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Does thoracic kyphosis severity predict response to physiotherapy rehabilitation in patients with osteoporotic vertebral fracture? A secondary analysis of the PROVE RCT

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Abstract

Objectives To describe participant characteristics based on kyphosis severity, examine the relationship between kyphosis and physical function, and investigate whether kyphosis severity predicts improvement after physiotherapy intervention.
Design and setting Secondary longitudinal analysis of the PROVE trial, a multicentre RCT. Data from all three trial arms were pooled and divided into quartile groups according to baseline kyphosis severity for linear mixed model analysis.
Participants 604 men and women with osteoporotic vertebral fracture.
Main outcome measures Estimated marginal means reported from adjusted mixed models for thoracic kyphosis, Six-minute Walk Test (6MWT), functional reach and Short Performance Physical Battery (SPPB).
Results Thoracic kyphosis improved at 4-months and 12-months in participants with moderate hyperkyphosis (-2.4 ° and -3.0 °) and severe hyperkyphosis (-5.7 ° and -8.0 °). Functional reach scores were lower in the severe hyperkyphosis group compared to normal and hypokyphosis groups by at least 2.3 cm. 6MWT scores were worse in the severe hyperkyphosis group compared to the normal kyphosis group by 39.6 m. SPPB scores were worse in severe hyperkyphosis group compared to the normal kyphosis group by 0.72 points, but all participants, regardless of kyphosis severity, improved SPPB at 4 months by 0.42 points and at 12 months by 0.25 points.
Conclusions Results suggest that presenting with hyperkyphosis and osteoporotic vertebral fracture does not prevent improvement in thoracic curvature and physical performance after physiotherapy compared with baseline values. While higher kyphosis correlated with poorer physical function scores, baseline kyphosis severity could not predict change in physical function measures.
Registry ISRCTN 49117867.

Key messages

- Hyperkyphosis in people with osteoporotic vertebral fracture is associated with greater pain, poorer walking capacity, back endurance, balance and physical function.
- People with severe hyperkyphosis and osteoporotic vertebral fracture showed the greatest improvement of thoracic kyphosis angle.
- Improvements in physical performance were not influenced by severity of thoracic kyphosis.

Keywords: Kyphosis; Spinal fracture; Osteoporosis; Rehabilitation

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Introduction

Osteoporosis is characterised by low bone mineral density and deterioration in bone structure, resulting in skeletal fragility and fractures. Osteoporotic vertebral fractures (OVF) are estimated to affect at least 20% of older adults in the UK, with 0.6% to 1.1% of this population incurring a new vertebral fracture each year [1]. OVFs cause spinal deformity including height loss and hyperkyphosis, with each fracture increasing kyphosis on average by 3 ° to 4 ° [2]. Thoracic kyphosis curvature in young adults is normally between 20 ° to 40 ° [3]. Hyperkyphosis is defined as exaggerated kyphosis curvature and affects approximately 40% of older adults [3]. OVFs and hyperkyphosis both typically progress with age, and while they are not synonymous physiological phenomena and can progress independently, they also interact and overlap in their presentation [4]. Both alter spinal biomechanics, and with each additional 15 ° of kyphosis there is a 1.9 times increase in the risk of sustaining a vertebral fracture [5].

The symptoms of OVF and hyperkyphosis include chronic back pain, restricted pulmonary function, lower self-image, fatigue, limitations in physical function, activities of daily living and social participation [2,6–12]. Increased kyphosis angles in people with and without osteoporosis impair balance and postural stability, decrease gait stability and increase the risk of falls and non-vertebral fractures [9,13–16]. All these factors can negatively and persistently impact on quality of life (QoL). Hyperkyphosis and OVF are also independently associated with increased mortality, older people with concurrent OVFs and hyperkyphosis being higher risk [17].

To increase understanding of the impact of kyphosis on people with OVF, an exploratory analysis was undertaken using data from the Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE) trial. The PROVE trial was a large, randomised controlled trial (RCT) designed to test the clinical effectiveness of three different physiotherapy approaches [18]. The aims of this study were to describe participant characteristics according to kyphosis severity, examine the relationship between kyphosis severity and physical function, and investigate whether kyphosis severity predicts improvement in physical function after physiotherapy.

Methods

Design

This was a secondary analysis of data from the PROVE trial, a multicentre 3-arm RCT [18]. The trial was registered (ISRCTN 49117867) and followed CONSORT guidelines. The PROVE trial recruited from 21 hospitals across England and randomised participants into one of three interventions: exercise, manual therapy or a single session of physiotherapy education. Exercise and manual therapy consisted of seven sessions of one-to-one outpatient physiotherapy plus a home exercise programme over 12-weeks; the single session intervention received one-hour of personalised advice from a specialist physiotherapist [18]. All arms were classed as active physiotherapy treatments. Clinical assessments were performed at baseline, 4 and 12 months [19]. For this analysis the data from all three treatment groups were pooled, with treatment type as a covariate, and comparisons were made between the time point and participants grouped according to kyphosis severity.

Participants

Men and women over the age of 18 were included in the trial if they: had a diagnosis of osteoporosis confirmed by a radiograph or Dual X-Ray Absorptiometry scan in the lumbar region; had at least one previous OVF; were postmenopausal if female; and were able to walk 10 metres independently (with or without an assistive device) [19]. People were excluded if they had any condition preventing them from participating in exercise or physiotherapy safely, or a condition that would confound results, or if they had undergone vertebroplasty, facet joint injection or physiotherapy treatment in the previous 12 weeks [19]. For this secondary analysis study, a participant's data were only included if they had completed their baseline thoracic kyphosis measurement.

Outcome measures

Information was extracted about participant characteristics including age, sex, height, body mass index (BMI), and number of OVFs. The QUALEFFO-41 questionnaire pain subscale, a validated QoL questionnaire for people with OVF, measured back pain with scores ranging from 0-100, with 100 being the worst [20]. Back extensor endurance was measured using the Time Loaded Standing (TLS) test, a valid test in this population [21,22].

Thoracic kyphosis was measured with a flexicurve which was moulded along the spine from C7 to L1 and traced onto graph paper [23]. The kyphosis index (KI) was calculated using the maximum perpendicular height and the length from C7 to L1: $KI = (height \div length) \times 100$; KI was transformed to the equivalent of the thoracic kyphosis Cobb angle using the conversion equation: $kyphosis\ angle = KI \times 3.1461 + 5.11$ [23]. The mean of three measurements was used.

Physical function measures included the Six-minute walk test (6MWT), Functional Reach (FR) test, and Short Performance Physical Battery (SPPB). The 6MWT measures functional walking capacity; the distanced (metres) walked in six minutes is recorded [24]. FR measures standing balance, and horizontal distance (cm) reached is measured [25]. The SPPB is a battery of three tests that measures lower extremity strength, standing balance and gait speed; the combined score ranges from 0 (lowest) to 12 (highest) [26]. Standardised testing is detailed in the trial protocol [19]. Outcome measures

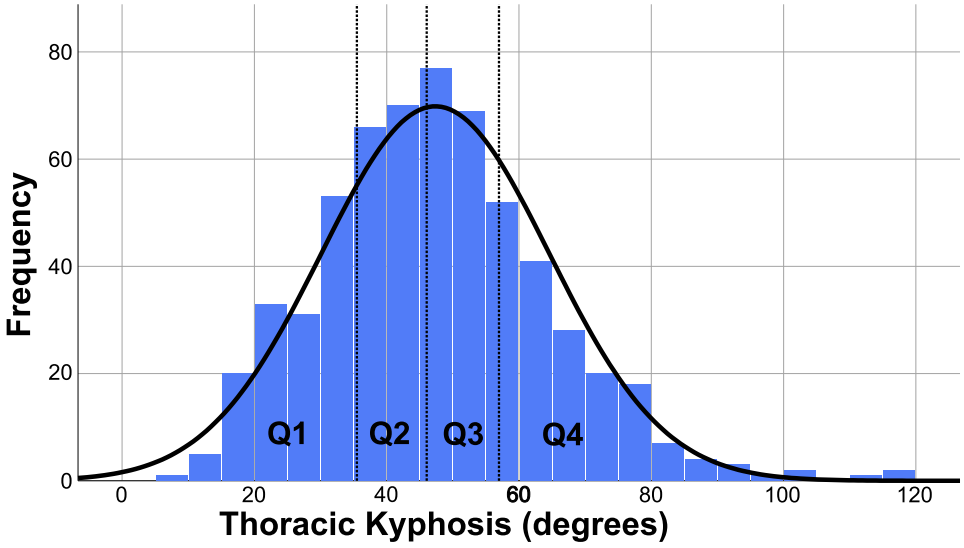

Fig. 1. Baseline thoracic kyphosis quartiles defined by: Q1 = Normal/hypokyphosis group; Q2 = Normal kyphosis group; Q3 = Moderate hyperkyphosis; Q4 = Severe hyperkyphosis.

were reported as estimated marginal means (EMM), which are means that have been controlled for by relevant covariates.

Statistical analysis

Since the main findings from the PROVE trial found no statistically significant differences between the three physiotherapy treatment approaches at 12 months [18], for this analysis the data from all arms were pooled into a longitudinal dataset. As no absolute threshold of normal kyphosis exists, the data were divided into four subgroups based on quartile ranges of thoracic kyphosis measured at baseline, in line with methods performed in other studies [27,28]. Standard descriptive statistics were used to summarise participant characteristics. Pearson's correlation coefficients were run to explore the baseline relationships between kyphosis and 6MWT, FR and SPPB. We interpreted 1.00-0.90 as very high correlation, 0.90-0.70 as high, 0.70-0.50 as moderate, 0.50-0.30 as low, and 0.30-0 as negligible [29]. Linear mixed models were utilised to accommodate the missing data and unequal variances in the repeated measures of the dataset. Separate models were constructed for each of the four dependent variables (thoracic kyphosis, 6MWT, FR, SPPB). For each model, kyphosis severity quartiles and the time point (baseline, 4 and 12 months) served as main effects and the kyphosis severity x time point interaction was inputted. Repeated covariance type was unstructured or Toeplitz, depending on the -2 Log Likelihood, Akaike Information Criterion and Schwarz's Bayesian Criterion values. We hypothesized that factors such as sex, height, BMI, age, number of OVFs, back extensor endurance, pain severity and allocated intervention may influence outcome thus models were adjusted with these covariates, then modified to represent the significant and most relevant covariates for each model. Pairwise comparisons were analysed using the Sidak test. Confidence intervals (95%CI) were reported, and Cohen's d was used to express effect sizes (ES) of EMM differences. In all statistical tests, a p value <0.05 was considered statistically significant. Analyses were performed using SPSS Statistics version 25.

Results

This study analysed 604 participants: 87% (n = 525) were female, mean age was 72 (SD 9) years and mean thoracic kyphosis angle was 47.4 ° (SD 17.3 °). Eleven participants from the full trial (n = 615) were excluded due to missing baseline kyphosis measurements. Linear mixed models accommodate for missing longitudinal data therefore all 604 participants were analysed. The subgroups based on thoracic kyphosis quartile were: (Q1) 8.7°-35.5 °, hypokyphosis to normal kyphosis; (Q2) 35.6°-46.0 ° normal kyphosis; (Q3) 46.1-56.9 ° moderate hyperkyphosis; and (Q4) 57.0°-119.8 ° severe hyperkyphosis (Fig. 1).

Participant baseline characteristics showed the severely hyperkyphotic group was older, shorter, had more spinal fractures, lower back extensor endurance and more severe pain (Table 1). BMI and sex showed no significant differences between quartiles.

Thoracic kyphosis

The mixed model for thoracic kyphosis showed both main effects (kyphosis severity and time point) and their interaction were significant (Supplementary file). Q4 improved kyphosis angle by 5.7 ° (95%CI 3.5 ° to 7.8 °, d = 0.23) at 4 months and by 8.0 ° (95%CI 5.4 ° to 10.7 °, d = 0.30) at 12 months. Similarly, Q3 improved by 2.4 ° (95%CI 0.3 ° to 4.6 °, d = 0.11) at 4 months and 3.0° (95%CI 0.4 ° to 5.6 °, d = 0.12) at 12

Table 1
Descriptive characteristics by kyphosis severity quartiles.

Baseline characteristics	Quartile (n)	Mean (95% CI)	F	p-value
Age (y)	Q1 (n = 151)	70 (68.8 to 72.0)		
	Q2 (n = 151)	71 (69.3 to 72.0)		
	Q3 (n = 151)	71 (69.3 to 72.4)		
	Q4 (n = 151)	75 (73.5 to 76.1)[a]		
	Total (n = 604)	72 (71.0 to 72.4)	8.156	<0.001
Height (cm)	Q1 (n = 151)	161 (160.0 to 162.4)		
	Q2 (n = 151)	160 (158.5 to 161.1)		
	Q3 (n = 146)	159 (157.1 to 159.9)[b]		
	Q4 (n = 149)	155 (153.4 to 156.2)[c]		
	Total (n = 597)	159 (157.9 to 159.3)	16.292	<0.001
BMI (kg/m2̂)	Q1 (n = 151)	25.2 (24.5 to 25.9)		
	Q2 (n = 151)	25.6 (24.9 to 26.3)		
	Q3 (n = 146)	25.6 (24.7 to 26.5)		
	Q4 (n = 148)	25.6 (25.0 to 26.3)		
	Total (n = 596)	25.5 (25.1 to 25.9)	0.309	0.82
Spinal fractures (number)	Q1 (n = 128)	2.0 (1.78 to 2.29)[d]		
	Q2 (n = 135)	2.7 (2.32 to 3.01)		
	Q3 (n = 139)	2.7 (2.37 to 3.04)		
	Q4 (n = 142)	2.8 (2.48 to 3.14)		
	Total (n = 544)	2.6 (2.40 to 2.73)	4.564	0.004
Back extensor endurance (s)	Q1 (n = 146)	77 (65.0 to 88.9)[e]		
	Q2 (n = 149)	54 (44.9 to 62.3)		
	Q3 (n = 149)	42 (34.1 to 50.3)		
	Q4 (n = 148)	28 (23.6 to 33.0)[f]		
	Total (n = 592)	50 (45.6 to 54.7)	21.55	<0.001
Pain domain of Qualeffo-41 (0-100, 100 indicating the highest pain score)	Q1 (n = 151)	48 (44.8 to 51.4)		
	Q2 (n = 149)	50 (46.8 to 54.0)		
	Q3 (n = 148)	55 (51.8 to 59.0)[g]		
	Q4 (n = 150)	57 (55.6 to 60.7)[h]		
	Total (n = 598)	53 (51.0 to 54.5)	5.586	0.001

a: Q4 significantly older than Q1 (p < .001), Q2 (p < .001), Q3 (p = .001).
b: Q3 significantly shorter than Q1 (p = .036).
c: Q4 significantly shorter than Q1 (p < .001), Q2 (p < .001), Q3 (p = .001).
d: Q1 significantly fewer spinal fractures than Q2 (p = .034), Q3 (p = .002), Q4 (p = .004).
e: Q1 significantly higher TLS scores than Q2 (p = .001), Q2 (p < .001), Q4 (p < .001).
f: Q4 significantly lower TLS scores than Q2 (p < .001).
g: Q3 significantly higher pain scores than Q1 (p = .021).
h: Q4 significantly higher pain scores than Q1 (p = .002), Q2 (p = .004).

months. Q1 and Q2 demonstrated no significant change at any point (Fig. 2).

Physical function outcomes

Baseline 6MWT and thoracic kyphosis correlation was negligible (r=-0.24, p < 0.001). The model indicated a significant kyphosis severity ($F(3,539.3) = 4.459$, $p = 0.004$) main effect, adjusting for age, height, gender, back extensor endurance, pain and intervention group (Supplementary file). The EMM of Q4 was worse than Q2 by 39.6 m (95%CI 8.8 to 70.5, d = 0.14, p = 0.004) (Fig. 2). At 12-months 6MWT scores improved from baseline ($F(2,485.1) = 3.042$, $p = 0.049$), and pairwise comparisons suggested most improvement occurred in those with moderate hyperkyphosis, with mean increase of 25.2 m (95%CI 3.5 to 46.8, d = 0.001).

Increased kyphosis was weakly correlated with lower FR distance (r=-0.30, p < 0.001). The model indicated that time point was not a significant main effect ($F(2,750.2) = 2.253$, $p = 0.11$), but kyphosis severity ($F(3,556.1) = 6.685$, $p < 0.001$) was significant, adjusting for age, height, gender, back extensor endurance, pain and intervention group (Supplementary file). Q1 and Q2 had higher EMMs by 3.0 cm (95%CI 1.1 to 4.9, d = 0.14) and 2.3 cm (95%CI 0.4 to 4.1, d = 0.10), respectively, compared to Q4 (Fig. 2).

Baseline SPPB and thoracic kyphosis correlation was negligible (r=-0.25, p < 0.001). The model indicated significant kyphosis severity ($F(3,547.9) = 3.75$, $p = 0.011$) and time point ($F(2,718.4) = 15.252$, $p < 0.001$) main effects, adjusting for age, back extensor endurance, pain and intervention group (Supplementary file). Q4 were lower than Q1 by a mean of 0.7 points (95%CI 0.1-1.3, d = 0.15, p = 0.007) (Fig. 2). EMMs at 4 months improved by 0.4 points (95%CI 0.2-0.6, d = 0.23, p < 0.001) and maintained 0.3 points (95%CI 0.1-0.5, d = 0.12, p = 0.010) improvement at 12 months compared to baseline. Furthermore, Q2, Q3 and

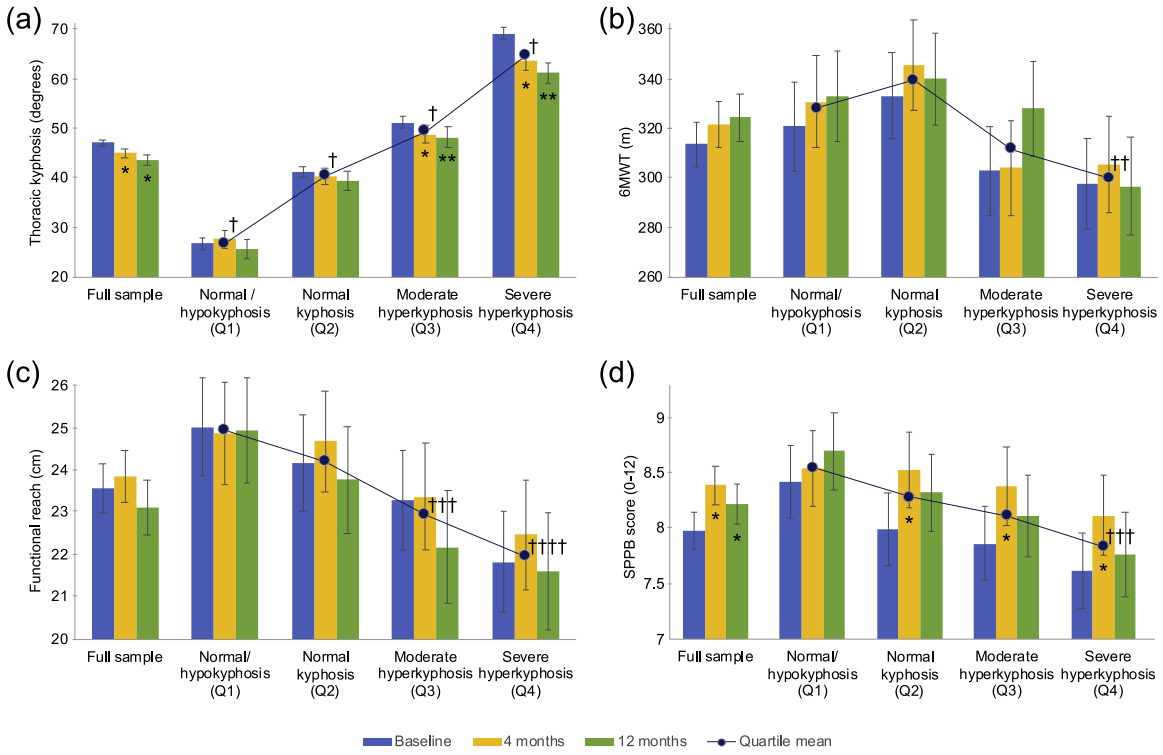

Fig. 2. Estimated marginal means (95% CI) of outcomes based on time point and baseline kyphosis severity quartiles: a) Thoracic kyphosis model shows significant differences between all severity quartiles, and smaller kyphosis angles at 4 months and 12 months compared to baseline, specifically in Q3 and Q4; b) 6MWT model shows shorter distance completed in Q4 compared to Q2; c) Functional reach model shows significantly shorter distance reached in Q3 and Q4 compared to Q1 and Q2; d) SPPB model shows lower scores in Q4 compared to Q1, and higher scores at 4 months and 12 months compared to baseline. * significantly different from baseline. ** significantly different from baseline and 4 months. † significantly different from all other quartiles. †† significantly different from Q2. ††† significantly different from Q1. †††† Significantly different from Q1 & Q2.

Q4 showed statistically significant improvements at 4 months (Fig. 2).

Discussion

Our secondary analysis was designed to investigate the physical characteristics of a large group of people with OVF and to consider potential for longitudinal changes in physical function according to their baseline thoracic kyphosis severity. We did not seek to make comparisons between treatment arms of the PROVE trial as this has been previously reported [18]. Our findings agree with previous studies in the literature, showing that increasing kyphosis severity is positively correlated with increased age, number of OVFs and pain, and negatively correlated with back muscle endurance and functional reach [2,13,14,30]. We found participants with hyperkyphosis were responsive to physiotherapy, regardless of the type of treatment administered in the PROVE trial, and importantly demonstrated significant clinically-relevant reductions in thoracic curvature. Our analysis also showed that adjusted short-term improvements in the SPPB scores were maintained in the long term for all quartiles, suggesting that physical performance has the potential to improve, regardless of kyphosis severity.

Relationship between thoracic kyphosis and physical function

Our results showed that functional walking capacity, standing balance and physical performance were more impaired in people with hyperkyphosis compared to those with normal/hypokyphosis. 6MWT findings were consistent with other studies that have found increased kyphosis is associated with poorer gait and walking capacity [13,15,31]. Our standing balance results align with Hirose et al. who found increased thoracic kyphosis correlated with decreased FR in a community-dwelling older adults [31]. While Q4 (21.9 cm) and Q1 (25.0 cm) EMMs are above the fall risk cut off for older adults (<18.5 cm), poorer FR scores are associated with higher risk of functional decline [32,33]. SPPB findings were consistent with those of Eum et al., who examined the relationship between SPPB and kyphosis severity in community-dwelling older adults and found as kyphosis increased, physical performance deteriorated [34]. Compared to Eum et al., the kyphosis distribution of our population with OVFs had a higher mean, shifted towards more hyperkyphotic curvatures, yet the same inverse relationship between kyphosis severity and lower SPPB scores remained [34].

Thoracic kyphosis response to physiotherapy treatment

The interaction between kyphosis severity quartile and time point suggested that participants responded differently to treatment according to kyphosis severity at baseline. Only those with hyperkyphosis showed improvement in kyphosis angle at 4 and 12 months. Greater mean changes were seen in the severely hyperkyphotic compared to the moderately hyperkyphotic group, and this was apparent even when the important factors of age, height, back extensor endurance and intervention group were adjusted for in the model. Although there was a lack of significant change in the normal/hypokyphotic quartiles, this does not necessarily indicate insufficient physiotherapy treatment but rather that as these participants were not hyperkyphotic they had limited ability to reduce kyphosis angle. Untreated kyphosis would be expected to progress, along with an accompanying deterioration in QoL and increased morbidity and risk of mortality [2,17,35]. Hence, preventing deterioration can be considered beneficial. Therefore, both the reduction in kyphosis angle in hyperkyphotic subgroups as well as the stabilisation of kyphosis angle in normal kyphosis subgroups are important [2,5,35]. While the main PROVE trial findings indicated no statistically significant thoracic kyphosis changes between treatment groups, larger and clinically relevant improvements were seen in thoracic kyphosis within exercise and manual therapy compared to the single session of physiotherapy [18]. Subdividing the sample into quartiles in this analysis gives a more comprehensive picture of the changes that occurred and showed which participants improved their posture.

Relationship between thoracic kyphosis and physical function over time

Under the assumptions of the mixed model design, the 6MWT scores improved, specifically revealing a statistically significant 12-month improvement of 25 m in the moderately hyperkyphotic group. This distance meets the minimum clinically important difference (MCID) for adults with fear-of-falling and restrictive pulmonary conditions, but not for a large meaningful change in community dwelling older adults [36]. In the SHEAF trial, an RCT with an intensive 6-month intervention of targeted kyphosis-reduction exercises and postural training for people with hyperkyphosis, 6MWT remained unchanged at 6 months [37]. Similarly, in the PROVE trial no changes were seen in 6MWT following manual therapy (including postural training), whereas significant short-term changes were seen in 6MWT following exercise therapy that included a walking programme [18,37]. Interpreting these results together, it suggests that while kyphosis curvature is associated with walking capacity, changing curvature alone does not have a strong influence on this metric as performance requires input from several physiological systems.

Kyphosis severity did not appear to affect short- or long-term FR changes. One reason we may not see kyphosis curvature influencing change in FR could be due to the other contributing factors, such as limb range of motion, muscle strength, balance, and reaching strategy, which might compensate for kyphosis [38]. Additionally, since all quartile baseline means were above the 18.5 cm falls risk cut-off, there may be a ceiling effect for change [33]. Therefore, whilst those with hyperkyphosis had lower FR scores, kyphosis severity was not shown predict change in FR.

Lastly, SPPB scores improved in the short-term with a small effect size which was sustained at 12 months, even when influential factors such as age, back extensor endurance, pain and intervention type were considered. While the short-term improvement of 0.42 points falls short of the MCID (0.5 points) for community-dwelling older adults, the mean baseline scores in our population are lower than the normative values in which the MCID was determined [36]. When stratified by kyphosis severity quartile, the statistically significant improvements were apparent in Q2, Q3 and Q4, suggesting even people with moderate and severe hyperkyphosis improved their physical performance. These findings align with results from Gladin et al. which found that people who had hyperkyphosis and low SPPB scores (equivalent to the mean scores in our population) showed improvement after a targeted kyphosis-reduction intervention [39].

Clinical implications

These findings suggest that clinicians should pay attention to kyphosis severity in estimating the potential for change in kyphosis post-treatment. Those with greater hyperkyphosis may be more responsive than those with curves within normal ranges. Furthermore, this analysis strengthens evidence that those with severe hyperkyphosis are generally older, have more OVFs, poorer back extensor endurance, more restricted walking capacity, worse balance, poorer physical performance and more pain. Yet in the context of physical performance, regardless of curvature severity, there was improvement from baseline. This suggest that clinicians should feel more confident that even older adults with more advanced disease have the potential to improve with physiotherapy.

Limitations

This dataset was analysed as a longitudinal dataset and although the intervention group was not found to have a significant effect as a covariate, it was included in all models. However, the trial was not designed or powered to undertake these exploratory analyses of secondary outcome measures, and our results should be considered in this light. Given the relatively small numbers of participants in each subgroup when looking at the three treatment arms divided to four groups of kyphosis severity, it would be underpowered to detect differences in the effect of the treatment group by kyphosis severity. Another limitation was a relatively high percentage of missing data (21% kyphosis outcome data

missing at 12 months) due to the nature of a large, multicentre physiotherapy intervention RCT focused on an older clinical population [18]. Linear mixed model analyses were employed to mitigate the impact of missing data; however, the interpretation of results must bear in mind the associated limitations and assumptions. A potential limitation is the non-invasive clinical tool used to capture thoracic kyphosis, the flexicurve. Whilst it is a widely-used tool in research and clinically that avoids additional ionising radiation exposure, Spencer et al. have recently shown that the flexicurve is more inaccurate as the angle of kyphosis increases and progressively underestimates the kyphosis angle starting from 40° [40]. Because the kyphosis analyses are based predominantly around kyphosis quartiles, this may slightly alter the statistical threshold between moderate and severe hyperkyphosis, but the general trend would remain as reported.

Conclusions

Hyperkyphosis in people with OVF(s) is associated with greater pain, poorer walking capacity, back endurance, balance and physical function. Importantly, presenting with hyperkyphosis does not necessarily prevent a response to physiotherapy, in particular kyphosis and physical performance. The results suggest that not only can physiotherapy stabilise thoracic curvature, it has the potential to improve it in people with hyperkyphosis and OVF. Research investigating the efficacy of physiotherapy treatments on hyperkyphosis should consider stratifying participants according to kyphosis severity to understand the impact of treatment.

Data Availability

Data will be made available on request.

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