants was applied to determine the assignment group. Upon enrolment in the study and completion of the primary and secondary outcome measurements (baseline data collection), the participants were assigned at random to the NMT group or the CRST group.

During follow-up, the participants and the investigator assessing the outcomes remained blinded to the group assignment of the patients. However, it was impossible to blind the physiotherapists delivering the training programmes to the patients because of their active role in

administering these sessions. The study protocol was registered on the US National Library of Medicine website (ClinicalTrials.gov) with the identifier NCT04246008 on 29 January 2020.

Participants

Patients were recruited at the cardiology service in a private tertiary hospital, and completed the proposed intervention at the university health clinic from February 2021 to January 2022. The following inclusion criteria were applied: participants aged 18–80 years with a diagnosis of ACS; with or without ST-segment elevation; moderate or low cardiac risk stratification according to the results of the Cardiopulmonary Exercise Test (CPET) and the guidelines published by the American Heart Association [18]; and a medical prescription for cardiac rehabilitation. All patients underwent cardiopulmonary exercise testing in the cardiology service of the tertiary hospital, and were categorised as low to medium risk, both in terms of ejection fraction (> 35%) and metabolic equivalents achieved in the stress test (> 5).

The exclusion criteria were the presence of any pathologies or acute conditions outlined in the ACSM guidelines with an absolute contraindication for physical exercise. Other conditions were CPET abnormalities, severe exercise-induced arrhythmia, ST-segment depression caused by exertion, unjustified hypertensive responses, thoracic pain, or inability to complete the questionnaires because of cognitive impairment.

Interventions

The intervention comprised a total of 20 sessions, and was designed following the FITT-VP model for structured prescribed exercise for cardiac rehabilitation patients according to the ACSM guidelines [5].

The ideal exercise intensity was a percentage heart rate of 65% to 85% of peak heart rate. The intervention included endurance and strength/resistance training, with training sessions, lasting 60 minutes, twice per week. Each session comprised a 10-minute warm-up, 20 minutes of endurance training, 20 minutes of strength/resistance training, and 10 minutes of cool-down and stretching exercises. All the participants maintained their pharmaceutical treatments for ACS throughout the study.

The endurance phase of the CRP was performed on a treadmill (Ergosprint; Ergoline, Bitz, Germany) or a bicycle ergometer (Ergoselect200; Ergoline), and was either continuous or interval depending on the individual risk stratification of each patient. Strength/resistance training depended on the group to which the participant had been assigned. In both groups, the intervention was designed to train the same muscle groups and to avoid bias in upper- and lower-limb performance between the groups. The CSRT group performed general upper- and lower-limb exercises which targeted all the large muscle groups, and progressed from open-chain to closed-chain body-weight exercises. The NMT group completed a battery of exercises designed to improve trunk stabilisation, upper-limb dissociation from the trunk, movement patterns, and muscle recruitment and control during a range of hip and knee motions.

All the participants were monitored during every session. Peripheral oxygen saturation and heart rate were measured continuously using a pulse oximeter (OXYM4000; Quirumed, Valencia, Spain) and heart rate monitor (Polar Team H10; Polar Electro, Kempele, Finland). In each session, the blood pressure of the patients was recorded at the beginning, after the cardiorespiratory exercises, and after the strength/resistance training with an Omron M6 Comfort blood pressure monitor (Omron Healthcare Europe, Hoofddorp, The Netherlands). Moreover, the patient's perceived exertion was registered using a Borg CR-10 scale at the beginning, after each training phase, and at the end of each session. Two experienced physiotherapists led each session (aerobic and strength/resistance phases), which were individualised for each patient.

Outcomes

The primary outcome of this study was patient performance according to the Incremental Shuttle Walking Test

(ISWT) which is used to predict VO_2 max. The ISWT was originally developed to assess patients with chronic obstructive pulmonary disease (COPD), and requires individuals to walk at a gradually increasing speed until they reach a heart rate or symptom limit. The wide range of walking speeds used means that it accommodates all ambulant patients, from those with minimal disability to those with more severe symptoms. The ISWT has demonstrable reliability in cardiac rehabilitation patients, and correlates well with VO_2 max and metabolic equivalents [19].

The secondary outcomes comprised several different functional variables. First, the Chester Step Test (CST) was used to assess aerobic fitness under submaximal conditions. This test has been shown to predict VO_2 max with an accuracy range of 5% to 15% [20]. The CST has been validated for different populations, from healthy adults to patients with COPD, and has been used as a predictor of CVD risk factors in several studies [21,22].

Second, the 30-Second Chair Stand Test (30CST) is a chair stand test that focuses on a standardised protocol time rather than several repetitions. It allows wide variations in patients' ability levels to be assessed, with scores ranging from 0 stands to more than 20 stands for very fit individuals. This test has been widely used in several populations with frailty or chronic diseases to screen for sarcopenia and lower-limb functional capacity [11].

Thirdly, hip flexor strength was measured using dynamometry (Lafayette Manual Muscle Tester; Lafayette, IN, USA), a reliable and validated metric that has been used in several different populations [23]. As the standardisation of isometric strength values according to body weight has been shown to be feasible, this test allows normal patterns to be established and for the impact of pathology to be assessed in terms of loss of muscle strength [24].

Finally, outcomes related to the psychosocial sphere of the patients (health-related quality of life and sexual dysfunction) were analysed immediately post-treatment and at 6-month follow-up. The results of these outcomes have been published recently by the authors' group [25].

It is important to note that the patients' medications were maintained unchanged throughout the intervention and the follow-up period. All the outcome metrics were assessed at baseline, after 20 rehabilitation sessions, and at 6-month follow-up.

Statistical analysis

The sample size was calculated using G*Power Version 3.1.9.2 [26] based on the authors' previous pilot study [*F*-tests and repeated measures and within–between interaction analysis of variance (ANOVA)]. A medium effect size of 0.58 (Cohen's *d*) for the primary outcome (ISWT) was used. This was estimated using the between-group difference in the ISWT in the pilot study. Assuming a possible 10% dropout rate, a total of 30 patients (15 in each group) were required to reach a 5% significance level with a power of 90%. Compliance with the assumption of normality was checked for each dependent variable and each study group using the Kolmogorov–Smirnov test.

Two-way mixed ANOVA was used to compare the study effects on the mean functional capacity of the patients, using time (baseline, post-treatment or 6-month follow-up) as the within-group factor and group (NMT or CRST) as the between-group factor. Post-hoc paired Student's *t*-tests with Bonferroni's adjustment for alpha inflation were performed to further explore the effects of the interaction between the factors (time and group). Effect sizes were estimated using partial eta^2, and interpreted following the Cohen guidelines [27] for small effect sizes ($\eta_p^2 = 0.01$, moderate effect sizes ($\eta_p^2 = 0.06$) and large effect sizes ($\eta_p^2 = 0.14$). Statistical analyses were performed based on intention-to-treat using SPSS Version 24.0 (IBM Corp., Armonk, NY, USA), and $P < 0.05$ was considered to indicate significance for all the analyses.

Results

In total, 30 participants were allocated at random to the NMT group ($n = 15$) or the CRST group ($n = 15$). Fig. 1 shows the progression of the participants through the trial, and the general characteristics of the study population are shown in Table 1. No dropouts were registered during the study at any of the time points, and no significant adverse

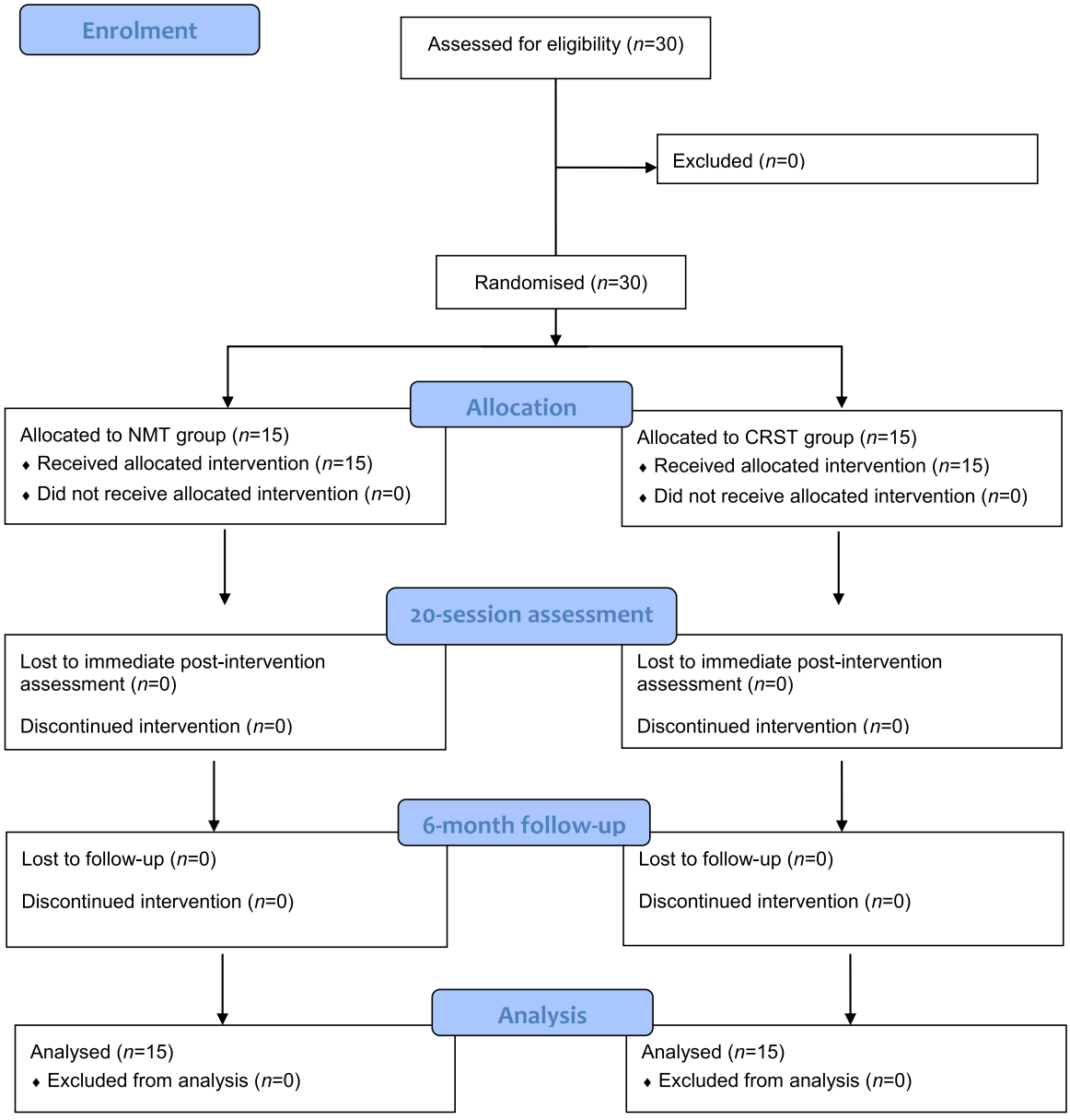

Fig. 1. Flow chart showing the progression of the participants through the trial.

Table 1
General characteristics of the study population.

Outcome	NMT ($n = 30$)	CRST ($n = 30$)
Gender (male/female)	14/1	14/1
Age (years)	55 (6)	57 (10)
Weight (kg)	91 (21)	84 (14)
BMI (kg/m²)	31 (7)	28 (4)
Resting heart rate (bpm)	68 (11)	72 (12)
Blood pressure (mmHg)	107 (15)	101 (10)
SaO_2 (%)	97 (2)	97 (1)

NMT, neuromuscular training; CRST, classic rehabilitation strength training; BMI, body mass index; bpm, beats per minute; SaO_2, oxygen saturation.
Data are mean (standard deviation).

effects were reported during the intervention period by the participants in either group (Figs. 2–5).

According to the two-way mixed ANOVA results, patients in the NMT group demonstrated greater improvement in the primary outcome (ISWT) than those in the CRST group, both immediately post-treatment and at 6-month follow-up (Table 2).

The post-hoc analysis of secondary outcomes found greater improvement in the NMT group for the CST at both time points, and for hip flexor strength at 6-month follow-up. No differences between the groups were found for the 30CST at any time point (Table 2). Moreover, the CST also

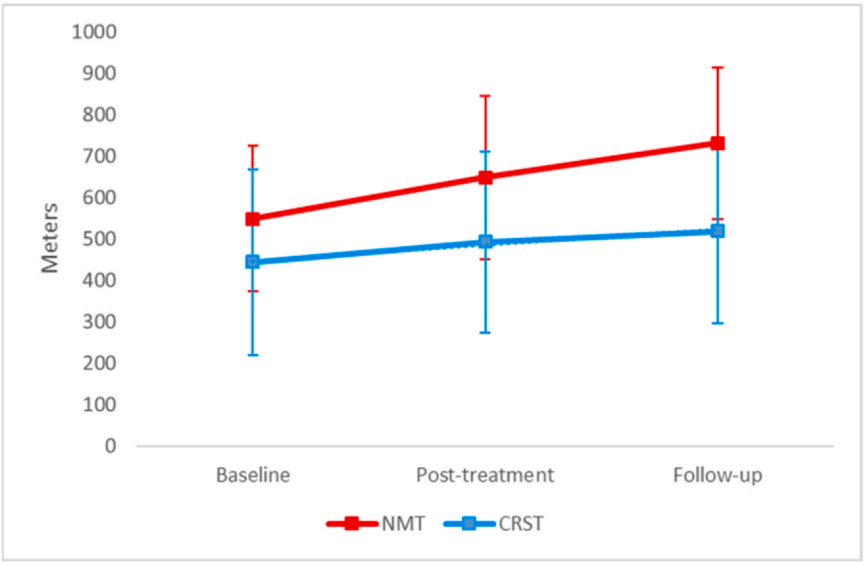

Fig. 2. Changes in the Incremental Shuttle Walking Test between the two groups throughout the study. NMT, neuromuscular training; CRST, classic rehabilitation strength training.

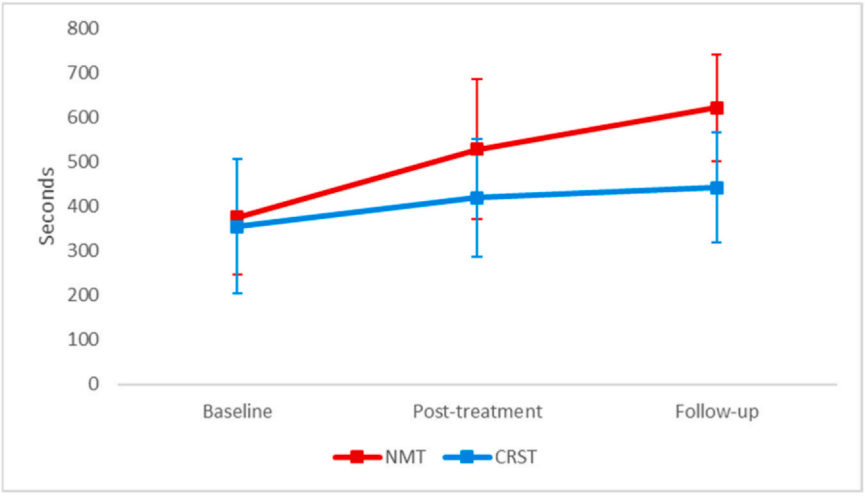

Fig. 3. Changes in the Chester Step Test between the two groups throughout the study. NMT, neuromuscular training; CRST, classic rehabilitation strength training.

showed a between-group difference immediately post-treatment ($P = 0.049$), with a moderate effect size ($\eta_p^2 = 0.13$). No differences between the groups were found for the 30CST at any of the time points. Additionally, the within-group post-hoc analysis (Table 3) showed a significant improvement in all variables ($P < 0.001$) in the NMT group, both post-treatment and at 6-month follow-up. However, only the ISWT ($P = 0.016$), CST ($P < 0.001$) and 30CST ($P = 0.021$) showed significant post-treatment improvements in the CRST group.

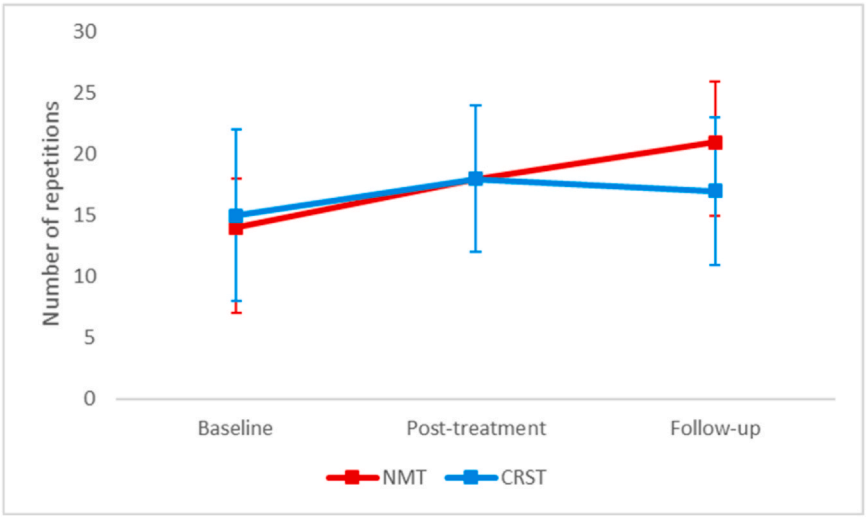

Fig. 4. Changes in the 30-Second Chair Stand Test between the two groups throughout the study. NMT, neuromuscular training; CRST, classic rehabilitation strength training.

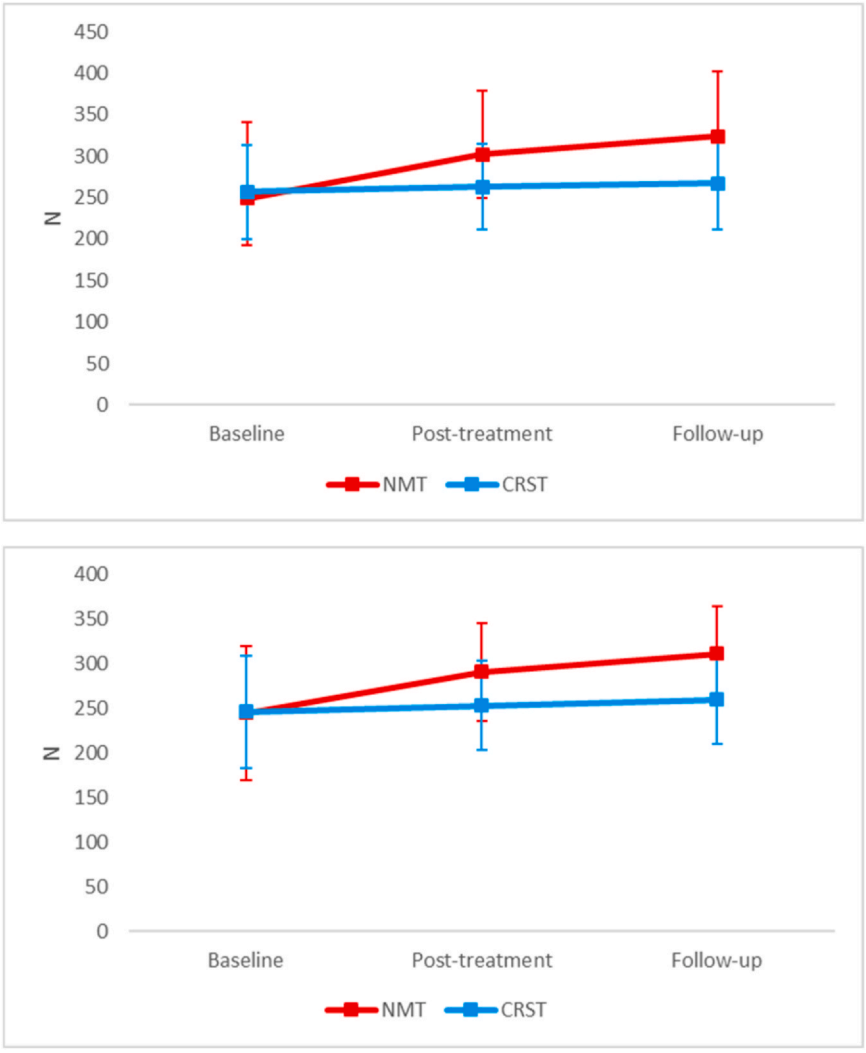

Fig. 5. Changes in right and left hip flexor strength between the two groups throughout the study. NMT, neuromuscular training; CRST, classic rehabilitation strength training; N, Newtons.

Table 2
Between-group differences in the outcome measures.

OUTCOME	Group						Between-group difference	
	Baseline		Post-treatment		Follow-up		Post-treatment	Follow-up
	NMT	CRST	NMT	CRST	NMT	CRST	NMT-CRST	NMT-CRST
ISWT (m)	549 (176)	443 (225)	648 (197)	493 (219)	732 (183)	518 (222)	155 (−1 to 310)[a]	214 (61 to 367)[a]
CST (seconds)	376 (130)	355 (151)	529 (158)	420 (132)	622 (119)	443 (123)	110 (1 to 218)[a]	179 (89 to 270)[a]
30-Second Chair Stand Test (*n* of repetitions)	14 (4)	15 (7)	18 (6)	17 (6)	21 (5)	17 (6)	1 (−3 to 6)	4 (−1 to 8)
Right hip flexor strength (N)	249 (92)	257 (57)	302 (77)	263 (52)	324 (78)	267 (56)	39 (−10 to 88)	57 (7 to 109)[a]
Left hip flexor strength (N)	245 (75)	246 (63)	291 (55)	253 (50)	311 (54)	260 (50)	38 (−2 to 77)	51 (12 to 90)[a]

NMT, neuromuscular training; CRST, classic rehabilitation strength training; ISWT, Incremental Shuttle Walking Test; CST, Chester Step Test; N, Newtons. Data are mean (standard deviation) for the raw values and mean (95% confidence interval) for between-group differences.
[a] $P \leq 0.05$.

Table 3
Intragroup comparisons.

Outcome	Time	NMT		CRST	
		Difference (95% CI)	*P*-value	Difference (95% CI)	*P*-value
ISWT (m)	T1-T0	99 (54 to 141)	<0.001	50 (8 to 92)	0.02
	T2-T1	84 (58 to 110)	<0.001	25 (−2 to 51)	0.07
CST (seconds)	T1-T0	153 (113 to 194)	<0.001	65 (25 to 105)	<0.001
	T2-T1	93 (56 to 131)	<0.001	24 (−14 to 61)	0.36
30-Second Chair Stand Test (*n* of repetitions)	T1-T0	4 (3 to 6)	<0.001	2 (0 to 3)	0.02
	T2-T1	3 (2 to 4)	<0.001	0 (−1 to 1)	0.85
Right hip flexor strength (N)	T1-T0	53 (20 to 86)	<0.001	6 (−27 to 39)	1
	T2-T1	22 (14 to 30)	<0.001	4 (−7 to 12)	0.62
Left hip flexor strength (N)	T1-T0	46 (9 to 84)	0.01	8 (−30 to 45)	1
	T2-T1	20 (10 to 29)	<0.001	7 (−3 to 16)	0.24

NMT, neuromuscular training; CRST, classic rehabilitation strength training; ISWT, Incremental Shuttle Walking Test; CST, Chester Step Test; N, Newtons. Data are mean (95% confidence interval).

Discussion

To the best of the authors' knowledge, this is the first randomised clinical trial to explore the efficacy of an NMT CRP compared with a CSRT protocol in patients with ACS. The study focused on functional capacity assessment, which is considered to be one of the key factors in ACS and is a potential key clinical outcome of CRP interventions [28].

The NMT group demonstrated greater improvements in the ISWT than the CST both immediately post-intervention and at 6-month follow-up, leading to an estimate of the intervention on the ISWT of 155 m [95% confidence interval (CI) −1 to 310 m]. Baseline values in the NMT group were slightly higher than in the CSRT group. One could expect a reduced scope for improvement in the NMT group due to these baseline values; however, this did not happen in this study. Furthermore, none of the tests or exercises performed by the two groups had been trained previously, so the learning curve was the same for both groups. In recent years, the ISWT has been used together with the 6-minute walking test (6MWT) [29] to monitor the rehabilitation of patients with cardiopulmonary pathologies. However, unlike the 6MWT, the ISWT was originally proposed as a maximum incremental test. Moreover, the ISWT correlates more strongly with cardiology laboratory tests, and is reproducible after a single practice walk [30].

Furthermore, in a comprehensive intragroup analysis, it can be observed that the improvements achieved in the NMT group meet the 70-m minimal clinically important difference (MCID) established for patients undergoing cardiac rehabilitation [31]. However, given the width of the CIs, these results should be interpreted with caution. There was also an improvement in the CRST both post-treatment and at 6-month follow-up, but the MCID for the ISWT was not achieved between the measurement time points. Concerning the intergroup comparison, a difference of 155 m in the ISWT was found post-treatment in favour of the NMT group. However, given the width of the CIs, these results should be interpreted with caution. A significant difference of 214 m was observed in favour of the NMT group at 6-month follow-up. Nevertheless, these results must be interpreted with caution because the CIs include a range of values lower than the MCID, and therefore it cannot be stated with confidence whether this improvement was clinically relevant.

There was a significant improvement in the CST between the groups, both immediately post-treatment and at 6-month follow-up, especially in the NMT group. Gilchrest *et al.* determined that the use of the CST in patients with ACS was valid, even in cardiovascular patients receiving beta-blockade [32]. Of note, polypharmacy in this group may include beta-blockers, which reduce both heart rate and blood pressure.

Finally, hip flexor strength was evaluated. The measurement of muscle strength has been widely used as a meaningful, non-invasive and repeatedly measurable prognostic indicator in this population [33]. Specifically, the strength of the quadriceps muscle seems to be a good predictor of mortality and exercise capacity in patients with coronary artery disease [23]. Quadriceps strength is strongly associated with frailty, and is a more relevant variable than muscle mass for assessing the aforementioned parameters. In turn, combined CRP training is more effective for improving muscle strength and endurance compared with rehabilitation based on aerobic or resistance training alone [34]. The present study found a significant improvement in both right and left hip flexor strength in the NMT group, both immediately post-treatment and at 6-month follow-up, when a significant difference was also observed in muscle strength between the groups.

The intragroup analysis showed an improvement in all variables in the NMT group immediately post-treatment and at 6-month follow-up, while only the ISWT, CST and 30CST showed significant post-treatment improvements in the CRST group. CRPs are recommended for patients with ACS to improve their cardiorespiratory parameters, and have proven to be beneficial in patients recovering from a cardiac event [35–37]. Thus, given the above, the intragroup improvement in the CRST group was predictable. Regarding the primary outcome (ISWT), although the results in the CRST group were moderate in this study, they support – in terms of distance – other studies carried out in patients with cardiovascular pathology after a CRP [38,39].

Despite these encouraging findings, it is necessary to highlight some of the limitations of this study. The main limitation was the small sample size, compared with work conducted by others for similar pathologies. This could have conditioned, on the one hand, a wide range of CIs for the data and, on the other hand, the difference between baseline tests, which could have influenced the power effect and caused a type II error. Furthermore, although NMT has been studied in large populations, its use has not, to the authors' knowledge, been extrapolated previously to patients with CVD. To confirm the patient safety of the intervention, the sample size was reduced, but it was consistent with the required sample size calculated before recruiting patients to this study. Finally, although the validity of all the variables used had been demonstrated previously, the CST had not been used previously as a metric in patients with ACS. The authors decided to use the CST because it is a validated test that has been used previously in several studies to predict risk factors for CVD [21,22]. In addition to having good correlation with peak VO_2 max, the use of the CST was advantageous compared with the ISWT because, given that it does not involve patient displacement, it could be employed in patients with reduced mobility.

In conclusion, these preliminary findings indicate that a CRP based on NMT for patients with ACS can improve their functional capacity in terms of patient performance, cardiorespiratory fitness and muscle strength. In addition, the improvements seen in these parameters in the study cohort immediately post-treatment were maintained at medium-term follow-up. However, it is not possible to confirm the clinical relevance of the observed changes. The results from this study could help improve the design of rehabilitation sessions, considering factors associated with performing everyday activities in patients affected by ACS. Further studies with a larger sample size are required to confirm these findings.

Ethical approval: This study was approved by the Research Ethics Committee at the University of CEU Cardenal Herrera (Ref. no. CEI18/111).

Funding: This work has been funded by Conselleria de Innovación, Universidades, Ciencia y Sociedad Digital-Generalitat Valenciana, Spain, CIGE/2022/176.

Conflict of interest:

None declared.

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