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ORIGINAL RESEARCH ARTICLE

Effectiveness of manual therapy with pragmatic physiotherapy for rotator cuff-related shoulder pain: a pilot randomized clinical trial

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ABSTRACT

Introduction: Physiotherapy for rotator cuff-related shoulder pain (RCRSP) typically includes patient education and exercise prescription, with manual therapy used as an adjunct to exercise. This parallel two-arm non-inferiority pilot trial determined the feasibility of a full randomised clinical trial comparing pragmatic physiotherapy with manual therapy (MT Group) to pragmatic physiotherapy without manual therapy (NoMT Group) for RCRSP, and explored preliminary treatment effects on patient-reported outcomes.

Methods: Sixty-eight participants with persistent RCRSP were randomised to MT or NoMT groups, receiving physiotherapy treatments over a 3-month period, with only the MT group receiving manual therapy. Feasibility outcomes were recruitment and retention rates, adherence, and intervention fidelity. Research outcome measures were patient-related outcomes at baseline, 3, and 6-month follow-up.

Results: Of 239 volunteers completing the online screening questionnaire, 108 were physically screened, and 70 (65%) were allocated. After two withdrawals, 33 in the MT group and 35 in the NoMT group completed baseline assessment. Retention, adherence, and fidelity exceeded 80% for both groups. Median treatment sessions were 7 for the MT group and 6 for the NoMT group. In the MT group, glenohumeral joint, thoracic spine, and soft tissue mobilisations were commonly used. Delivery of patient education and exercise prescription was similar between groups. QuickDASH between-group mean differences were below the non-inferiority margin. Self-efficacy favoured the MT group at 6-month follow-up.

Conclusion: Results support feasibility for a full trial. Strategies to improve participant diversity are required. Definitive outcomes require confirmation in a full trial.

Keywords: Feasibility, Manual therapy, Physiotherapy, Shoulder pain

What is already known about this topic?

- *Manual therapy is used by physiotherapists as an adjunct to exercise and physical activity prescription, as well as self-management support, as part of a multi-modal intervention for rotator cuff-related shoulder pain.*

What does the study add?

- *The study demonstrates feasibility for undertaking a full randomised clinical trial. Participants' shoulder-related disability improved similarly between the groups, those that received manual therapy and those that did not, as part of a multi-modal intervention.*

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Background

Shoulder pain is common in the community, with global incidence estimates ranging from 7.7 to 62 per 1000 persons per year (1). Rotator cuff-related shoulder pain (RCRSP) is one of the most common shoulder conditions in middle- and older-aged adults seeking primary care for shoulder pain (2,3).

It is often episodic or persistent, diminishing both quality of life and function (4). Non-surgical management is the first-line treatment for RCRSP, with individualised patient education and shoulder-specific exercise prescription having the highest level of evidence for patients with RCRSP (5). Due to multi-factorial contributors for pain and disability associated with RCRSP, physiotherapy treatments may also incorporate manual therapy, taping, promotion of physical activity, and lifestyle interventions (5).

Manual therapy involves purposeful action, delivering a force by the therapist, most commonly through their hands, to a patient's soft tissue and underlying tissues that may include joints, to reduce pain and improve function (6). In New Zealand, that commonly includes passive mobilisation techniques based on the Maitland concept (7), movement-with-mobilizations based on Mulligan's concepts (8), spinal mobilisations or manipulations, neurodynamics (9), or soft tissue mobilisations (10). Physiotherapists typically integrate these techniques, based on their values, patient preference, clinical reasoning, research evidence, shared decision-making, and experience (11).

The understanding of analgesic effects of manual therapy has evolved from original biomechanical models (6,12) to complex neurophysiological mechanisms within the nervous system (13-15), leading to increased pain threshold and decreased perceived pain (16). A contemporary person-centred approach considers that diverse patient factors (biological, psychological, and social) contribute to patient-unique pain experiences, and that response to manual therapy involves complex interactions influenced by contextual factors and therapeutic alliance (11). An umbrella review supports the use of manual therapy for RCRSP at the shoulder or spine in combination with exercises to reduce pain and disability, particularly in the short term (17). Conversely, a systematic review found that manual therapy and exercise were not more effective than exercise alone (18). A more recent systematic review found that most randomised clinical trials (RCTs) on manual therapy for shoulder disorders were not 'trustworthy' due to either not being pre-registered or due to a high risk of bias (19). Pragmatic studies are needed to determine the effect of an intervention in the usual care setting in which it will be applied (20).

Given the debate surrounding manual therapy (21) and the need for high-value physiotherapy interventions, establishing the benefits of manual therapy when added to a holistic, multi-modal approach is essential. Pragmatic RCTs of such complex interventions require graduated preparatory progressions, including proof-of-concept studies, end-user engagement, and pilot and feasibility studies (22). The overall aim of this trial was to determine the feasibility of conducting a full RCT comparing pragmatic physiotherapy with manual therapy (MT Group) to pragmatic physiotherapy without manual therapy (NoMT Group) for individuals with RCRSP. Process objectives were to: (i) estimate recruitment rates, allocation, and retention rates; (ii) determine adherence, treatment fidelity, and safety; (iii) determine return rates of patient diaries for weekly exercise and physical activity, pain medication use, and other health care; (iv) describe interventions provided to participants, and (v) assess clinician-patient communication style. Research objectives are to: (i) explore between-group differences for the proposed main trial primary outcome measure (shortened Disability of Arm, Hand and Shoulder injuries, QuickDASH) with reference to a non-inferiority margin; and (ii) explore between-group differences for secondary outcome measures (fear avoidance, pain self-efficacy, estimated physical activity, and patient satisfaction).

Methods

Design and setting

We used a pragmatic parallel, two-arm, single-blinded pilot RCT. The pragmatic intervention for each group is outlined using the Template for Intervention Description and Replication (TIDier) checklist (Appendix 1). Trial reporting adheres to the CONSORT statement with extension to randomised pilot and feasibility trials (23). The trial was prospectively registered with the Australia New Zealand Clinical Trials registry (ACTRN12623000034639, 12th January 2023). The New Zealand Health and Disability Ethics Committee approved the trial. All participants provided informed written consent to participate.

Interventions were delivered in the University of Otago School of Physiotherapy clinics in Dunedin and Christchurch, operating as private physiotherapy clinics and serving university and community patients. Following university-wide changes that closed the Christchurch clinic, we recruited a private physiotherapy clinic affiliated with the School of Physiotherapy to continue the trial in that region. To enhance generalisability, we conducted audits of clinical notes and clinician-patient interactions to characterise interventions in both groups.

Participants

Inclusion criteria were: (i) men and women, age ≥ 35 years; (ii) primary complaint of shoulder pain with or without referral in the upper limb for ≥3 months (24), (iii) shoulder pain attributed to a RCRSP using the diagnostic guidelines of the British Elbow and Shoulder Society (25). Exclusion criteria were: (i) any shoulder surgery in the past, (ii) known systemic inflammatory disorders, (iii) frozen shoulder or clinical full-thickness rotator cuff tears, and (iv) cervical repeated movement testing affecting shoulder pain and/or range of movement.

Recruitment, screening, and eligibility

We recruited participants via community advertisements and social media platforms. Adverts and posts included QR codes or URLs directing potential participants to a University of Otago webpage. The webpage contained study information and a link to an online questionnaire (REDCap, an electronic data capture tool hosted by the University). The online questionnaire assessed respondents against inclusion criteria (i) and (ii) and exclusion criteria (i) and (ii), and their availability to attend physiotherapy treatments at the clinic locations. Eligible respondents (based on those criteria) were then directed to a second online form requesting contact details. The project manager followed up with a phone

call and scheduled appointments for physical screening to assess inclusion criterion (iii) and exclusion criteria (iii) and (iv). The likelihood of a frozen shoulder was excluded based on restriction of passive glenohumeral movement of at least 30% for two or more directions, clinical signs of full rotator cuff tears by gross shoulder weakness in the absence of limiting pain, and cervical source by reproducing shoulder pain during active cervical movement or sustained end-of-range positions. On confirmation of eligibility, participants completed the baseline survey before allocation, and their initial physiotherapy appointment was scheduled. Contact details of ineligible respondents were permanently deleted, while reasons for exclusion were retained.

Sample size

A formal sample size calculation is not required for pilot studies, but can be based on practicalities and estimating rates (23). We recruited 29 participants across the two centres within 3 months in a previous one-group feasibility study (26), a rate of 10 participants per month. To fully describe the fidelity of the complex interventions, we planned to recruit a minimum of 30 participants in each group (No MT Group vs MT group; total = 60) during a 6-month period. Due to available remaining funding and a higher recruitment rate than expected, we increased the sample size to 68 participants.

In accordance with the Treaty of Waitangi obligations and Aotearoa New Zealand ethical guidance (27), preferential recruitment was used for participants identifying as Māori and Pasifika. Māori are the Indigenous peoples of Aotearoa, New Zealand, and Pasifika are Pacific peoples; both peoples experience persistent and well-documented health inequities (28). Preferential recruitment was used to support equitable participation and to ensure the study generated evidence that is relevant and beneficial to these priority communities, who are often under-represented in health research. This approach aligns with national ethical standards that require explicit consideration of Māori inclusion and equity in health research (27,28). While all other eligible respondents were invited to physical assessment sequentially, those identifying as Māori or Pasifika were offered physical screening appointments at their earliest convenience.

Randomisation and allocation

Randomisation was undertaken by the project manager (CD) at the main centre using an electronic (Microsoft® Excel) *a priori* computer-generated list stratified by sex (men/women) and ethnicity (Māori/Pasifika versus all others), with block randomisation to ensure similar group sizes in each clinic. The biostatistician (AS) verified the sequence generation. Participants were considered to have entered the study when allocated to a group.

Blinding

Patients and physiotherapists were unblinded to the treatment allocation. There was no outcome evaluator, as all data were self-reported by participants on REDCap. The biostatistician was blinded to group allocation until after the data of primary outcomes, the 3-month follow-up, were analysed.

Interventions

Six physiotherapists provided the intervention: four had less than 10 years of musculoskeletal clinical experience, and two had more than 10 years of musculoskeletal clinical experience. Except for one, all physiotherapists held University post-graduate certificates, diplomas, or a Master's degree. All physiotherapists provided interventions to both groups to minimise confounding by the physiotherapist-patient relationship (29). Participants of both groups received individualised interventions, based on the physiotherapists' clinical and collaborative reasoning with the participant (Appendix 1) (30). Up to eight sessions were offered over a 3-month period. Both groups received comprehensive patient education and prescription of exercise and physical activity, as described in our one-group feasibility study (26). *Patient Education* used co-designed web resources (Online) addressing shoulder anatomy, age-related changes, pain beliefs about pain, and pain triggers. Education also covered the impact of general health, lifestyle, and stress on pain, alongside self-management strategies (26).

Individualised glenohumeral and scapular-focussed exercise prescription followed a phased approach from low intensity, controlled movements, to isotonic exercises, adding trunk and lower limb strength exercises and paced physical activity. Patients of both groups were asked to complete a daily exercise diary of their (1) shoulder-specific exercises and (2) general physical activities. The hard copy diary also included tips for pain self-management.

Physiotherapists were asked to provide person-centred care, considering patient engagement and reflective listening using principles of motivational interviewing and coaching skills (29). To monitor the patient-clinician communication skills, physiotherapists were asked to audio-record all sessions in a specified two-week period, with participants' prior written consent. The physiotherapists documented assessments and treatments as per clinic requirements and also completed a checklist of interventions provided in each session (31). The physiotherapist made the usual collaborative decisions with the patient for discharge. Where indicated, patients were referred to general practitioners (GPs, medical doctors), based on the physiotherapist's usual collaborative practice. Referrals were documented, and patients were asked to report any concomitant treatments received during the trial (e.g., pain medication or injection therapy) in the diaries.

Patients in the MT group received manual therapy for at least four sessions (26). The selection of techniques was impairment-based, following a patient-described symptom-reduction approach, targeting the shoulder region and cervical/thoracic spine. The physiotherapist used their preferred individualised clinical reasoning processes to select relevant techniques and dosage. Selection and continued use were based on within- and between-session patient responses (10). Physiotherapists were asked to document these in the clinical notes, including the technique, intensity of application, frequency, and volume.

Physiotherapists attended a one-day course in Dunedin. Training focused on the patient education resources, delivery of the phased exercise prescription, physical activity, and manual therapy, and required clinical notes documentation. The Behavioural Medicine researcher (NS) provided training for the person-centred communication style. One follow-up session was held via Zoom (Version 5.15.5) mid-way through the recruitment period.

Outcomes

Process objectives

The monthly recruitment rate was determined. The trial was considered feasible if a retention rate of ≥80% was attained for participants completing the intervention until formal discharge or a maximum of eight sessions, and for completion of the 3-month follow-up questionnaire. We documented intervention characteristics across both treatment groups by conducting clinical notes and checklist audits, and recorded clinician-patient interactions during a two-week mid-intervention period, focusing on communication style.

Adherence refers to the intervention dose or the extent to which the individual's behaviour coincides with healthcare provider recommendations (32). Two components were considered: (1) primary adherence related to completing physiotherapy sessions until formal, individualised discharge by the physiotherapist, or up to the maximum number of eight sessions; (2) secondary adherence related to participants' diary completion of individualised physical activity and specific exercise.

Fidelity assessments evaluated whether interventions adhered to protocol (32). The MT group's primary fidelity criterion required manual therapy delivery during at least four sessions versus less than four sessions. For the NoMT Group, fidelity required the complete absence of manual therapy across all sessions, with inclusion during any session constituting non-compliance.

Adverse events were recorded by the physiotherapists. Physical harms were categorised as:

- Normal exercise-induced muscle soreness (muscle stiffness) was recorded by participants in their diaries. Exercises were modified if the participant considered the soreness excessive.
- Exercise-related pain flare-ups persisting beyond 24 hours: physiotherapists discussed acceptable levels of discomfort or pain expected during the exercises. Participants recorded these in their diary and/or reported them to the physiotherapist, triggering exercise modification.
- Manual therapy discomfort: Participants' responses were assessed during and following the application, with the technique adjusted as needed. Pain persisting more than 24 hours post-treatment was documented as an adverse response.
- GP referrals for concerning symptoms were recorded in clinical notes and checklists.

Research outcomes

Patient-reported outcomes were collected via REDCap at the baseline, 3- and 6-month timepoints. The primary outcome measure was the QuickDASH (assessing shoulder-related disability and pain/symptoms) (33) (Table 1). Secondary outcomes included the International Physical Activity Questionnaire (IPAQ) (33), the Fear-Avoidance Belief Questionnaire (FABQ) (34), the Pain Self-Efficacy Questionnaire (PSEQ) (35), the Patient Acceptable Symptoms State (PASS) (36), patient satisfaction with treatment and duration (three-point Likert scales) (37), and the Global Rating of Change Score (GROC) (38). All outcomes are described in Appendix 2.

Analysis

Process objectives

We used descriptive statistics for recruitment, retention, adherence, fidelity, and adverse events. Treatment parameters (session number, duration, frequency) and clinical audit data were summarized descriptively. The number of adverse events for each group was recorded and reported descriptively. Audio recordings of and clinical notes documented clinician-patient interactions and verified interventions delivered. A random sample of audio-recordings was assessed by NS (31) using an iteratively developed template created by three team members. The evaluation instrument examined: (1) patient communication quality (greeting, status assessment, education review, goal setting, exercise adherence) and (2) intervention delivery documentation accuracy. We used binary ratings for each item (yes/no/not applicable), and calculated percentage scores per physiotherapist for person-centred communication and documentation accuracy.

Research objectives

We used descriptive statistics to describe participant baseline characteristics. This included numbers and percentages for categorical variables and mean and SD or median and IQR as appropriate for continuous variables. As a pilot study, the main purpose of the statistical analysis was to assess their feasibility in a fully powered future study. Non-inferiority analyses will be used in the full RCT to determine whether the effect of a new intervention (physiotherapy intervention without MT) is not worse than the comparator (physiotherapy intervention including MT) by more than the non-inferiority margin.

Outcome measures with continuous scales were analysed using mixed-effect linear regressions. These models can be used to analyse repeated data with both fixed and random effects, allowing within-person correlation structures. Categorical variables were analyzed using a binary version of Generalized Estimating Equation (GEE) models after dichotomising to avoid categories with small numbers. This analysis accounts for the within-person correlation in repeated outcome measures. The interaction between group and time was included in all models. These models can compare outcomes

TABLE 1 - Schedule of enrolment, interventions, and assessments

		Study Period				
	Instrument	**Enrol-ment**	**Allo-cation**	**Post-allocation**		**Close-out**
Timepoint		*-t_1*	*0*	*BL*	*3 m*	*6 m*
Enrolment						
Eligibility screen		X				
Informed consent		X				
Allocation			X			
Interventions						
Manual Therapy Group				◊	◊	
No Manual Therapy Group				◊	◊	
Assessments						
Demographics				X		
Presence of self-reported comorbidities (49)				X		
Musculoskeletal Outcome Data Evaluation Management System - Patient Expectation Survey (50)				X		
Primary outcomes						
Shoulder-related pain and disability	QuickDASH (33, 51)			X	X	X
Secondary outcomes						
Estimated physical activity	International Physical Activity Questionnaire, IPAQ (38)			X	X	X
Pain beliefs and behaviour	Fear-avoidance Belief Questionnaire, FABQ (34)			X	X	X
Self-confidence in living with pain	The Pain Self-efficacy Questionnaire, PSEQ (35)			X	X	X
Patient satisfaction with their condition	The Patient Acceptable Symptoms State, PASS (36)			X	X	X
Patient satisfaction	Patient satisfaction with treatment and duration (three-point Likert scales) (37)				X	
Patient-rated change	Global Rating of Change Score, GROC (38)				X	X

-t_1: Enrolment and Baseline assessment; 0: Allocation; BL: baseline; 3m: 3-month follow-up; 6m: 6-month follow-up following the first physiotherapy sessions.

between groups at specific time points, as well as the overall change in outcomes over time. All data were assessed for underlying assumptions before using them in statistical analyses. Principles of intention-to-treat analysis were followed.

Due to the exploratory nature of a pilot study, we reported mean differences with 95% confidence intervals to describe potential trends and variability in the data. The mean differences of the QuickDASH at each time point were then

compared to the *a priori* selected conservative non-inferiority margin of 11 points (out of 100 points) (33). All quantitative analyses were undertaken with Stata® software (College Station, TX: StataCorp LLC).

Results

Process objectives

Recruitment, allocation, and retention

From May 2023 to November 2023, 239 volunteers completed online screening and provided contact details (37 per month, Fig. 1). Of these, 50 were unreachable or excluded when recruitment ended, 62 failed telephone screening, and 9 missed scheduled physical assessments. The remaining 108 volunteers (17 per month) attended the physical screening.

Seventy participants (39% of phone-eligible; 65% of physically-screened volunteers) met the inclusion criteria, completed the baseline questionnaire, and received group allocation (12 participants/month over 6 months) (Table 2). Two participants (one per group) withdrew before intervention initiation and requested data withdrawal. Of 68 participants starting intervention, 63 completed the 3-month follow-up (93% retention), and 60 completed the 6-month follow-up (88% retention). Participant demographics, pain-related characteristics prior to shoulder pain treatments, and treatment expectations for each group are presented in Table 3.

Intervention adherence, fidelity, and safety

Four participants of the MT Group and five of the NoMT Group did not complete the intervention to formal clinical discharge (ill health, moved region, time constraints, referral back to GP, and other surgery), resulting in an 87% patient adherence rate to treatment (Table 2). Forty-nine participants (72%) submitted their diaries. Most had completed their shoulder-specific exercises for 12 weeks, and 20 participants had entered pain medication or referrals to health care providers or imaging (29% of all participants).

MT group fidelity of MT provided during a minimum of four sessions was 94%. Two participants (6%) had received manual therapy in one session only: one had a total of four treatments (then moved to another region, unable to attend further sessions). Another reported increased pain after soft tissue mobilisations and requested no further manual therapy applications. No further adverse responses to the interventions were noted.

Fidelity for not providing manual therapy for the NoMT group was also 94%. Two participants (6%) were provided with MT for one and two sessions, respectively, focusing on cervical mobilisation and thoracic manipulation. The physiotherapist initially forgot the group allocation.

Based on the clinical documentation, nine MT Group participants (27%) and six of the NoMT Group (17%) were referred for further healthcare, including radiological imaging (X-ray, ultrasound, or magnetic resonance imaging), or GP or orthopaedic surgeon consultations (Appendix 3). One of those participants (NoMT Group) was subsequently diagnosed with a full rotator cuff tear, chose to withdraw from further sessions, but completed a 3-month follow-up.

Treatment and interventions

The MT Group and NoMT Group had a median of 7 and 6 treatment sessions, respectively (Table 4). The intervention period extended beyond 12 weeks for three participants of the MT Group and nine for the NoMT Group, partly explained by

TABLE 2 - Descriptive statistics for feasibility outcomes

	All participants (n = 68)	Manual Therapy Group (n = 33)	No Manual Therapy Group (n = 35)
First online screening rate per month	n = 37	--	--
Physical screening rate per month	n = 17	--	--
Recruitment rate per month*	n = 12	--	--
Proportion of participants enrolled from total screened online*	39%	--	--
Proportion of participants enrolled from total physical screen*	65%		
Drop-out / retention rates at 3 months (T3)	7%/93%	9%/91%	6%/94%
Drop-out / retention rates at 6 months (T6)	12%/88%	15%/85%	9%/91%
Patient adherence to treatment sessions (attended until clinical discharge or maximum of 8 sessions)	87%	88%	86%
Submission of diaries: exercises completed for most weeks	72%	76%	69%
Submission of diaries: pain medication or healthcare referral included	29%	30%	29%
Physiotherapist fidelity to intervention	94%	94%	94%

* Includes two enrolled participants who withdrew prior to treatment initiation, one per group (n = 70).

TABLE 3 - Demographic table

Variable	Manual Therapy group (N = 33)	No Manual Therapy group (N = 35)
Age, years (mean, *SD*)	58.5 (9.9)	58.4 (10.9)
Gender, *n* (%) women	17 (51.5)	19 (54.3)
Ethnicity, *n* (%)		
New Zealand European	29 (87.8)	31 (88.6)
Māori	2 (6.1)	1 (2.8)
Pasifika	1 (3.0)	0
Other	1 (3.0)	3 (8.6)
Duration of shoulder symptoms, months (*Med*, IQR)	18 (7.5 to 36)	24 (12.0-36.0)
Side dominance *n* (%) right dominant	28 (84.8)	30 (85.7)
Painful side dominance, *n* (%) dominant side	17 (51.5)	22 (62.9)
Prior shoulder pain treatments *n* (%)		
None	12 (36.6)	16 (45.7)
Physiotherapy	10 (33.3)	11 (31.4)
Osteopathy/Chiropractic	1 (3.0)	0
Massage	3 (9.1)	4 (11.4)
Cortisone injection	7 (21.2)	5 (14.3)
Pain medication	13 (39.4)	16 (45.7)
Acupuncture	2 (6.1)	1 (2.0)
Comorbidity count, *n* (%)		
0	8 (24.2)	16 (45.7)
1	10 (30.3)	10 (28.6)
2	5 (15.2)	3 (8.6)
3 or more	10 (30.2)	6 (17.2)
Patient expectation scale, MODEM_E: median (IQR)	4.3 (3.8-4.8)	4.0 (3.7-4.5)

IQR: Interquartile Range; MODEM_E: Musculoskeletal Outcome Data Evaluation Management System: Expectations

weeks lost during the summer holiday. The median number of treatment sessions, including manual therapy for the MT Group, was 5 (range 1-8). The three most common manual therapy techniques were soft tissue mobilisations to the shoulder and spine (76% of participants), and passive glenohumeral (67% of participants) and thoracic spine mobilizations (58% of participants). Themes for patient education and exercise prescription appeared similar between groups as per checklists and patient clinical notes (Table 4). Most participants in both groups were satisfied or very satisfied with the treatments (MT Group: 100%; No MT Group: 96.9%), the frequency and duration of treatments, and time spent with the physiotherapist (Table 5).

Person-centered communication

Eleven audio-recordings and clinical notes were assessed for person-centred communication. These were all in the middle of the intervention series, that is, neither the first nor last session for the participant. The median (range) rating for the person-centeredness was 54% (10-100%), where 100% reflects high levels of person-centeredness and a low rating a predominantly directive approach. Examples for high ratings were using affirming responses to participants, phrases to reduce fear, and open, non-judgemental questions exploring diary entries. Low ratings were reflected by superficial or rushed questions about participants' responses to previous treatment, diary entries, and participants' understanding, not replying to their responses, directive discussions about the treatment or exercises, and minimal discussion relating to progression towards the participant's goals.

Research objectives: patient-reported outcomes

The primary outcome, QuickDASH, decreased for both groups from baseline to 3 months. Mean between-group differences were lower than the non-inferiority margin of 11 points, with no between-group differences, based on the 95% confidence intervals at the three timepoints (Table 6, Figs 2 and 3). Secondary outcomes improved for both groups with no between-group differences, except for the Pain

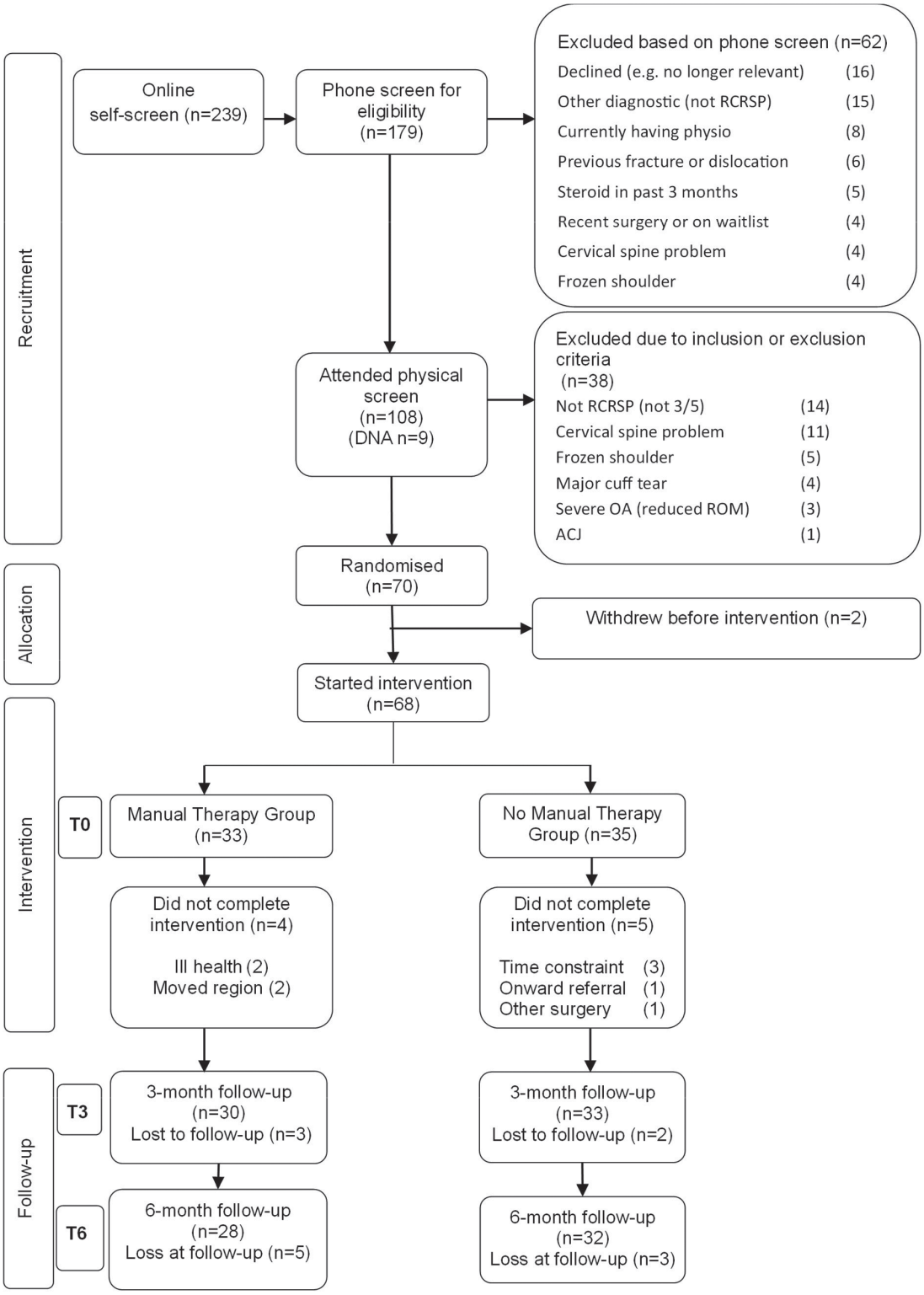

FIGURE 1 - Flowchart for recruitment, allocation, intervention, and follow-up.

TABLE 4 - Number of treatment sessions and number of treatments for each intervention

	Manual Therapy Group		No Manual Therapy Group	
	N (%)	Number of treatment sessions Median (Range)	N (%)	Number of treatment sessions Median (Range)
Treatment sessions	33 (100)	7 (2-8)	35 (100)	6 (1-8)
Manual therapy sessions	33 (100)	5 (1-8)	2 (5.7)	0 (0-2)
Treatment programme duration (weeks)		12 (1-17)		12 (1-17)
Manual Therapy				
Glenohumeral joint mobilisations	22 (66.7)	3 (1-8)	0	0
Scapulothoracic techniques	9 (27.3)	1 (1-4)	0	0
Cervical joint mobilisations	12 (12.4)	2 (1-6)	1 (2.9)	1
Thoracic joint mobilisations	19 (57.6)	2 (1-7)	0	0
Spinal joint manipulations (thrust/grade V)	4 (12.1)	1 (1-3)	1 (2.9)	2
MWM, glenohumeral joint	7 (21.2)	3 (1-5)	0	0
SNAG, cervical or thoracic spine	3 (9.1)	1 (1-2)	0	0
SSMP with manual support	4 (12.1)	1.5 (1-4)	0	0
Soft tissue/Massage shoulder, cervical or thoracic spine	25 (75.8)	3 (1-8)	0	0
Patient Education				
Shoulder anatomy/disorder	32 (97.0)	2 (1-6)	35 (100)	2 (1-6)
Treatment plan/progression	24 (72.7)	2 (1-5)	30 (85.7)	2 (1-5)
Physical activity	30 (90.9)	4 (1-8)	30 (85.7)	4 (1-8)
Whole body health, moods/emotions, sleep, stress	27 (81.8)	2 (1-4)	24 (68.57)	2 (1-7)
Pain response to exercise and activity	28 (84.9)	2 (1-5)	26 (74.3)	2 (1-6)
Pain education and self-management	22 (66.7)	2 (1-5)	21 (60.0)	2 (1-5)
Posture retraining				
• Sitting	8 (24.2)	1	5 (14.3)	1 (1-2)
• Sleeping	1 (3.0)	1	2 (5.7)	1
• Postural awareness, with or without SSMP	5 (15.2)	2 (1-2)	6 (17.1)	1
Exercise prescription, including home exercise				
General glenohumeral strengthening	26 (78.8)	4.5 (2-8)	31 (88.6)	6 (1-8)
Rotator cuff-focussed motor control and strengthening	25 (75.8)	4 (1-8)	28 (80.0)	5 (1-8)
Scapular-focussed motor control and strengthening	13 (39.4)	4 (1-7)	11 (31.4)	4 (1-8)
Upper limb closed chain strengthening	22 (66.7)	4.5 (1-7)	21 (60.0)	4 (1-8)
Upper limb plyometric exercises	3 (9.1)	2 (1 -2)	2 (5.7)	1 (1, 1)
Shoulder mobility, stretching	26 (78.8)	3 (1-8)	21 (60.0)	4 (1-8)
Spinal mobility	21 (63.6)	3 (1-8)	14 (40.0)	4 (1-8)
Whole body strengthening	10 (30.3)	1 (1-5)	14 (40.0)	2 (1-5)
Trunk control and strengthening	7 (21.2)	2 (1-5)	6 (17.1)	2 (1-5)
Lower limb strengthening	1 (3.0)	1.5 (1-2)	7 (20.0)	3 (1-5)

MWM: Mulligan's Movement With Mobilisations; SSMP: Shoulder Symptom-Modification Procedures; SNAGs: Mulligan's Sustained Natural Apophyseal Glides

TABLE 5 - Participant satisfaction with treatment (n = 62)

	Manual Therapy Group	No Manual Therapy Group
Satisfied with the physiotherapy treatment: not satisfied/satisfied/ very much satisfied	0 / 5 (16.7) / 25 (83.3)	1 (3.1) / 8 (25.0) / 23 (71.9)
Satisfied with frequency of physiotherapy treatments: not enough / just right / too much	1 (3.3) / 29 (96.7) / 0	0 / 31 (96.9) / 1 (3.1)
Satisfied with duration of treatments: too short / long enough / too long	3 (10.0) / 287 (90.0) / 0	0 / 32 (100) / 0
Satisfied with time spent with physiotherapist: too short / long enough / too long	1 (3.3) / 29 (96.7) / 0	1 (3.1) / 31 (96.9) / 0
Figures reflect frequency (%)		

TABLE 6 - Group Scores for outcome measures and between-group mean differences at all timepoints

	Manual Therapy Group (n = 33)	No Manual Therapy Group (n = 35)	Mean differences (95% CI)
QuickDASH (0-100, mean, SD)			
T_0	27.1 (14.0)	24.7 (12.7)	-2.5 (-8.6 to 3.7)
T_3	14.3 (13.1)	16.7 (11.)	0.8 (-5.5 to 7.0)
T_6	13.4 (13.7)	16.7 (12.7)	1.9 (-4.5 to 8.2)
FABQ (0-96, mean, SD)			
T_0	32.3 (16.1)	30.6 (15.7)	-0.4 (-8.7 to 7.9)
T_3	21.9 (18.4)	22.9 (14.7)	1.43 (-7 to 9.9)
T_6	19.4 (18.4)	24.3 (18.3)	4.4 (-4.2 to 13.0)
PSEQ (0-60, mean, SD)			
T_0	50.5 (10.8)	46 (11.6)	-4.4 (-9.2 to 0.3)
T_3	53.3 (10.9)	51.6 (8.0)	-1.2 (-6.1 to 3.7)
T_6	55.4 (8.8)	48.9 (10.4)	-6.3 (-11.2 to -1.4)
GROC (-7 to 7; mean, SD)			
T_3	5.0 (1.9)	4.2 (2.7)	-0.8 (-2.1 to 0.4)
T_6	4.9 (2.6)	4.1 (2.7)	-1.0 (-2.2 to 0.3)
Number (%) of active participants measured using IPAQ (n, %)			
T0	20 (60.6)	19 (54.3)	-6.3 (-30.0 to 17.0)
T3	20 (66.7)	16 (48.5)	-14.5 (-39.0 to 10.0)
T6	20 (71.4)	21 (65.6)	-3.7 (-27.0 to 20.0)
Number (%) of participants satisfied with their condition (PASS; n, %)			
T0	10 (30.3)	14 (40.0)	9.8 (-13.0 to 32.0)
T3	22 (73.3)	22 (66.7)	-6.5 (-29.0 to 16.0)
T6	22 (78.6)	22 (68.8)	-10.4 (-33.0 to 12.0)

"Difference" is taken as No Manual Therapy Group minus Manual Therapy Group.

FABQ: Fear Avoidance Belief Questionnaire; GROC: Global Rating of Change Score; IPAQ: International Physical Activity Questionnaire, category 3, meeting World Health Organisation physical activity guidelines; PASS: Patient Acceptable Symptom State, rating of being 'satisfied' or 'very satisfied' with their condition; PSEQ: Pain Self-Efficacy Scale; QuickDASH: Disabilities of Arm, Shoulder and Hand

Self-Efficacy Questionnaire (PSEQ) (35). At 6-month follow-up, the MT Group had higher scores than the No MT Group based on the 95% CI's for estimated between-group differences. The estimated mean difference of 6.3 out of 60 points may be clinically meaningful (39).

The Global Rating of Change (GROC) suggests that, on average, participants of both groups considered their condition to have improved 'moderately' or 'quite a bit better' at 3 and 6 months, respectively (Table 6). The PASS suggests that the number of participants being 'satisfied' or "very satisfied"

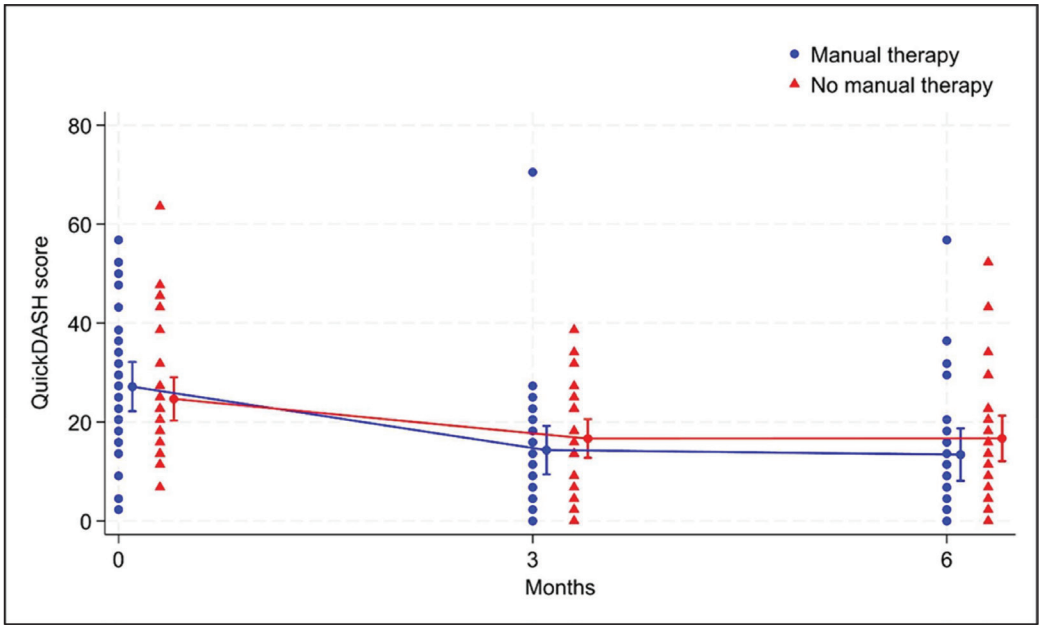

FIGURE 2 - Mean group scores for Disability of Arm, Shoulder and Hand Questionnaire (QuickDASH).

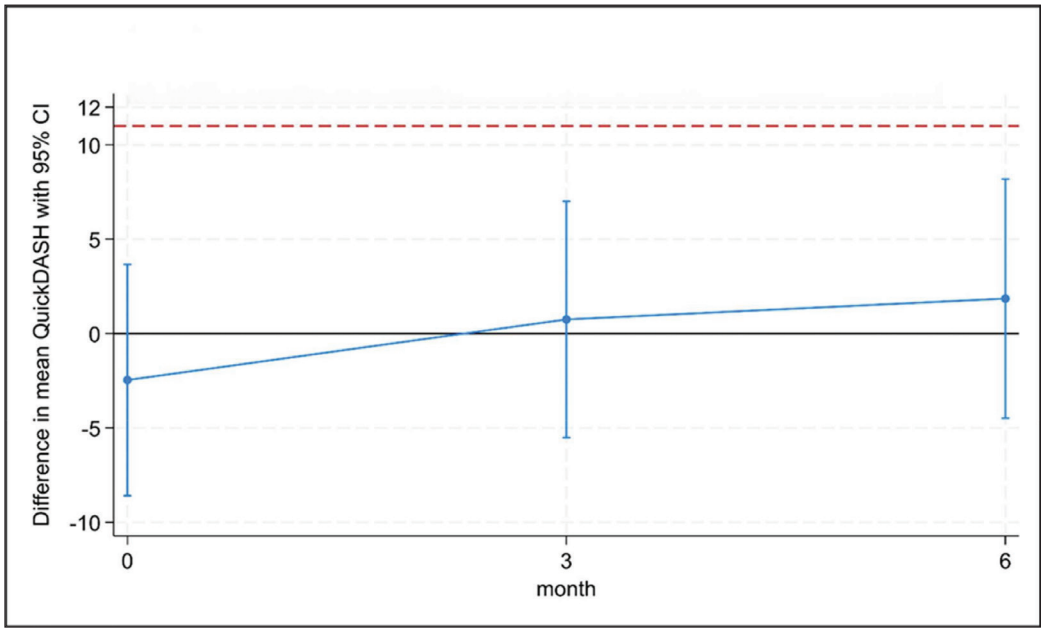

FIGURE 3 - Between-group differences for the Disability of Arm, Shoulder and Hand Questionnaire (QuickDASH) at the three timepoints (NoMT Group—MT Group). The non-inferiority margin was defined as 11 out of 100 points (red line).

with their condition increased from Baseline to the 3-month follow-up, stabilising to the 6-month follow-up. Roughly half to two-thirds of participants met the World Health Organisation guidelines for physical activity based on the IPAQ, with slight improvement for the NoMT Group at 6 months.

Discussion

This pilot RCT assessed the feasibility of a future full non-inferiority trial and provided an exploratory clinical outcomes analysis; a full trial is feasible using our recruitment strategies, based on the recruitment and retention rates, adherence for completing physiotherapy sessions until discharge, collecting the outcome measures of interest, fidelity for delivering or excluding manual therapy from the pragmatic multi-modal interventions, and practically no adverse events. With four of the physiotherapists having clinical experience in musculoskeletal physiotherapy between three and ten years, it reflects the reality of the New Zealand physiotherapy workforce, in which the average clinical career appears to be seven years (40). Our findings reflect the feasibility of a trial within a relatively young or non-specialist workforce in primary care.

In our previous one-group feasibility study, we recruited participants via newspaper adverts and researchers' individual

social media accounts at a rate of 21 respondents per month, completing the online screen and providing their contact details (26). In the current study, the University's marketing team undertook a social media campaign across two cities, with a rate of 37 respondents per month completing the online survey, thus reaching participants faster. The 3-month follow-up retention rate, adherence rate for completing the physiotherapy intervention until formal discharge, and fidelity for delivery or exclusion of manual therapy were above the pre-defined 80%, supporting full trial feasibility. Fidelity of the treatment delivery was high, with just one physiotherapist providing up to two sessions that included thoracic spine manipulations or cervical spine mobilisations for two participants of the NoMT Group. The lower rate of 72% for diary return and variable quality of entries is a common limitation for monitoring home exercise, physical activity, medication, and other healthcare access for shoulder pain during the trial. To mitigate these limitations, future trials may consider electronic delivery with weekly reminders, while maintaining hard copies to cater to participant preferences (41).

Participant characteristics

Participants in the two groups appeared comparable for demographic, pain-related characteristics, and expectations for physiotherapy at baseline, satisfaction with their condition (PASS), and perception of change (GROC) across the three timepoints. A large range was evident for the baseline QuickDASH scores (from below 10 points to above 50 points), reflecting various levels of shoulder-related disability, typical for patients seen in primary care (3). The mean baseline QuickDASH scores were slightly lower than those of a recent full RCT with individuals with RCRSP (42) and studies included in a systematic review defining minimal important clinical differences for QuickDASH for individuals with shoulder pain (33). Improvement appeared greater from baseline to the 3-month timepoint compared to the period up to the 6-month timepoint, a common finding for pain and disability for participants with RCRSP when receiving "usual" care (43).

Despite preferential recruitment, only four participants (6% of the total sample) self-identified as Māori or Pasifika. Socioeconomic and geographic constraints influence physiotherapy and other healthcare access (44,45). Accident Compensation Corporation (ACC, NZ's national taxpayer-funded no-claim injury compensation system) statistics suggest that Māori and Pasifika are under-represented in "soft tissue" shoulder claims. Lower access to physiotherapy for these ethnicities and other equity groups may be due to transport costs or time constraints off work, unaffordability, unawareness of the value of physiotherapy, divergent health beliefs, unhelpful past experiences with health care, long waiting lists in the hospital clinics, or low trust in the health system (44,45). Individuals with RCRSP and other musculoskeletal disorders with insidious, non-traumatic onset are not eligible for ACC funding. Such individuals self-fund healthcare for their pain or seek national health system care, albeit often with long waiting lists for orthopaedic conditions (46). To address New Zealand's health challenges, a future trial should consider strategies to recruit participants in underserved areas. This might be achievable by including clinics that are located rurally or in areas of socioeconomic deprivation, and including patient and clinician stakeholders from the inception of the trial design (47).

Intervention

New Zealand physiotherapists offer direct access, that is, patients do not need a medical referral, and provide comprehensive assessments and individualised interventions. Physiotherapists may refer patients to medical doctors, other healthcare professionals, and for radiographs and ultrasound imaging. The pragmatic intervention approach adds to external validity for New Zealand-contextualised clinical practice (46,48). A person-centred approach was intended to enhance trial applicability for current and future healthcare (30). Despite pre-trial training, a range of ratings for our person-centredness template was evident amongst the physiotherapists. Such a range is likely to reflect current usual practice, particularly where appointment time constraints or conflicting patient expectations may lead to directive decision making and provision of advice or education (46). If a full future trial intends to incorporate a person-centred approach, more training of physiotherapists may be needed. That may also be achievable by audio-recording participant-physiotherapist interactions earlier in the trial (rather than mid-way, as in this pilot), providing individualised feedback to the physiotherapist to improve fidelity (31).

Significance for the healthcare system and future trials

Current healthcare challenges require high-value care that can be delivered external to hospital systems, and can reach people in rural and socioeconomically deprived communities (45). As direct access providers, physiotherapists have a critical role in reducing the orthopaedic burden in the hospital system (45). To address challenges for equity of access, physiotherapy services need to be flexible and adaptable (44,47). If excluding manual therapy from a pragmatic, person-centred physiotherapy intervention is shown to be non-inferior, confidence of both the clinicians and the patients for remote consultation and interventions, such as with telehealth delivery, may increase and, thereby, potentially increasing the reach of physiotherapy to more members of the communities.

A future definitive trial should be fully powered to answer underlying mechanisms for patient responses to interventions. Sub-group characteristics of participants likely to benefit from early use of manual therapy could be explored, based on baseline pain levels, levels of fear avoidance, and patients' understanding of their condition and of navigating the health system. Based on our exploratory findings, the MT group had higher PSEQ scores at 6 months than the NoMT group, potentially challenging the notion that use of manual therapy increases patient reliance on the clinician. Our findings provide further justification for a full trial.

Methodological considerations

Having access to social media experts for advertising the trial in the communities facilitated the required recruitment within the trial timeframe. An inadvertent change from the

registered protocol occurred with the use of a Microsoft® Excel spreadsheet with randomisation, as the group allocation was not concealed from the project manager, but was concealed from all other members of the research team. In a full trial, we will use the REDCap feature for allocation, allowing allocation across multiple centres, while maintaining concealment throughout the trial (48). We used an iterative process to design the assessment template for participant-clinician interactions for the context of this trial, similar to a previous report (31). In future studies, we will explore validated tools for the assessment of person-centeredness and the clinician-patient interaction, such as the OPTION scale (Observing PaTient InvOlvemeNt) (29), as well as participants' level of pain self-management skills.

Conclusion

Our pilot trial showed that it is feasible to undertake a definitive pragmatic RCT in New Zealand to determine the effectiveness of education, manual therapy, and exercise versus education and exercise for people seeking care for RCRSP. Strategies are needed to improve participant adherence to completing diaries for exercise, medication, and other healthcare-related visits for the shoulder condition. If the intent of the trial is to include a person-centered approach with a strong self-management component, more training may be needed for the physiotherapists, as well as monitoring throughout the trial.

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Data availability statement: The datasets used and/or analysed during this study are available from the corresponding author upon reasonable request.

Ethics declarations: Ethical approval and consent to participate. The study was approved by the New Zealand Health and Disability Ethics Committee (2022 FULL 13022, 30th January 2023). All participants were informed about the purpose, content, and potential risks and benefits of the study and signed an informed written consent to participate.

Consent for publication: All participants provided written informed consent for the publication of their anonymised personal and clinical data.

Clinical trial registration: The trial was prospectively registered with the Australia New Zealand Clinical Trials registry (ACTRN 12623000034639, 12th January 2023, Online).

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