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Research

A progressive exercise and structured advice program does not improve activity more than structured advice alone following a distal radial fracture: a multi-centre, randomised trial

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KEY WORDS

Distal radial fracture
Exercise
Advice
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ABSTRACT

Question: Does a program of exercise and structured advice implemented during the rehabilitation phase following a distal radial fracture achieve better recovery of upper limb activity than structured advice alone? **Design:** A phase I/II, multi-centre, randomised, controlled trial with concealed allocation, assessor blinding and intention-to-treat analysis. **Participants:** Thirty-three adults (25 female, mean age 54 years) following distal radial fracture managed in a cast. **Intervention:** The experimental intervention was a 6-week program of progressive exercise and structured advice implemented over three consultations by a physiotherapist. The control intervention was a program of structured advice only, delivered by a physiotherapist over three consultations. **Outcome measures:** The primary outcome was upper limb activity limitations, assessed by the Patient-Rated Wrist Evaluation and the shortened version of the Disabilities of the Arm, Shoulder and Hand outcome measure (QuickDASH). The secondary outcomes were wrist range of movement, grip strength and pain. All measures were completed at baseline (week 0), after the intervention (week 7) and at 6 months (week 24). **Results:** There were no significant between-group differences in upper limb activity as measured by the Patient-Rated Wrist Evaluation at week 7 and week 24 assessments (mean difference –4 units, 95% CI –10 to 2; mean difference 0 units, 95% CI –3 to 3, respectively), or QuickDASH at week 7 and week 24 assessments (mean difference –5 units, 95% CI –16 to 6; mean difference 0.3 units, 95% CI –6 to 7, respectively). The secondary outcomes did not demonstrate any significant between-group effects. **Conclusion:** The prescription of exercise in addition to a structured advice program over three physiotherapy consultations may convey no extra benefit following distal radial fracture managed in a cast. **Trial registration:** ACTRN12612000118808. **[Bruder AM, Shields N, Dodd KJ, Hau R, Taylor NF (2016) A progressive exercise and structured advice program does not improve activity more than structured advice alone following a distal radial fracture: a multi-centre, randomised trial. *Journal of Physiotherapy* 62: 145-152]**

Introduction

Distal radial fractures are a common upper limb fracture,[1,2] with a greater incidence in older women who have been diagnosed with osteoporosis and have a history of falling.[1–3] Ongoing problems after distal radial fracture can include pain, stiffness and weakness, which can lead to difficulty completing everyday functional tasks[4,5] such as preparing meals, housework and shopping.[6] People who have had a distal radial facture are regularly referred to physiotherapy for rehabilitation to restore full joint range of movement and regain functional ability.[7] Exercise and advice are the most commonly used interventions by physiotherapists during rehabilitation after distal radial fracture.[8]

Prescription of exercise by a physiotherapist after distal radial fracture focuses on promoting movement, which is a key principle of fracture management.[9] Adherence to prescribed exercise has been found to be moderately-to-strongly associated with short-term improvements of impairment and activity following this type of fracture.[10] Exercise prescription and advice to encourage movement in usual tasks of daily living are interventions that promote patient independence through the use of a self-management approach.[11] Self-management programs typically focus on equipping patients with chronic illnesses with the knowledge and skills needed to manage their conditions,[12] including decision-making, symptom management, expected trajectory of recovery, and self efficacy.[13] The application of these self-management principles may also be appropriate in distal radial fracture rehabilitation.

Despite their widespread use,[8] the interventions of exercise and advice have never been independently evaluated as programs of treatment for this patient group in a randomised, controlled trial.[14] A high-quality trial has compared a single session of

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physiotherapist-led advice and exercise compared with no physiotherapy intervention, and identified short-term benefits in pain and activity.[15] That trial suggested that exercise and advice could be useful in people after distal radial fracture; however, it was unclear how much benefit was contributed by each intervention. Given this, there was a need for a randomised, controlled clinical trial to find out if a progressive exercise program prescribed by a physiotherapist could improve activity and decrease impairment after distal radial fracture. Such a trial would provide evidence for clinicians about the effectiveness of prescribing a progressive exercise program, with a possible medium-term impact on older adults following a distal radial fracture.

Therefore, the research question for this randomised trial was:

Does a program of exercise and structured advice implemented during the rehabilitation phase following a distal radial fracture achieve better recovery of upper limb activity than structured advice alone?

Method

Design

A multi-centre, two-group, randomised, controlled trial was conducted, incorporating concealed allocation, blinding of outcome assessors where possible, and intention-to-treat analysis of repeated measures. The trial was conducted across two hospital-based physiotherapy departments between June 2012 and July 2013. The trial is reported here according to the CONSORT guidelines.[16]

Participants were randomly allocated to either the experimental or control group after baseline assessment. A researcher, who was not involved in patient recruitment, assessment or treatment, used a web-based system (randomization.com) to generate the random allocation sequence in permuted blocks of six. The permuted blocks were stratified for location and hand dominance. Allocations were sealed in sequentially numbered, opaque envelopes, which were kept off site. After the assessor had completed the baseline assessment, the next envelope in the sequence that matched the participant's department location and hand dominance was selected and assigned by the treating physiotherapist.

The treating physiotherapists were provided with an information sheet for each consultation, which outlined the advice that should be given to both groups, and an information sheet with diagrams and explanations for each of the exercises that should be prescribed to the experimental group. At the end of each consultation, the treating physiotherapist recorded the following details: whether the participant attended, the duration of the session in minutes, whether the participant reported any adverse effects, any changes made to the prescribed program, and comments about the participant's adherence to the intervention.

All participants completed assessments at baseline (week 0), immediately following the intervention phase of the study (week 7) and at 6 months (week 24). These assessments were conducted by an assessor who was unaware of group allocation and was not involved in administering treatment.

Participants, therapists and centres

Adults with a distal radial fracture and who were referred to physiotherapy for rehabilitation after removal of their cast were invited to participate if they were: aged $\geq$ 21 years; able to follow simple written and verbal instructions in English; and willing and able to provide informed consent to participate. Volunteers were excluded if they had: a history of a pre-existing inflammatory joint condition; signs and symptoms of complex regional pain syndrome; a previous wrist fracture on the affected side; or bilateral wrist fractures.

Three senior musculoskeletal physiotherapists with experience in outpatient services ranging from 5 to 17 years delivered all interventions. These same physiotherapists were involved in the design of the program of structured advice that was administered to both groups, and assisted with the selection of exercises prescribed to the experimental group. None of the treating physiotherapists were involved in randomisation or participant assessment. Given that the treating physiotherapists were responsible for providing the intervention (advice only or advice and exercise), they could not be blinded to group allocation.

Intervention

The experimental group received a program of exercise and structured advice over three physiotherapy consultations (approximately 20 to 30 minutes each) in weeks 1, 3 and 5 (from removal of cast) as shown in Table 1. This was in addition to their usual activities. In week 1, the patient received structured advice[15] and seven exercises[15,17] that were outlined in a home exercise diary and an exercise program instruction booklet (see appendix 1 on eAddenda). Participants were asked to record the number of sets and repetitions they completed for each exercise in their home diary. At the end of each week the participants were asked to return their exercise diary to the researchers using a reply paid envelope. In week 3, the participant received further advice on sleep, relaxation and work strategies, as necessary. The seven exercises were reviewed and progressed by the physiotherapist, by either adding an exercise with an increased challenge or increasing the resistance of an existing exercise. In week 5, the participant received advice on medium-term goal setting and discharge planning, and had their exercises progressed to heavier loads and/or increased weight-bearing.

The control group received three physiotherapy consultations of similar duration to the experimental group in weeks 1, 3 and 5, but received only the program of advice. All participants were provided with an elastic threaded compression sleeve for the wrist and forearm, and educated on its application to help control swelling.

Outcome measures

Primary outcome

The primary outcome was upper limb activity, as measured by the Patient-Rated Wrist Evaluation[18] and the shortened version of the Disabilities of the Arm, Shoulder and Hand outcome measure (QuickDASH) questionnaires.[19] Participants completed the 10-item activity-specific section of the Patient-Rated Wrist Evaluation (sections 2A and 2B), in which they rated wrist-related activity limitations from 0 (no difficulty with the activity) to 10 (unable to perform the activity). An overall score was calculated out of 50 by adding the scores for the 10 items and dividing by two. This questionnaire was developed to assess people with wrist pathology and has been used in previous trials involving participants with distal radial fractures. It has been shown to be a sensitive, valid and reliable assessment tool.[20] The 19-item QuickDASH questionnaire[19] (including one compulsory 11-item disability module, and two four-item optional work and sports modules) asked participants to rate their ability to perform upper limb tasks from 1 (no difficulty) to 5 (unable to perform). The score was calculated by adding the total number of all the responses, dividing it by the number of answered responses and subtracting 1 from the result. This score was then multiplied by 25 to give a QuickDASH disability score out of 100 for the 11-item module, and for the optional work and sports modules. The QuickDASH measures disability in people with upper extremity musculoskeletal disorders and has been shown to have good psychometric properties.[21] The minimum clinically important difference on the Patient-Rated Wrist Evaluation and QuickDASH have been determined as 14 points out of 100[22] and 15 points out of 100,[23] respectively.

Secondary outcomes

The secondary outcomes measured impairments: wrist range of movement, grip strength and pain. Range of movement of wrist

Table 1
Intervention.

Intervention provided by the physiotherapist	Dosage	Session when the intervention was provided to the participants		
		Session 1 (Week 1)	Session 2 (Week 3)	Session 3 (Week 5)
Program of advice				
advice to manage movement		E, C	E, C	E, C
advice to prevent and manage swelling and pain and skin care	-	E, C	E, C	E, C
explanation of fracture healing principles	-	E, C	E, C	
advice to promote sleep and relaxation (as necessary)	-		E, C	E, C
advice regarding work strategies (as necessary)	-		E, C	E, C
advice for return to work	-		E, C	E, C
goal setting – short-term	-		E, C	E, C
goal setting – long-term	-		E, C	E, C
explanation of anatomy and function of the wrist	-	E, C		
advice for return to leisure activities	-			E, C
discharge planning	-			E, C
Program of exercises				
active finger ROM	2 sets x 20 reps, 3/day	E	E	
ball squeeze	3 sets x 10 reps, 3/day	E	E	E
active wrist flexion and extension ROM	2 sets x 20 reps, each direction, 3/day	E	E	
active pronation and supination ROM	2 sets x 20 reps, each direction, 3/day	E	E	E
active radial and ulnar deviation ROM	2 sets x 20 reps, each direction, 3/day	E	E	E
active-assisted wrist extension ROM	1 set x 5 reps with 15 sec hold, 3/day	E	E	
wrist and forearm flexor and extensor strength exercises	2 sets x 10 reps, 1/day	E		
partial weight-bearing wrist extension ROM	1 set x 3 reps with 10 sec hold, 3/day		E	E
forearm flexor and extensor passive stretch	1 set x 3 reps with 15 sec hold, 3/day		E	
wrist and forearm flexor and extensor strength exercises using light weights	2 sets x 10 reps, 1/day		E	
wrist weight-bearing stretch	1 set x 5 reps with 15 sec hold, 3/day			E
wrist and forearm flexor, extensor and supinator strength exercises using heavier weights	2 sets x 10 reps, 1/day			E

C = control group, E = experimental group, reps = repetitions, ROM = range of movement.

flexion, wrist extension and supination were measured using a goniometer, as recommended by the American Society of Hand Therapists.[24] Isometric grip strength was measured in kg using a calibrated Jamar dynamometer[a] on setting two to ensure maximal grip strength[25] and with the elbow flexed to 90 deg. Pain was measured using the five-item pain-specific module of the Patient-Rated Wrist Evaluation; participants rated their wrist-related pain from 0 (no pain) to 10 (severe pain). The overall total score on a scale out of 100 was also calculated for the Patient-Rated Wrist Evaluation, where pain and function problems were weighted equally.[26]

Adherence to the home-based exercise program was measured using an exercise diary. Participants were asked to make daily entries about the number of exercise sessions they performed and the number of exercises they completed per session. To calculate adherence, the amount of performed exercise was compared to the amount of prescribed exercise.[10] Adherence to the intervention protocol in the control and experimental groups was recorded by the physiotherapist at each consultation.

Data analysis

A sample size of 15 in each group was calculated as sufficient to identify a between-group difference of 14 points on the Patient-Rated Wrist Evaluation as statistically significant,[22] based on a standard deviation of 13 on a transformed 0 to 50 scale.[15] This was based on a Type 1 error rate of 0.05, which was consistent with recommendations,[27] and power of 0.80. Data analysis was performed using standard software[b]. Descriptive statistics were calculated for the characteristics of the participants and treating physiotherapists, and for all available data on each outcome measure at each time point.

Treatment outcome for all primary and secondary measures between the experimental and control groups was analysed with ANCOVA using the baseline measures as covariates, from baseline to 7 weeks and from baseline to 24 weeks. The primary analysis was carried out as intention-to-treat using all available data, but without using imputation methods.[16]

In addition, a per-protocol analysis was completed to investigate whether there was an association between intervention protocol adherence and outcomes. An adherence threshold for the experimental group was set at a participant performing $\geq$ 70% of the prescribed exercise program. This was determined by calculating a ratio, where the number of exercise repetitions *performed* per week (as recorded in the home exercise diary) was divided by the number of exercise repetitions *prescribed* per week and multiplied by 100. The relationship between exercise program adherence in the experimental group and change in treatment effect as measured on the QuickDASH questionnaire, Patient-Rated Wrist Evaluation and grip strength was explored using the Pearson product-moment (r) correlation coefficient.

The number of participants who demonstrated the minimum clinically important difference in upper limb activity was calculated on the Patient-Rated Wrist Evaluation and QuickDASH questionnaires. Relative risk calculations were completed using a web-based calculator[c] to determine the chance that a participant would demonstrate the minimum clinically important difference on either the Patient-Rated Wrist Evaluation or QuickDASH questionnaires.

Results

Flow of participants, therapists and centres through the study

Seventy adults with a distal radial fracture were referred (Figure 1). Thirty-three adults met the inclusion criteria, consented to participate in the trial and were randomised to either the experimental (n = 19) or control (n = 14) group. Two participants from the experimental group dropped out during the intervention phase; one due to medical reasons and one did not attend after the first physiotherapy session. Two adults from the control group failed to attend the week 24 follow-up assessment session.

The two groups were similar in terms of age, gender distribution, type of distal radial fracture, and management of

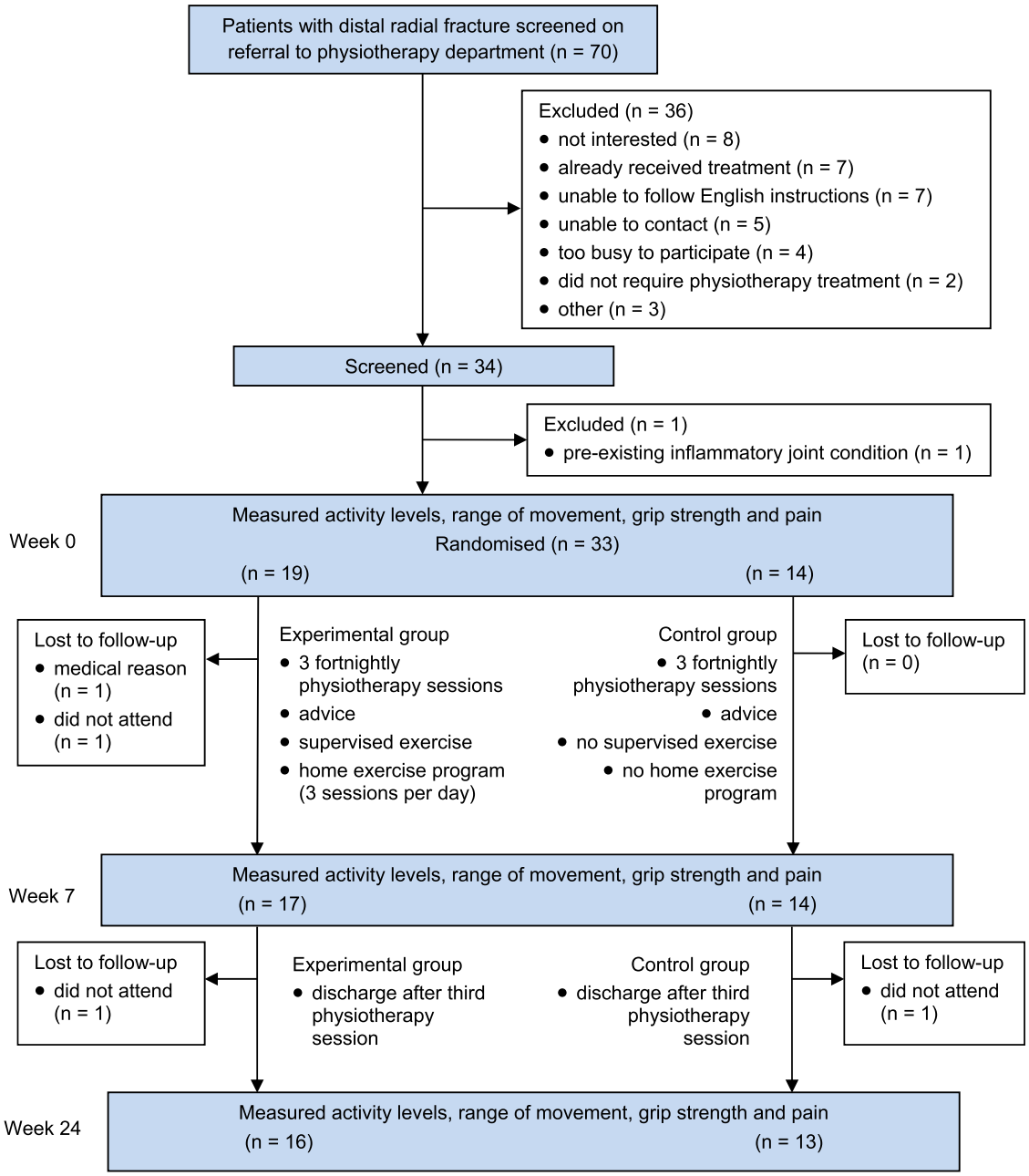

Figure 1. Design and flow of participants through the trial.

distal radial fracture (Table 2). Almost equal recruitment was achieved across the two trial sites. Two of the three senior physiotherapists provided 88% of the interventions, due to the third therapist resigning from the health service during the trial.

Compliance with trial method

On average, the control group attended 2.9 (SD 0.3) out of the three physiotherapy consultations and the experimental group attended 2.7 (SD 0.6) consultations. Of the 14 participants allocated to the control group, one was reported by the treating physiotherapist as having not adhered to the program of advice, due to commencing self-prescribed exercises. Of the 19 participants allocated to the experimental group, 10 adhered to the intervention protocol threshold, completing ≥70% of the prescribed exercises.

No serious adverse effects were reported. There were two minor adverse effects. One participant allocated to the experimental group reported wrist pain after commencing the exercises in week 1. The physiotherapist reduced the training intensity and the participant was able to resume and complete the training program in weeks 5 and 6. A second participant allocated to the control group reported wrist pain and stiffness to the treating therapist at the week 5 session and to the assessor at week 7.

Effect of the intervention

Primary outcome

There were no significant between-group differences for upper limb activity, as measured by the Patient-Rated Wrist Evaluation, at either the week 7 assessment (MD –4 points, 95% CI –10 to 2) or week 24 assessment (MD 0 points, 95% CI –3 to 3), as shown in Table 3. Similar results were found for the per protocol analysis, which is presented in Table 4. Individual participant data are presented in Table 5 (see eAddenda for Table 5).

There were no significant between-group differences for upper limb activity, as measured on the QuickDASH disability module, at either the week 7 assessment (MD –5 points, 95% CI –16 to 6) or week 24 assessment (MD 0 points, 95% CI –6 to 7), as shown in Table 3. Similar results were found for the per protocol analysis, which is presented in Table 4. Individual participant data are presented in Table 5 (see eAddenda for Table 5).

Table 2
Baseline characteristics of participants, therapists and centres.

Characteristic	Randomised (n = 33)		Lost to follow-up (n = 4)	
	Exp (n = 19)	Con (n = 14)	Exp (n = 3)	Con (n = 1)
Participants				
Age *(yr)*, mean (SD)	51 (17)	58 (18)	57 (23)	55 (-)
Gender, n males (%)	4 (21)	4 (29)	1 (33)	0 (0)
Hand dominance, n (%)				
right	17 (90)	13 (93)	2 (67)	1 (100)
left	1 (5)	1 (7)	1 (33)	0 (0)
ambidextrous	1 (5)	0 (0)	0 (0)	0 (0)
Mechanism of fracture, n (%)				
fall from level	13 (68)	11 (79)	2 (67)	1 (100)
fall from height or medium speed injury	4 (21)	3 (21)	1 (33)	0 (0)
other	2 (11)	0 (0)	0 (0)	0 (0)
Side of fracture, n dominant (%)	12 (63)	9 (64)	2 (67)	0 (0)
Type of fracture, n (%)				
extra-articular	11 (58)	8 (57)	1 (33)	0 (0)
intra-articular	8 (42)	6 (43)	2 (67)	1 (100)
Type of fixation, n (%)				
cast	19 (100)	14 (100)	3 (100)	1 (100)
Period of immobilisation *(wk)*, mean (SD)	6.5 (0.8)	6.1 (0.5)	7.2 (1.3)	6.5 (-)
Time from initial injury to initial assessment *(wk)*, mean (SD)	7.5 (0.9)	7.2 (1.1)	8.1 (1.2)	8.1 (-)
Time from cast removal to baseline assessment *(d)*, mean (SD)	7.5 (3.1)	7.8 (6.5)	6.3 (1.2)	9.0 (-)
Physiotherapy session attendance, mean (SD)	2.7 (0.6)	2.9 (0.3)	2.0 (1)	3.0 (-)
Therapists				
Treated one participant, n (%)	2 (11)	2 (14)	0 (0)	0 (0)
Treated two participants, n (%)	8 (42)	5 (36)	2 (67)	1 (100)
Treated three participants, n (%)	9 (47)	7 (50)	1 (33)	0 (0)
Centres				
Participants treated, n (%)				
health service 1	10 (53)	7 (50)	2 (67)	1 (100)
health service 2	9 (47)	7 (50)	1 (33)	0 (0)

Con = control group, Exp = experimental group.

The chance that a participant would demonstrate the minimum clinically important difference on the Patient-Rated Wrist Evaluation at week 7 was similar for both groups, with a relative risk of 1.12 (95% CI 0.81 to 1.55). There was an identical result for the QuickDASH at week 7, with a relative risk of 1.12 (95% CI 0.81 to 1.55).

There was no correlation between adherence with the home exercise program and change in Patient-Rated Wrist Evaluation from baseline to week 7 ($r = 0.12$, n = 17). There was a small negative correlation between adherence with the home exercise program and change in QuickDASH from baseline to week 7 ($r = -0.31$, n = 17), indicating that those who adhered to the exercise program did not improve as much as those who did not complete the prescribed exercises.

Secondary outcomes

There were no significant between-group differences for wrist flexion, wrist extension and supination range of movement, pain or grip strength at either week 7 or week 24 for either intention-to-treat or per protocol analyses. There was no relationship between adherence with the home exercise program and change in grip strength from baseline to week 7 ($r = 0.04$, n = 17).

Discussion

This trial found no difference in outcomes between a physiotherapist-led program of exercise and structured advice compared with a program of structured advice only in people following a distal radial fracture. There were no significant between-group differences immediately after the program (week 7) or at follow-up (week 24) for any outcome, irrespective of whether data were analysed by intention to treat or per protocol. This is not consistent with previous research, which found people following a wrist fracture who adhered to an exercise program achieved better short-term improvements in wrist extension and arm use.[10] However, since both treatment groups in the present trial received extensive structured advice from a physiotherapist, the results may be consistent with previous research suggesting that physiotherapist-led rehabilitation programs are beneficial for people following a distal radial fracture.[15,28]

One explanation for the present results could be that a structured advice program may be more important than a set of prescribed exercises following a distal radial fracture; that is, the provision of prescribed exercises to a structured advice program provided no added benefit. Movement is a key principle of fracture management[9] and was incorporated into every physiotherapy advice consultation. Participants were encouraged to continue with their usual tasks of daily living, such as washing the dishes, hanging wet clothes up on a line and getting dressed – all activities that require wrist strength and range of movement. Although not the aim of this trial, one interpretation of the results could be that a program of structured advice is beneficial for people following a distal radial fracture. A previous trial that examined one session of advice and exercise provided by a physiotherapist demonstrated improved outcomes of patients after a wrist fracture compared with no physiotherapy intervention.[15] Currently, there are no trials that have examined advice as the manipulated variable in a randomised, controlled trial for this patient population. There has been an attempt to examine the effect of advice for other musculoskeletal conditions. A systematic review of randomised, controlled trials that examined the effect of advice for the management of low back pain found that simple advice to stay active and continue normal daily activities was as effective as advice and specific exercise for improving pain, back-specific function and work disability in people with acute low back pain.[29] Frost et al found that people with sub-acute low back pain were no better off on the Oswestry disability index or the Roland Morris disability questionnaire when they received routine physiotherapy compared with one assessment and advice session by a physiotherapist.[30] These results suggest the hypothesis that a structured advice program to move during the acute stage of musculoskeletal conditions could be effective. Future research should investigate whether a structured advice program as the manipulated variable in a randomised, controlled trial improves activity for people following a distal radial fracture, and how physiotherapists can best encourage and motivate people to move.

Table 3
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups as per intention to treat.

Outcome	Groups						Difference within groups				Difference between groups	
	Week 0		Week 7		Week 24		Week 7 minus week 0		Week 24 minus week 0		Week 7 minus week 0	Week 24 minus week 0
	Exp (n = 19)	Con (n = 14)	Exp (n = 17)	Con (n = 14)	Exp (n = 16)	Con (n = 13)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
PRWE activity section *(0 to 50)*	24 (11)	25 (11)	3 (2)	7 (11)	2 (5)	2 (4)	−20 (9)	−18 (15)	−21 (11)	−23 (11)	−4 (−10 to 2)	0 (−3 to 3)
*Quick*DASH 11-item *(0 to 100)*	43 (13)	44 (23)	10 (7)	16 (21)	5 (8)	5 (11)	−31 (14)	−28 (24)	−35 (14)	−38 (19)	−5 (−16 to 6)	0 (−6 to 7)
*Quick*DASH (work) 4-item *(0 to 100)*	50 (29)	40[a] (27)	10 (10)	15[a] (20)	5 (13)	6 (13)	−35 (22)	−25 (28)	−41 (31)	−38 (21)	−7 (−17 to 4)	−1 (−12 to 9)
*Quick*DASH (sport) 4-item *(0 to 100)*	70[b] (26)	54[c] (43)	8[d] (11)	50[c] (48)	2[e] (5)	23[f] (39)	−59 (29)	−5 (47)	−63 (30)	−34 (36)	−45 (−84 to −6)	−24 (−55 to 7)
Wrist extension range *(deg)*	48 (14)	46 (12)	57 (12)	59 (7)	64 (8)	61 (8)	10 (9)	13 (10)	14 (9)	17 (9)	−2 (−8 to 3)	0 (−5 to 6)
Wrist flexion range *(deg)*	34 (12)	31 (13)	49 (11)	49 (11)	54 (13)	56 (11)	15 (7)	17 (10)	18 (11)	24 (9)	−2 (−8 to 4)	−4 (−12 to 3)
Wrist supination range *(deg)*	50 (13)	42 (11)	63 (15)	61 (12)	68 (15)	65 (11)	13 (13)	19 (14)	17 (12)	23 (16)	−2 (−12 to 7)	−1 (−11 to 9)
Grip strength *(kg)*	5 (4)	6 (9)	12 (6)	13 (12)	14 (5)	16 (13)	7 (4)	7 (5)	9 (5)	10 (5)	0 (−3 to 4)	−0 (−4 to 4)
PRWE pain section *(0 to 50)*	23 (7)	19 (9)	10 (5)	10 (11)	7 (7)	5 (6)	−12 (8)	−9 (10)	−15 (9)	−13 (6)	−1 (−7 to 5)	−0 (−5 to 4)
PRWE total *(0 to 100)*	47 (15)	44 (17)	13 (7)	17 (22)	9 (11)	8 (10)	−31 (15)	−27 (22)	−36 (19)	−36 (15)	−4 (−15 to 7)	1 (−7 to 9)

Con = control group, Exp = experimental group, PRWE = Patient-Rated Wrist Evaluation.
[a] n = 13, [b] n = 9, [c] n = 5, [d] n = 8, [e] n = 7, [f] n = 4.

Table 4
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups as per protocol.

Outcome	Goups						Difference within groups				Difference between groups	
	Week 0		Week 7		Week 24		Week 7 minus week 0		Week 24 minus week 0		Week 7 minus week 0	Week 24 minus week 0
	Exp (n = 10)	Con (n = 13)	Exp (n = 10)	Con (n = 13)	Exp (n = 10)	Con (n = 12)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
PRWE activity section *(0 to 50)*	23 (9)	25 (11)	3 (2)	7 (11)	3 (6)	2 (4)	−20 (9)	−18 (15)	−20 (12)	−23 (12)	−4 (−12 to 4)	1 (−4 to 5)
*Quick*DASH 11-item *(0 to 100)*	39 (14)	44 (24)	11 (9)	16 (22)	7 (10)	6 (11)	−28 (16)	−28 (25)	−33 (16)	−38 (20)	−3 (−18 to 12)	2 (−7 to 11)
*Quick*DASH (work) 4-item *(0 to 100)*	41 (29)	37 (26)	10 (12)	15 (21)	7 (16)	6 (14)	−31 (20)	−22 (27)	−34 (32)	−35 (18)	−6 (−20 to 9)	1 (−13 to 4)
*Quick*DASH (sport) 4-item *(0 to 100)*	70[a] (33)	42[a] (40)	5[a] (6)	53[a] (54)	3[a] (6)	27[b](47)	−66 (37)	11 (36)	−67 (39)	−17 (4)	−64 (−136 to 7)	−37 (−94 to 20)
Wrist extension range *(deg)*	48 (10)	44 (11)	58 (10)	58 (7)	63 (8)	60 (7)	10 (10)	14 (10)	15 (11)	17 (9)	−1 (−8 to 6)	1 (−5 to 8)
Wrist flexion range *(deg)*	31 (6)	30 (12)	47 (9)	47 (10)	53 (15)	54 (10)	16 (8)	18 (11)	19 (13)	25 (9)	−1 (−9 to 6)	−5 (−15 to 4)
Wrist supination range *(deg)*	46 (12)	41 (11)	61 (20)	62 (12)	6 (17)	65 (11)	15 (16)	21 (13)	19 (13)	25 (15)	−4 (−17 to 9)	−3 (−15 to 10)
Grip strength *(kg)*	5 (5)	4 (5)	13 (7)	11 (9)	15 (6)	13 (9)	8 (6)	7 (5)	10 (6)	9 (5)	1 (−4 to 5)	0 (−5 to 5)
PRWE pain section *(0 to 50)*	23 (6)	19 (10)	11 (6)	10 (12)	8 (8)	6 (7)	−11 (8)	−9 (10)	−14 (9)	−12 (6)	−1 (−9 to 7)	1 (−5 to 7)
PRWE total *(0 to 100)*	46 (13)	44 (18)	14 (8)	17 (23)	11 (13)	8 (11)	−32 (14)	−27 (23)	−34 (19)	−36 (16)	−4 (−19 to 11)	3 (−8 to 13)

Con = control group, Exp = experimental group, PRWE = Patient-Rated Wrist Evaluation.
[a] n = 4, [b] n = 3.

Another possible explanation is that exercise can be effective, but the particular exercise regimen used in the present study was not an effective one. It has been proposed that variation in the quality of administration of complex interventions, including education programs, could influence their effectiveness.[31] The selection of the exercises was based on previous research,[15,17] which demonstrated between-group improvements in activity and impairment measures in favour of people after a distal radial fracture. In addition, three experienced musculoskeletal physiotherapists contributed to the exercise program design and implementation in the present study. At the end of each physiotherapy consultation, the treating therapist was asked to record information about whether they had made changes to the prescribed program and make comments about the participant's adherence to the intervention. This enabled checking to see if the physiotherapists had implemented the exercise intervention as designed. Based on this, the authors are confident in the design of the exercise program and the implementation of the exercise intervention.

Other considerations when interpreting the lack of statistically significant results are the participants' adherence to the prescribed program and the submitted exercise diaries. Only 10 of the 19 participants allocated to the experimental group completed at least 70% of the prescribed exercises. Even though the per protocol analysis found similar results to the intention-to-treat analysis, poor adherence may be one explanation for the results, rather than a lack of treatment efficacy.[32] Strategies such as providing the participants with written and illustrated exercises,[33] maintaining an exercise diary[34,35] and regular monitoring[35] were implemented, as research suggests that combining these types of strategies may help to optimise adherence.[36] Future research might consider implementing a similar exercise program but include other strategies to optimise adherence such as a telephone or SMS reminder and/or improving patient motivation through techniques such as motivational interviewing.[37] It would also be useful to examine participant outcome expectations at commencement of the program to analyse how expectations may influence exercise program adherence in people following a distal radial fracture.

Some strengths of this multi-centre trial were that participants were randomly allocated to groups, allocation was concealed and the two groups were similar at baseline. The assessor remained blind to participant allocation at all assessment time points, and measures of at least one outcome were obtained from $>$ 85% of the participants initially allocated to each group. Data analyses were completed as intention-to-treat and per protocol for all outcome measures. Given this, the authors are reasonably confident that there was a low risk of bias. A systematic review examining the effect of exercise on reducing impairment and increasing activity in the rehabilitation of people with upper limb fractures[14] identified a need to investigate exercise as the manipulated variable in a randomised, controlled trial. Another strength of this trial was that it attempted to investigate the effect of exercise by controlling the type and amount of advice provided to each group, which has not been previously attempted with people following a distal radial fracture.

A limitation of the present trial was a protocol variation. It was intended to use accelerometers as a third primary outcome to quantify the extent of arm usage (the amount and intensity of arm activity) of participants using the mean total activity over seven consecutive days. However, accelerometry data were obtained on only 51% of the sample. These data are available from the authors, who intend to report elsewhere on the feasibility of measuring arm use in this population. Another possible limitation of the present trial was that the outcomes focused on impairment and activity and did not include information about employment or rate of return to work. Rate of return to work may have impacted on pain levels at the week 7 assessments and could be one explanation for no significant between-group differences. We did not measure the rate of improvement by assessing participants during the intervention implementation phase and may have failed to detect one group improving faster than another. However, 6 weeks after cast removal is a reasonable time frame, when the fracture would be expected to be at the stage of consolidation.[9] There is also the possibility of contamination bias given that two physiotherapists provided treatment to 88% of the participants. However, consultations were monitored and so contamination bias is not thought to have influenced the findings.

For clinical practice, the results suggest that the additional prescription of exercise to a structured program of advice over three physiotherapy consultations may convey no benefit following a wrist fracture managed in a cast. Exercise is an intervention frequently used by physiotherapists in distal radial fracture rehabilitation, but no high-quality trials had investigated its effect as the manipulated variable in a randomised, controlled trial.[8] The present trial was the first to do so, with the results supporting previous research, which found inconclusive evidence for the benefit of exercise following an upper limb fracture,[14] and insufficient evidence of how best to manage distal radial fractures during rehabilitation.[4] The present trial did not aim to investigate the role of physiotherapy, as both groups received physiotherapy. Also, it did not aim to investigate whether advice to move was beneficial following a distal radial fracture. However, one interpretation could be that advice is a useful intervention. Given this, future research is needed to determine whether a program of structured advice, as the manipulated variable in a randomised, controlled trial, improves activity for people following a distal radial fracture.

What is already known on this topic: Fracture of the distal radius can result in pain, stiffness, weakness and impaired function. Physiotherapist-led advice and exercise improve pain and activity in this population. However, it is unclear how much benefit is contributed by each intervention.
What this study adds: The prescription of exercise in addition to a structured advice program over three physiotherapy consultations may convey no extra benefit following distal radial fracture managed in a cast.

Footnotes: [a]Jamar hand dynamometer, Lafayette Instrument Company, Lafayette, USA. [b]Predictive Analysis Software V.21, SPSS, Chicago, USA. [c]Relative Risk Calculator V.14.12.0, MedCalc, Ostend, Belgium.

eAddenda: Table 5 and Appendix 1 can be found online at doi:10.1016/j.jphys.2016.05.011

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Competing interests: Nil

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