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Title page:

The immediate effects of passive hip joint mobilisation on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function. A randomised, placebo-controlled crossover trial

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Conflict of interest

None declared.

Ethical approval

The study was approved by the Medical University of Vienna Ethics Committee (EK-Nr: 1940/2018) and Sheffield Hallam University Research Ethics Committee.

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Trial Registration

This study was registered in ClinicalTrial.gov with the registration number NCT03771495.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Abstract

Background: Anterior knee pain (AKP) is often associated with persistent hip muscle weakness and facilitatory interventions may be beneficial for managing patients with AKP (pwAKP). Physiotherapists often employ passive oscillatory hip joint mobilisations to increase hip muscle function. However, there is little information about their effectiveness and the mechanisms of action involved.

Objectives: To investigate the immediate effects of passive hip joint mobilisation on eccentric hip abductor/external rotator muscle strength in pwAKP with impaired hip function.

Design: A double-blinded, randomised, placebo-controlled crossover design.

Method: Eighteen patients with AKP participated in two sessions of data collection with one week apart. They received passive hip joint mobilisation or placebo mobilisation in a randomised order. Eccentric hip muscle strength was measured immediately before and after each intervention using a portable hand-held dynamometer.

Results: An ANCOVA with the sequence of treatment condition as the independent variable, the within-subject post-treatment differences as the dependent variable and the within-subject pre-treatment differences as the covariate was conducted. Patients showed a significant mean increase in eccentric hip muscle strength of 7.73% ($p=0.001$) for the mobilisation condition, compared to a mean decrease of 4.22% for the placebo condition. Seventeen out of eighteen participants reported having no pain during any of the strength testing.

Conclusion: These data suggest that passive hip joint mobilisation has an immediate positive effect on eccentric hip abductor/external rotator muscle strength in pwAKP with impaired hip function, even in the absence of current pain.

Registration Number (ClinicalTrial.gov): NCT03771495

Manuscript

1. INTRODUCTION

Anterior knee pain (AKP) is one of the most frequent reasons for consultation in the context of knee conditions in young adults, especially when they participate in sports. Smith et al.[1] reported an annual prevalence of 22.7% in the general population. AKP is rarely a self-limiting condition and is recurrent or chronic in 70-90% of cases.[2] Since AKP frequently occurs in young working adults, it may have important societal impacts due to work absences and may involve substantial treatment expenses.[3]

The aetiology of AKP is typically multifactorial involving local, proximal and distal factors.[4] Hence, there is no single right treatment and the treatment approach has to be tailored to the individual patient.[5] In recent years much attention has been paid to the relationship between hip function and AKP. Recent studies propose that greater hip adduction and internal rotation, especially during weight-bearing activities, may lead to altered knee and patellofemoral joint kinematics and therefore present a potential risk factor for AKP.[6,7] These altered movement patterns may result from impaired gluteal hip muscle function. Many studies have demonstrated an association between AKP and weak hip abductors, external rotators and hip extensors.[8–10] A recent systematic review has shown that hip muscle strengthening is effective in reducing pain intensity and improving function and therefore has an important role in the management of patients with AKP (pwAKP).[11] However, their findings regarding the treatments' ability to improve muscle strength were equivocal. Alternative therapy modalities targeting the hip which augment traditional strength training may therefore prove beneficial to pwAKP.

Manual therapy techniques have previously been used as facilitatory interventions to increase immediate muscle activation and strength before performing strengthening exercises.[12–14] With regard to the hip joint, Albertin et al.[15] recommend the use of passive hip joint mobilisation to improve patient function, especially when patients present with hip range of motion (ROM) limitations. Coupled with the fact that reduced hip joint ROM has also been associated with AKP,[16] it seems plausible that pwAKP and impaired hip muscle function may benefit from hip joint mobilisation as an additional treatment modality. In fact, there is evidence to support low-velocity hip joint mobilisation as an effective facilitatory intervention to improve hip muscle strength in asymptomatic individuals. Specifically, a grade IV inferior hip joint mobilisation was found to increase hip abductor strength and a grade IV posterior to anterior hip joint mobilisation was found to

increase hip extensor strength.[17,18] The only identified trial investigating patients with knee injuries used a high-velocity low-amplitude hip mobilisation technique and reported significant increase in hip extensor muscle strength but no increase in hip abductor strength.[19] However, there has been no previous study that investigates the effects of a low-velocity hip joint mobilisation on hip muscle strength in a patient population.

The mechanisms of action behind the benefits seen from passive joint mobilisations are still of speculative nature. However, the recently updated and comprehensive model by Bialosky et al. [20] suggests that any benefit is likely based on complex neurophysiological mechanisms associated with pain inhibition. Within this model, it is argued that the interaction between provider and patient may play a decisive role, while the specific mechanical stimulus may be of subordinate importance. On the other hand, other authors argue that central and peripheral explanatory models associated with passive mobilisation should not be considered exclusive from each other.[21,22] They emphasise the fact that improvements in motor function are not always associated with pain reduction.[14] This trial is well suited to give further insights into the question of whether other non-pain related mechanisms may play a decisive role regarding the benefit seen from passive mobilisation. This is because pwAKP often show gluteal muscle weakness, though they normally neither present any pain at the hip area at all nor present any (knee) pain during gluteal muscle strength testing. A greater understanding of the mechanisms of action involved would help clinicians identify potential responders and would therefore facilitate a personalised and more effective use of mobilisation techniques.

Consequently, the primary aim of this trial was to investigate the immediate effects of low-velocity passive hip joint mobilisation on hip abductor/external rotator muscle strength in pwAKP. Participants additionally had to present with signs of hip impairment in order to ensure a homogenous population which was likely to benefit from the hip mobilisation intervention. A secondary aim was to provide further information on the hypothesised mechanism of action involved.

2. METHODS

2.1 Study design

A double-blinded, randomised, placebo-controlled crossover design was used to evaluate the immediate effects of passive hip joint mobilisation on hip abductor/external rotator muscle strength. Participants diagnosed with AKP and hip impairments were recruited from primary and secondary care settings in Vienna (Austria) from December 2018 to April 2019 using posters and Facebook advertising. The study was conducted in a private physiotherapy practice. Prior to the beginning of the study, all participants received an information leaflet and provided written informed consent. The study was approved by the Ethics Committee of the Medical University of Vienna (EK-Nr: 1940/2018) and was conducted and reported according to the CONSORT guidelines.[23]

2.2 Participants and recruitment

Eligible participants were all adults aged 18 or over who met the recently published checklist for diagnosis of AKP.[24] Participants additionally had to present with signs of hip impairment, as follows: (1) impaired hip kinematics during single leg squat, (2) weak ipsilateral hip abductors/external rotators and (3) reduced ipsilateral passive hip joint mobility (see Appendix A: Eligibility Criteria). Participants were excluded if they had bilateral AKP, a non-musculoskeletal origin of AKP, a known intra-articular tibio-femoral joint pathology, previous lower limb surgery/trauma, any evidence of pain referred from the lumbar spine, severe and or recurring ankle sprains or other relevant co-morbidities (such as neurological, rheumatological or psychiatric diseases, osteoporosis or malignancy).

The researcher telephoned potential participants who expressed an interest in the study to check preliminary eligibility and then invited them to attend the clinic to conduct baseline tests to ensure eligibility. Participants who were eligible and happy to proceed signed the consent form and were then randomised to the study (*Figure 2*).

2.3 Interventions

The active intervention consisted of the application of a passive rhythmic anterior-to-posterior (AP) mobilisation to the proximal femur of the affected limb (grade III for four minutes, participant in supine with a knee roll), followed by passive rhythmic mobilisation of each individual's most restricted physiological hip joint movement (grade III for one minute, participants' position varied and depended on the respective movement

direction).[25] Before the intervention, participants received a verbal education of the proposed underlying effect mechanisms using an approach of predominantly peripherally acting reflexogenic mechanisms (for approximately two minutes).[21,22]

The placebo intervention involved the same positioning of the patient during active treatment (supine with a knee roll), delivered in the same setting, the same duration and with a very similar verbal education (the only difference lying in the source of the afferent impulse within our applied reflexogenic explanatory model: Superficial receptors in the skin and fascia represented the source for the placebo condition, whereas deep muscle, tendon and joint receptors represented the source for the active intervention). The therapist applied the hands to the same contact point as in the mobilisation condition. However, instead of an actual AP mobilisation, a placebo mobilisation with minimal to no movement (grade I) was applied for five minutes,[17,18,26] and no additional individualised mobilisation technique was applied.

Both active and placebo intervention lasted for a total of seven minutes.

2.4 Outcome measures

The primary outcome measure used in this study was eccentric hip abductor/external rotator muscle strength and was measured using a portable hand-held dynamometer (HHD) ("MicroFET2", Hoggan Scientific, LLC, Salt Lake City, USA). For all testing, the end-position of the popular non-weight bearing gluteus medius exercise called the "clam-exercise" (*Figure 1*) was used.[27,28] Prior to measurement, a mark was placed five centimetres proximal to the knee joint line to provide a consistent landmark for dynamometer placement. The participant was instructed to lift the knee of the superior leg as far as possible while keeping the heels in contact, without allowing any compensatory movements. Following a warm-up consisting of one submaximal trial, participants performed three maximal eccentric muscle contractions with a 30 seconds rest between each contraction. The instructions for the break test were "Push as hard as you can; now, don't let me move your leg!". Consistent verbal encouragement was provided during the timed, 5-second contraction period for all tests. If compensatory movements were present, values were discarded and another contraction performed after 30 seconds. The investigator noted if any pain was present during testing (yes/no).

Muscle strength data were normalised by the weight of each participant

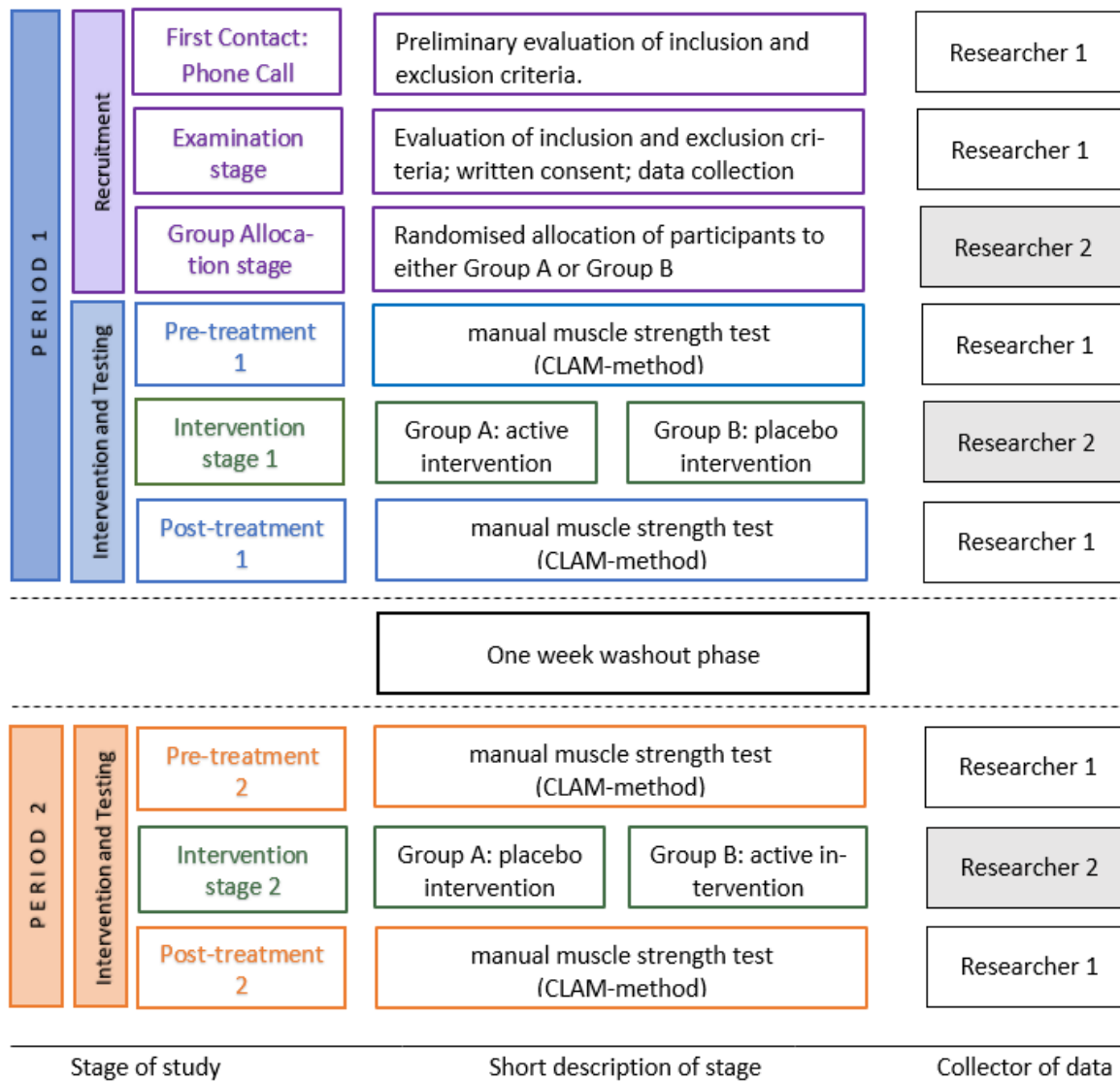
(strength[kgf]/weight[kg]) and mean values were calculated for each participant (see Appendix B: List of Variables).[27] An intra-rater reliability exercise was conducted as part of the study to ensure consistency of the measurer: The intra-rater reliability was excellent with an ICC of 0.93 (95% CI[0.82-0.98]).

Figure 1: Clam-method for measurement of hip abductors/external rotators with a HHD (hand-held dynamometer)



2.5 Procedure

Figure 2: Recruitment and procedure of the current trial



The recruitment and study procedures are outlined in *Figure 2*. Following consent and randomisation, participants attended on two occasions (Period 1 and 2). Both visits were conducted in the same temperature-controlled therapy room using the same equipment. Participants received both interventions (hip mobilisation and placebo mobilisation) on two different occasions in a randomised order. At the first session (Period 1), the baseline strength measurements (Pre-treatment 1) were administered. Participants then received the intervention that was randomly assigned for that period and, immediately afterwards, the strength measure was reassessed (Post-intervention 1). After one week, this procedure was repeated for the second intervention (Period 2).

The treatment allocation sequence was randomised using an online application called “Sealed Envelope”[29] (using random block sizes of 4 and 6) and concealed from the investigator who took the measurements. An experienced physiotherapist, trained in manual therapy with more than 7 years of clinical experience, applied both experimental conditions and was blind to the measurement results.

Discussion between researchers and subjects was minimised during treatment in order to facilitate participant blinding and reduce potential interactions. No feedback was given on performance until after the final session. The extent of participant blinding was assessed through a short post-experiment questionnaire, in which participants were asked to indicate whether they had experienced a physiotherapy treatment in any of the sessions, and if so, in which session.[30,31]

2.6. Statistical analysis

Data were analysed using R;[32] statistical significance was set at $p < 0.05$. Descriptive statistics (mean and SD) were calculated to describe the anthropometric and clinical characteristics of participants. Prior to the assessment of the treatment effect, a t-test (with the group allocation as the independent variable) with the sums of both Post-treatment values was applied to assess the presence of a possible carry-over effect [33]. The normality of distribution of the data was evaluated by visual inspection and by using the Shapiro-Wilk test.[34]

The main question of interest was whether there was a significant difference in outcome between the two treatment conditions. As recommended for 2x2 crossover trials with baseline measurements, analysis of covariance (ANCOVA) with the group allocation as the independent variable, the within-subject post-treatment differences as the dependent variable and the within-subject pre-treatment differences as the covariate was applied to assess the treatment effect.[35]

2.7 Sample size calculation

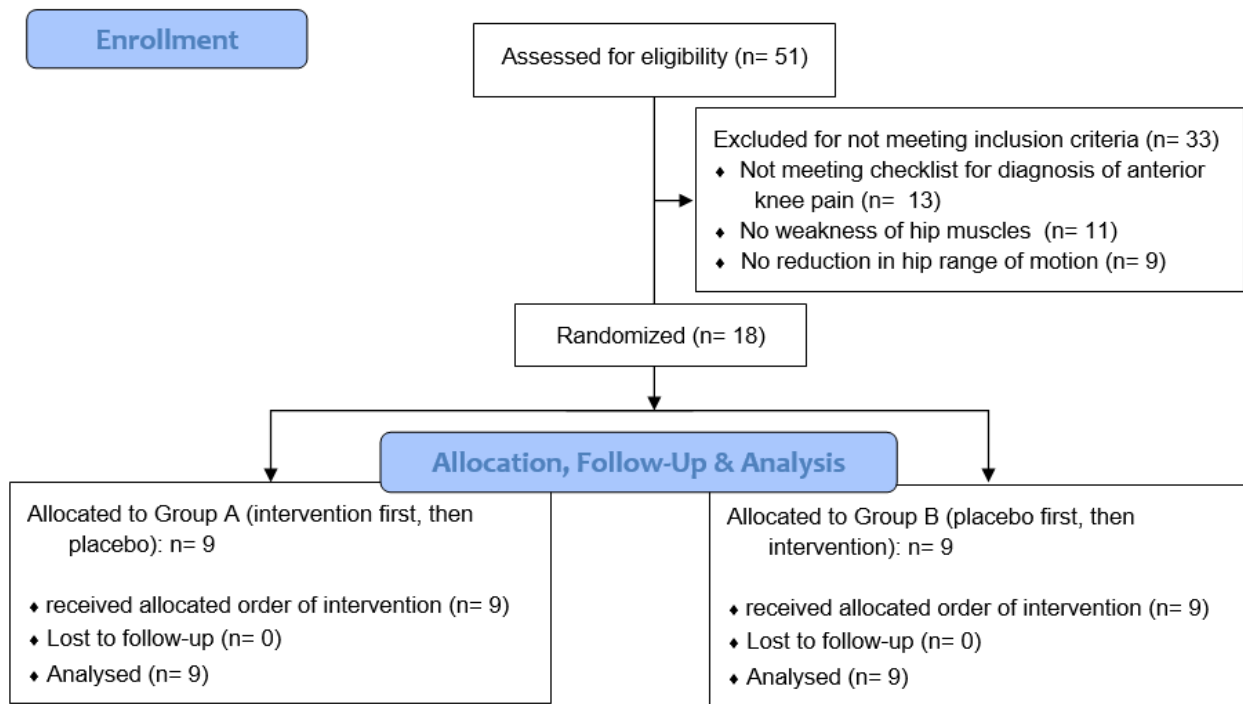
The sample size was calculated based on the alpha value of 0.05, the statistical power of 0.8, the estimated effect size and the expected measurement variance.[33,36] The results of a similar study [17] was used for reference to estimate the effect size for this study. The expected measurement variance (0.032kgf/kg) had been determined with the aid of a small pilot study. Therefore, on the bases of these values and assuming an unpaired t-

test,[33] the appropriate sample size for this study had been calculated to be 16 (8 per group).

3. RESULTS

3.1 Participant flow and recruitment

Figure 3: CONSORT flow diagram of participant enrolment, allocation, follow-up & analysis



A total of 51 patients with anterior knee pain were assessed for eligibility, of which 18 (8 male, 10 female) fulfilled the inclusion criteria and agreed to participate (*Figure 3*). All participants completed the study; no one was excluded from analysis. No adverse events were noted during the study.

Twenty participants were registered initially as the sample size to accommodate a 20% dropout rate. However, considering the single-session nature of the experiment, recruitment stopped when 18 participants had been recruited.

3.2 Baseline data

The individual demographic characteristics (age, height, weight, BMI) of all 18 participants (10 female, 8 male) are summarised in *Table 1*.

The mean differences of passive hip joint ROM in comparison to the other, unaffected side at baseline-evaluation of inclusion and exclusion criteria had been measured with a digital goniometer ('Easy Angle'[37]) and are also illustrated in *Table 1*. Overall, the trend shows limited ROM for most directions of movement, especially for hip external rotation

movements, with external rotation in 0° flexion being the only statistically significant motion when applying paired t-tests (with the Holm-Bonferroni sequential correction).

Table 1: Baseline data for participant: Demographic characteristics and mean differences of passive hip joint range of motion in comparison to the other, unaffected side (via a digital goniometer called 'Easy Angle' (N = 18)

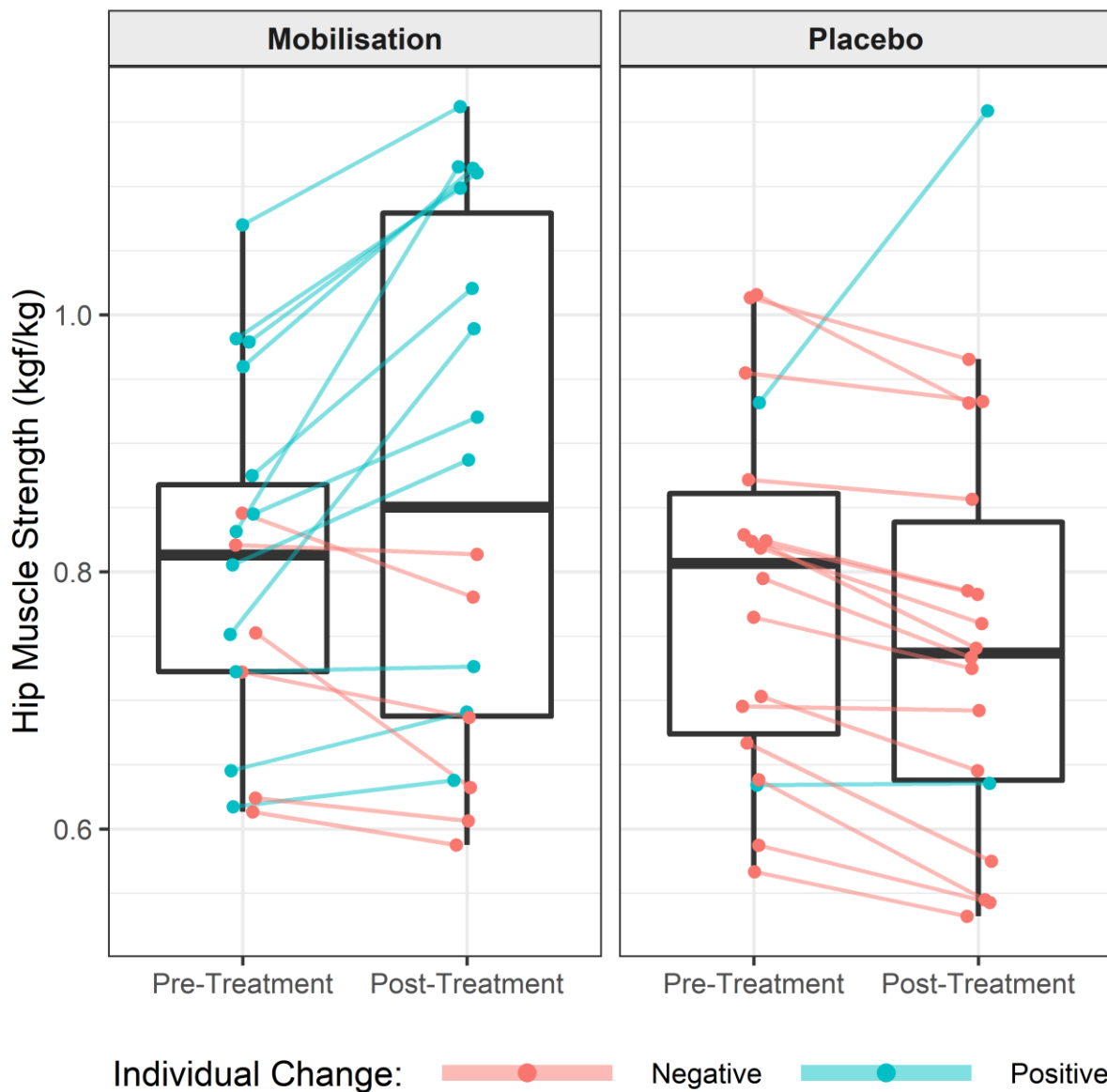
	Mean	SD
Demographic Characteristics		
Age (years)	27.9	6.5
Height (cm)	173.8	9.5
Weight (kg)	66.2	10.1
BMI (kg/m ²)	21.9	2.8
Direction of Movement (in °)		
Flexion (F)	-1.1	5.3
External Rotation (in 90° F)	-3.9	6.0
Internal Rotation (in 90° F)	+0.6	9.1
Abduction (in 0° F)	-2.5	3.9
Adduction (in 0° F)	-2.4	4.1
External Rotation (in 0° F) *	-12.1*	7.4
Internal Rotation (in 0° F)	+0.1	4.6
Extension	-1.3	2.6
*statistically significant side-to-side difference (p=0.000)		

3.3 Effects on hip muscle strength

There was no significant result (p=0.086) for the unpaired t-test with the sums of the Post-treatment values, suggesting that there was no carry-over effect between Period 1 and Period 2.

The Shapiro-Wilk test showed a normal distribution for the outcome data (p=0.64). The ANCOVA indicated that there was a significant difference between the treatment conditions, $F(1,15)=16.24$, $p=0.001$, $\eta^2=0.52$. A post-hoc power analysis showed a power of 98%. *Figure 4* illustrates the distribution of hip muscle strength data for both mobilisation- and placebo condition over time, incorporating the individual improvement/decline of each participant.

Figure 4: Box and whisker plot of hip muscle strength data for both experimental conditions, additionally highlighting individual improvement/decline



There was an estimated increase of 7.73% (95% CI[1.04;13.00]) in muscle strength for the mobilisation condition compared to a decrease of 4.22% (95% CI[-8.49;-0.83]) for the placebo condition (Table 2).

Table 2: Pre- and postexperiment values (mean, SD, percentage change) of the normalised muscle strength data (kgf/kg)

Condition	Time point	Mean (SD)	Change (in %)
Mobilisation	Pre	0.803 (0.136)	+ 7.73
	Post	0.866 (0.205)	
Placebo	Pre	0.785 (0.139)	- 4.22
	Post	0.752 (0.169)	

Presence of pain

Seventeen participants reported having no pain at all during strength measurements. Only one participant reported the presence of mild (knee) pain. However, this pain did not change between pre-treatment and post-treatment measurements.

3.4 Blinding

From the post-experiment questionnaire, none of the 18 participants suspected neither of the two sessions to be a placebo session, providing confidence in the double-blind nature of the study.

4. DISCUSSION

This is the first study to investigate the effects of low-velocity hip joint mobilisation on abductor/external rotator muscle strength in a patient population. However, the results are in line with previous studies investigating the effects of different low-velocity hip mobilisation techniques in healthy individuals that showed a positive effect on gluteal muscle strength immediately after mobilisation, only differing in the reported amount of change (+14% in hip extensor strength and +17.4% in hip abductor strength respectively).[17,18] The study investigating high-velocity low-amplitude hip mobilisation in patients with knee injuries reported a 15.3% increase in gluteus maximus strength, compared to no significant increase in gluteus medius strength.[19]

In the management of pwAKP, the strengthening of the gluteus medius muscle may play an important role since pwAKP show significant weakness in hip abduction, external rotation and extension (which complies with the function of gluteus medius and superior part of gluteus maximus)[38]. The tensor fascia latae (TFL), in addition to being an abductor, is an internal rotator of the hip and can also exert a lateral force on the patella via connections to the iliotibial band.[39] Both, excessive hip internal rotation and lateral patellar displacement, have been linked to AKP.[40] Therefore, measurement methods to detect hip abductor/external rotator weakness in pwAKP should promote gluteal activation as well as minimise TFL recruitment. Selkowitz et al.[41] examined eleven different exercises on the basis of electromyographic signals using fine-wire electrodes and found that the clam-exercise had by far the most favourable gluteal-to-TFL activation ratio and recent studies confirmed excellent reliability and validity of the clam-method as a measurement method to assess hip abductor/external rotator muscle strength in healthy individuals[28] as well as in pwAKP[27]. Hence, this study used the clam-method to assess hip abductor/external rotator muscle strength. In contrast, side-lying hip abduction, the measurement method Neto et al.[19] used when they reported no significant increase in gluteus medius strength, showed no such favourable activation ratio. This difference in the measurement method might explain why our findings indicate an increase in gluteus medius strength following mobilisation, whereas the findings of Neto et al.[19] do not. However, there are several other factors that could have contributed to the differing results, such as different study populations or different mobilisation techniques explored or the fact that Neto et al.[19] did not utilise a randomised placebo-controlled study design, in contrast to this trial.

In addition, the reported limitation of hip external rotation (in 0° flexion) of participants in

the current trial might be a consequence of overactive TFL paired with weak gluteus medius.[42] However, further research is needed to confirm this hypothesis. Furthermore, future studies still need to clarify which hip muscle groups may (and may not) profit from mobilisation and investigate the effects of low-velocity versus high-velocity techniques on hip strength in pwAKP.

Mechanism of action involved

The findings of the current study indicate that the model by Bialosky et al.[20] might be limited by relating all clinical outcomes with mechanisms associated with pain inhibition, since passive joint mobilisation seems to have the potential to immediately improve motor function even in the absence of current pain (only one of eighteen participants reported mild pain during the outcome measurements). However, further similar trials examining subjects without pain/whose pain has ceased, but whose motor function remain impaired, are needed to strengthen this body of evidence.

The current results also provide support for the importance of the mechanical stimulus which does appear to provide a therapeutic effect, since the solely major difference between active and placebo intervention lay within the applied mechanical stimulus.

4.1 Strengths

The current study is representative of clinical physiotherapy practice, for several reasons: To our knowledge, this was the first study to investigate the immediate effects of low-velocity mobilisation on local muscle strength in a patient population with hip impairments that are commonly associated with AKP. Furthermore, due to the applied method of measuring muscle strength, as using a HHD while performing a 'break test' is very similar to the manual muscle strength tests commonly used in clinical practice. Another reason being the adding of a verbal explanation of the proposed mechanism of action involved. In addition, this study was designed, conducted and planned in accordance with CONSORT recommendations; it achieved blinding of patients and treatment providers and recruited a sufficient sample size.

4.2 Limitations

This study has a number of limitations. First, a no-treatment comparison group, which would account for factors such as the natural history of the disorder and the magnitude of the placebo/nocebo effect, was not included.[43] Consequently, it is not clear if the reported decrease in muscle strength associated with the placebo condition is caused by

natural fatigue or by any other mechanism (such as nocebo). However, previous trials investigating the effect of mobilisation on motor function reported similar declines for a manual-contact placebo condition.[18,44,45] Sterling et al.[46] even reported a decline, when compared to the no-treatment control condition. In order to figure out if such a decline is due to negative expectations or due to any other mechanism, future studies could collect data on the individual expectation for the effectiveness of the different treatment conditions. Second, there was no assessor blinding (regarding the affected side) during the assessment of eligibility criteria. Hence, the reported findings of limited hip joint ROM at baseline need to be treated carefully due to the possibility of bias involved. Furthermore, the clinical relevance of the findings of this trial remains speculative and further research investigating the clinical value of imbedding passive hip joint mobilisation in the management of pwAKP is warranted.

4.3 Clinical implications

The findings of this study suggest that hip joint mobilisation represents an adequate supplementary treatment modality that may be beneficial to the management of a subpopulation of pwAKP (presenting impaired hip kinematics, reduced hip joint ROM and hip abductor/external rotator weakness in bilateral comparison). Hence, in clinical practice it may be useful to apply hip joint mobilisation immediately before muscle performance exercises in order to take best advantage of its facilitatory effect and thereby counteracting persistent muscle weakness. Furthermore, these findings may broaden the reasoning of clinicians who apply joint mobilisation in general, as it shows that improvements in motor function through passive mobilisation seem not to be dependent on the presence of current pain and mechanisms associated with pain inhibition. In addition, this trial confirms the outcomes of previous works[27,28] by showing that the clam-method is a reliable and practical method for assessing hip abductor/external rotator muscle strength in a patient population.

5. CONCLUSION

The results of this trial suggest that passive hip joint mobilisation has an immediate positive effect on eccentric hip abductor/external rotator muscle strength in patients with AKP and impaired hip function, even in the absence of current pain. Consequently, passive joint mobilisation may be an adequate supplementary facilitatory treatment modality to counteract persistent muscle weakness and thereby be beneficial to the management of a subpopulation of pwAKP. However, the specific mechanisms of action involved as well as the clinical relevance of these findings remain speculative.

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