Effectiveness of proprioceptive training versus conventional exercises on postural sway in patients with early knee osteoarthritis – A randomized controlled trial protocol

Ashish John Prabhakar [a,*], Abraham M. Joshua [a], Srikanth Prabhu [b], Yogeesh Dattakumar Kamat [c]

[a] Department of Physiotherapy, Kasturba Medical College, Mangalore, Manipal Academy of Higher Education, India
[b] Department of Computer Science & Engineering, Manipal Institute of Technology, Manipal Academy of Higher Education, Manipal, India
[c] Consultant Knee & Hip Surgeon, KMC Hospital, Ambedkar Circle, Mangaluru. Adjunct Faculty, MAHE, India

ARTICLE INFO

ABSTRACT

Introduction: In recent times, 'early osteoarthritis' (EOA) has achieved recognition as a disease entity. The importance of defining EOA is in the fact that a variety of joint preservation treatments are available. Development of the sense of proprioception is a known vital element of most exercise rehabilitation programmes. Postural sways have been found to be prevalent in arthritic patients. It follows therefore that correction of early postural aberrations should help patients with EOA. The current study aims to determine the effectiveness of such proprioceptive training versus conventional exercises in patients with EOA.
Method: This study is a randomized controlled trial. A total of 100 participants between the age of 20–45 years will be recruited. Participants will be randomly assigned to conventional or interventional group. Participants in both the groups will receive 12 session of treatment over a period of four weeks. Outcome measure considered are center of pressure excursion, joint position sense, hand held dynamometer, visual analog scale and knee injury and osteoarthritis Outcome Score for functional outcome.
Results: Data collected will be analyzed by mean, SD and 2 factor ANOVA for repeated measure, followed by Bonferroni post hoc analysis. Data will be analyzed using SPSS package version 17.0, $p < 0.05$ will be considered as significant.
Conclusion: The authors hope to determine whether proprioceptive training improves outcome better than conventional exercise therapy and hope to contribute to an improved targeted treatment for patients with Early osteoarthritis.

1. Introduction

Knee osteoarthritis (OA) is one of the major causes of pain and physical disability in older adults [1]. It has been stated that osteoarthritis affects 33.6% of the population over 65 years old and surprisingly, 13.9% of the population over 25 years old [2]. Approximately 80% of population in India who claim to have knee pain show signs of OA, of which, 20% report incapability in daily activities [3]. considering this it has been suggests that primary prevention of knee OA should become a major aim of health care [1].

Recent literature shows a growing interest in 'early osteoarthritis' (EOA) [4,5]. EOA could be defined as the clinical recurrence of

pain and discomfort of the knee, short periods of stiffness, with in between long periods of very little clinical manifestations [2]. There is ample evidence that anterior cruciate ligament rupture, meniscal tear, smoking, vitamin D deficiency, physical inactivity, muscle weakness, leptin, dietary fatty acid intake and mechanical/neuromuscular changes are some of the risk factors associated with EOA [2,4].

Neuromuscular changes for instance, decreased strength and proprioceptive accuracy of the knee extensors in people with EOA had increased postural sway during single leg stance, which could be associated with altered muscle activation patterns, altered proprioception, sluggish reaction time, valgus and varus instability at the knee [6,7].

Proprioception is the conscious and unconscious recognition or perception of joint position. Proprioception, activates and regulates muscles function which stabilize the joint and produce controlled

---

* Corresponding author.
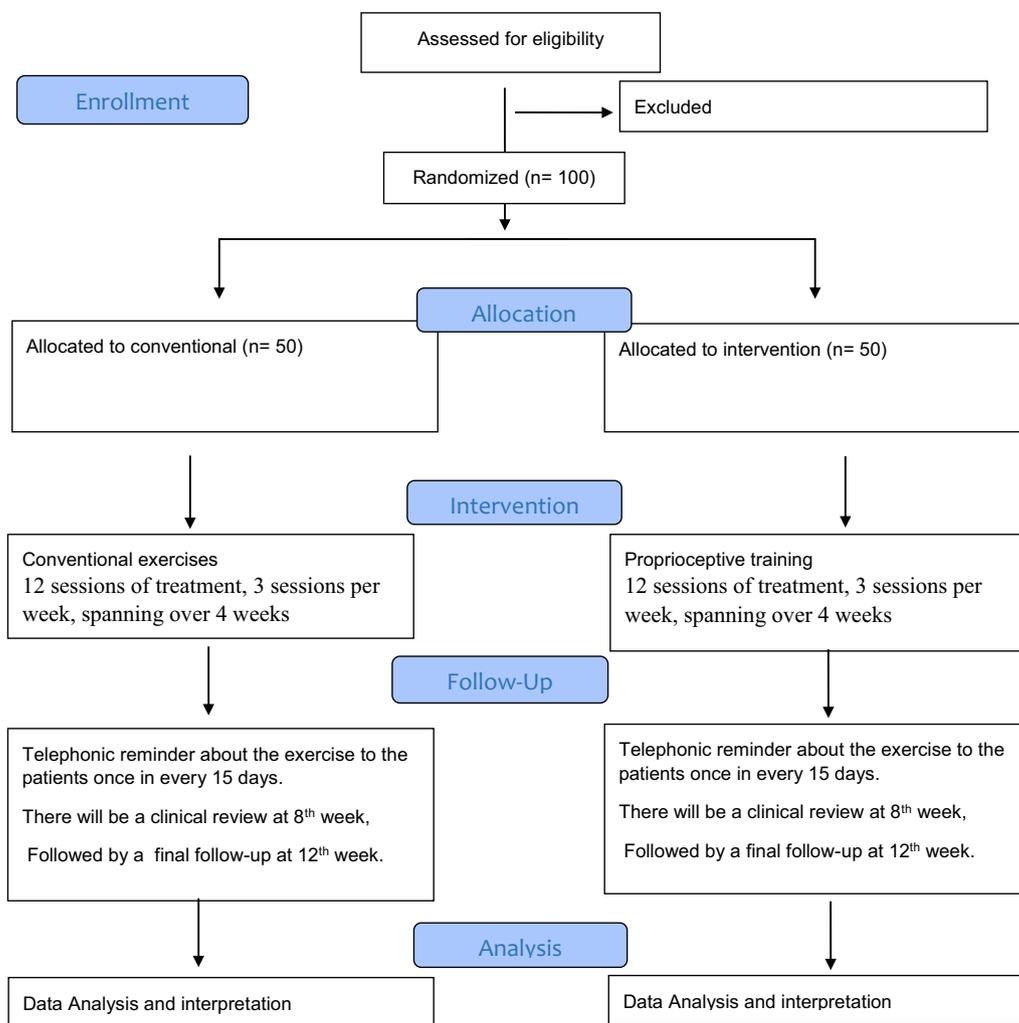 E-mail address: ashish.john@manipal.edu (A. John Prabhakar).

Fig. 1. Study Flow chart.

joint movements [8]. Pain, inflammation or mechanical stress may contribute to proprioceptive deficiency [9]. Proprioceptive deficiency have shown to cause building up of unusual pressure in the surrounding tissue which might cause abnormal joint position sense and could increase the incidence of injury [9]. It has been claimed that early cartilage defects and other soft tissue injury are reversible, particularly in younger people [6]. Therefore it is important to recognize individuals presenting with early symptoms [5].

Conservative management for EOA include non-pharmacological interventions (lifestyle modifications, exercise therapy, physical therapy, dietary supplements), pharmacological therapies (NSAIDS, glucosamine and chondroitin) [2,10]. Exercise therapy including isometric and isotonic exercises for quadriceps, cycling on a static cycle [11]. Exercise helps to decrease pain, improve health status and physical function and prevent the condition from progressing [10].

Under normal loading conditions, weight bearing joints have been found to experience forces as high as 10 times body weight [12], considering this we hypothesize that some of the exercises though it strengthens the muscles, it might adversely affect the joint.

Abnormal mechanical loading of the articular cartilage can aggravate pain and possibly lead to cartilage destruction. Proprioceptive training on the other hand strengthens the proprioceptive

system in a more static activity and less impactful when compared to routine exercises. In addition to the above, the data to support the use of proprioceptive training in early OA is limited. With this background the current study aims to investigate the effect of proprioceptive training on postural sway, joint position sense, muscle function, pain and functional outcome in patients with EOA and to determine the effectiveness of proprioceptive training versus conventional exercises in patients with EOA.

2. Methods

2.1. Trial design

We are conducting a single blinded, randomized controlled trial among adult participants with early osteoarthritis. This randomized controlled trial has received ethical approval from Institutional Ethics Committee of Kasturba Medical College, Mangalore. Manipal Academy of Higher Education (MAHE). (Ref – IEC KMC MLR 08-18/171). This Trial is also registered with Clinical Trials Registry – India (CTRI), URL- ctri.nic.in. The registration number for the trial is CTRI/2019/01/017049.

The study has already commenced in the mid-2019, will continue for the next 2 years and will be completed at Department of Physiotherapy and Department of Sports injury and Joint

replacement at Kasturba Medical College Hospitals, Ambedkar circle, Mangaluru. The trial will be stated as per SPIRIT and CONSORT guidelines. Figure 1 demostrates outline of the study.

2.2. Participants

Based on sample size calculation following our pilot study, we plan to enroll 100 participants in the study, before enrollment in to the study each participant will providing their written consent, which will be obtained by the primary investigator. Participants will be enrolled based on inclusion and exclusion criteria. Considering a attrition rate of 20%, we expect up to 80 participants to complete the study, with 40 participants in each group. However, if the dropouts are beyond 20%, an intention to treat analysis instead of per protocol analysis will be undertaken. Inclusion and exclusion criteria are mentioned in Table 1.

2.3. Randomization/allocation/blinding

Upon enrollment into the study, the patients will be allocated to groups, i.e. conventional and interventional group., for the same sequence generation will be done by block randomization and allocation concealment will be done using sealed opaque envelopes. Following the allocation of the groups, an independent assessor who is blinded to the intervention, having adequate knowledge about the assessment tools will record the outcome measures. Data will be recorded at baseline, once every week till the completion of intervention and at the third month. Both the groups will receive 12 sessions of treatment, 3 sessions per week, spanning over 4 weeks. Post which the participants will be advised to carry out home exercise programme for the next two months.

2.4. Follow-up

Patients will also be asked to maintain a diary to keep a track of theirs exercises sessions. The primary investigator will give a reminder call about the exercise to the patients once in every 15 days. There will be a clinical review at 8th week, followed by a final follow-up at 12th week. After inclusion, patients with acute flare-up of symptoms with a need of analgesics for more than 5 days and/or intercurrent illness lasting for more than 7 to 10 days will no longer be part of the study.

2.5. Interventions

Both the conventional and interventional group would have treatment without outward apparent differences. The time needed for each session would be similar. Participants will receive interferential therapy for 20 minutes for relieving possible exercise induce pain, irrespective of their study group at the end of the exercise

session [13]. The intervention will be given by a qualified Physiotherapist.

2.6. Interventional group - [14–16]

1. Static balance on trampoline
- Partial squatting exercise with both legs
- Pass the ball while knee bent to approx. 60° (both leg stance)
- Standing on single leg
- Heel raise while standing on one leg
- Balance with perturbation
- Standing on single leg, passing the ball to the team mate with trunk rotation.
2. Using bobath ball and wall support
- Semi squats two leg stance
- Semi squat one leg stance
- Sitting on bobath and single leg support balance.

2.7. Conventional group

1. Hip muscle strengthening
- Hip Flexors
- Abductor, adductor strengthening
- Hip extensor strengthening
2. Knee muscles strengthening
- Dynamic quads
- Hamstring curls
- Gastrocnemius strengthening
- Squatting
3. Static cycling

2.8. Outcome Measures

Primary outcomes:

1. Postural sway

The participants will be asked to stand on the force-plate and maintain that posture as stable as possible. Data will be collected in both eye open and closed scenario, during eye open they will be asked to fix their view on a spot which will be marked on the wall at a distance of 3 m. Test will be repeated 3 times for 30sec each with a rest period of 1 min between each attempt [21].

Following recording the data center of pressure excursion (COPE) area will be determined by creating a rectangular area defined by maximum limit of excursion in each direction. The area on the graph will be calculated using grid method, where each grid square is 1 cm. For calculation following equation will be used "Area = Width × Height", and it value will be expressed in 'cm²'.

Table 1
Inclusion and Exclusion criteria.

Inclusion criteria
1. Age $\geq$ 20 and < 45 years
2. Satisfying 4 out of 6 clinical symptoms criteria i;e Recurrent pain, pain following a duration of rest, discomfort at rest, swelling, instability, reduced range of motion.
3. Subject with clinically and radiological confirmed diagnosis of EOA by an Orthopaedician or a Rheumatologist.

Exclusion criteria:
1. If patients demonstrate with any neurological, neuromuscular or musculoskeletal condition other than EOA, RA and other inflammatory arthritis.
2. Obesity (BMI > 30 kg/m^2)
3. Subjects with history of vertigo (vestibular dysfunction)
4. Patients with hypertension.
5. K & L, grade 3 and above.
6. Recent surgeries and significant injuries of lower limb

These parameters will be analyzed using artificial intelligence (AI) for better understanding of the outcome.

2. Joint position sense

Active joint position sense (JPS) will be testing with the help of digital goniometer. Subjects will be examined in supine position with lower limb exposed, and eyes closed. The fulcrum of the goniometer will be placed over later knee joint line. At completer extension, the goniometer and the starting position will be set to be 0°. The target angles will be as 15°, 30°, 45° and 60°. The angle of concern will be instructed to the subjects twice before the measurement. Then, the subjects will be instructed to find the correct angle, with six time repetitions. The deviations of the average of the six measurements from the target angle were recorded for all angles.[9]

Secondary outcomes:

3. Muscle strength

Patient will be asked to sit on an adjustable examination couch in a high sitting position (hip and knee at 90-degree flexion), with a gap of 1–2 cm between the back of knee joint and the couch. The height of the couch should be such that the there is a gap of at least 10 cm between the patients feet and the floor. Patient has to hold the side edge of the couch for support and perform a maximum voluntary isometric contraction with a hold of 5sec.

For knee extensor strength assessment, the dynamometer will be kept on anterior part of leg, just above the talotibial joint line and for knee flexor strength assessment, the dynamometer will be placed on the posterior part of leg above malleolar level.

Test will be repeated 3 times with 5 sec hold and 60 sec rest period between each test.[18]

4. VAS

It is a 10 cm line (i.e. 100 mm), where the patient will be asked to mark a point on the line representing their pain intensity. Pain intensity is categorized as no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm) and severe pain (75–100 mm).

5. Functional outcome measure (KOOS)

KOOS is an instrument specific to the knee joint, developed to evaluate the patient's viewpoint about their problems related to the knee joint. It helps to assess short and long-term consequences simultaneously. It consists of 42 items which is divided in 5 subscales which consists of pain, other symptoms (ADL), sport and recreational activity (sport/rec), and Quality of life related to knee (QOL). [19]

2.9. Data analysis

Pilot study:
We initially conducted a pitot study, for which 12 participants were recruited based on the inclusion and exclusion criteria mentioned in Table 1. Six participants received conventional management, and the other 6 participants received proprioceptive training. Each participant was followed for 3 months, with 2 dropouts. The outcome measure analyzed were COPE (center of pressure excursion) for postural sway, joint position sense for proprioception, Hand held dynameters for muscle strength, VAS for pain and KOOS (Knee Injury and Osteoarthritis Outcome Score) for quality of life. Collected data (Table 2) were analyzed by mean, standard deviation and 2 factor ANOVA for repeated measure,

followed by Bonferroni post hoc analysis. $p < 0.05$ was considered to be significant. Based on the results obtained from the pilot study, the sample size for the current study was calculated.

Power calculation
According to data from our preliminary pilot study (Table 2), at 90% power, n = 39 subjects in each group was estimated, Considering dropout rate of approximately 20%, a total of 100 participants will be recruited.

Statistical analysis
Data Collected will be analyzed by mean, SD and 2 factor ANOVA for repeated measure, followed by Bonferroni post hoc analysis. Data will be analyzed using SPSS package version 17.0, $p < 0.05$ will be considered as significant.

Data management
Every questionnaire, screening tool, and consent will contain a separate trial no unique for each participant. All the data entry and analysis will be done using the trial no. Hard copies of the data will be kept in securely locked filling cabinets at department and only study investigators will have access to the hard copies. Moreover, Password protected computer and data bases will be used to maintain confidentiality of electronic data. In addition, the backup files for electronic data will also be maintained to prevent loss of data.

Ethics and dissemination
Approval for the conduction of this study has been granted by Institutional Ethical Review Committee. Informed written consent to participate will be obtained from all participants. The findings of this study will be communicated with all the healthcare providers via Seminar, CME, scientific paper, and conference presentation.

3. Discussion

3.1. Potential impact and significance

There is a need to conduct this RCT to better understand the outcome of the study, as the results of the pilot study revealed a promising potential with proprioceptive training. This study is also first to use Artificial Intelligence (AI) to analyze parameters derived from force plate, which could be developed as an effective monitoring tool. On the other hand, the force plate outcome can also be used as a feedback tool, the visual feedback provided by a repeated force plate assessment might help encourage patients to improve compliance and acceptance of exercise techniques.

According to recent studies open kinetic chain (OKC) exercises decreases joint proprioception and synergistic muscle activation, leading to increased shear forces and there by adversely affect the joint [20]. Proske U and Gandevia SC stated that concentric and eccentric exercise too disturbed both senses of joint position and force [21].

In study by Veena Kirthika et al. [16] and G Panics et al. [22], it was stated that proprioceptive activation exercises have a direct effect on the joint position sense, mobility and pain sensations and restoration of proprioception is essential during the rehabilitation of patients with knee OA.

As per the current guidelines of AAOS (American Academy of Orthopaedic Surgeons), persons with symptomatic knee should consider exercise therapy as a preventive non-surgical treatment strategy best before mechanical derangement sets in, postponing or avoiding early surgical procedures which are unwarranted [23]. According to previous studies, force plates have been able to pick up changes in arthritis [17]. Our pilot study too demonstrates that they are sensitive enough to early changes and relatively minor differences. There is huge potential in using these as a prognostic and monitoring tool. Furthermore use of artificial

Table 2
Pilot study results.

Outcome	Parameters	Groups					
		Paired difference		Bonferroni P value	Paired difference		Bonferroni P value	Bonferroni P value for control VS experimental group
		Mean	SD		Mean	SD		
COPE(cm^2)	Eye closed pre-3 months	1.626	1.958	1.000	3.286	2.485	0.036*	0.274
	Eye open Pre – 3 months	−0.064	0.384	1.000	3.750	2.774	0.586	0.092
Proprioception	15 degree pre-3 months	5.000	1.871	0.036*	5.429	3.207	0.036*	0.796
	30 degree Pre-3 months	4.200	4.087	1.000	4.000	3.830	0.035*	0.933
	45 degree pre-3 months	4.200	4.550	1.000	6.571	5.159	0.023*	0.430
	60 degree Pre-3 months	3.600	3.209	0.993	3.714	3.684	0.036*	0.957
Muscle Strength	Extension pre-3 months	−7.200	4.658	0.039*	−8.500	2.811	0.011*	0.581
	Flexion pre-3 months	−3.800	2.049	0.021*	−3.833	1.472	0.021*	0.976
VAS	Pre-3 months	4.000	1.225	0.028*	2.643	3.065	0.940	0.375
KOOS	ADL pre −3 month	−0.400	13.145	1.000	−21.000	19.565	0.099	0.077
	Pain pre −3 month	−4.000	11.402	1.000	−20.107	19.954	0.842	0.144
	QOL pre −3 month	−11.200	8.289	0.587	−31.333	27.998	0.611	0.158
	Sports pre −3 month	−8.000	14.405	1.000	−24.667	24.386	0.038*	0.213
	Symptoms pre −3 month	−7.800	15.073	1.000	−12.833	16.774	0.043*	0.217

intelligence in measuring the centre of pressure plot will help objectivize the measurements for easier interpretation.

Hence we hypothesize that proprioceptive training could prevent impact loading of the joints and help to prevent progression of the injury and could improve strength and balance at the same time. Proprioceptive training could be used as an alternate to more time consuming, strenuous and impactful conventional exercises, thereby helping in reducing pain, reduce progression of the condition, better joint and muscle health and improve functional quality of patients with EOA.

4. Consent

Informed Consent will be obtained from the patients.

5. Registration of Research Studies

This Trial is also registered with Clinical Trials Registry – India (CTRI), URL- ctri.nic.in.
The registration number for the trial is CTRI/2019/01/017049

6. Guarantor

On behalf of all the contributors I (Ashish Prabhakar) will act as guarantor and will correspond with the journal from this point onward and I declare that all the contributors have participated towards the completion of the manuscript

Funding

NIL

Ethical approval

This randomized controlled trial has received ethical approval from Institutional Ethics Committee of Kasturba Medical College, Mangalore. Manipal Academy of Higher Education (MAHE). (Ref – IEC KMC MLR 08-18/171).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] C. Cooper, S. Snow, T.E. Mcalindon, et al., Risk factors for the incidence and progression of radiographic knee osteoarthritis, Arthritis Rheum. 43 (5) (2000) 995–1000.

[2] R. Grazina, R. Andrade, R. Bastos, et al., Clinical Management in Early OA: Osteochondral Tissue Engineering, 1st ed., Springer International Publishing, Switzerland, 2018, pp. 111–135.

[3] C.S. Azad, A.K. Singh, P. Pandey, et al., Osteoarthritis in India: an epidemiologic aspect, Int. J. Recent Sci. Res. 8 (10) (2017) 20918–20922.

[4] M. Favero, R. Ramonda, M.B. Goldring, S.R. Goldring, L. Punzi, Early knee osteoarthritis, Rmd Open. 1 (1) (2015) 1–7.

[5] T.S. De Windt, L.A. Vonk, M. Brittberg, D.B. Saris, Treatment and prevention of (early) osteoarthritis using articular cartilage repair—fact or fiction? A systematic review, Cartilage 4 (3) (2013) 5s–12s.

[6] L.D. Duffell, D.F. Southgate, V. Gulati, A.H. Mcgregor, Balance and gait adaptations in patients with early knee osteoarthritis, Gait Posture 39 (2014) 1057–1061.

[7] T. Masui, Y. Hasegawa, J. Yamaguchi, T. Kanoh, N. Ishiguro, S. Suzuki, Increasing postural sway in rural-community-dwelling elderly persons with knee osteoarthritis, J. Orthop. Sci. 11 (2006) 353–358.

[8] J.F. Holla, M.V. Leeden, W.F. Peter, et al., Proprioception, laxity, muscle strength and activity limitations in early symptomatic knee osteoarthritis: results from the check cohort, J. Rehabil. Med. 44 (2012) 864–868.

[9] D. Akseki, G. Akkaya, M. Erduran, H. Pinar, Proprioception of the knee joint in patellofemoral pain syndrome, Acta Orthop. Traumatol. Turc. 42 (5) (2008) 316–321.

[10] E. Kon, G. Filardo, M. Drobnic, et al., Non-surgical management of early knee osteoarthritis, Knee Surg. Sports Traumatol. Arthrosc. 20 (2012) 436–449.

[11] A. Ahmad, M. Daud, A comparative study between joint mobilization and conventional physiotherapy in knee osteoarthritis, Int. J. Physiother. 3 (2) (2016) 159–162.

[12] Z.A. Cohen, H. Roglic, R.P. Grelsamer, et al., Patellofemoral stresses during open and closed kinetic chain exercises, Am. J. Sports Med. 29 (4) (2001) 480–487.

[13] M.L. Buenavente, C.B. Gonzalez-Suarez, M.A. Lee-Ledesma, L.A. Liao, Evidence on the effectiveness of interferential current therapy in the treatment of knee osteoarthritis: a metaanalysis, OA Arthritis 2 (1) (2014) 1–9.

[14] S. Modam, S. Babu, R. Kumar, J. Prakash, A comparative study of proprioceptive exercises versus conventional training program on osteoarthritis of knee, Res. J. Recent Sci. 1 (12) (2012) 31–35.

[15] S.B. Ju, G.D. Park, S.S. Kim, Effects of proprioceptive circuit exercise on knee joint pain and muscle function in patients with knee osteoarthritis, J. Phys. Ther. Sci. 27 (2015) 2439–2441.

[16] V. Kirthika, S. Sudhakar, K. Padmanabhan, S. Ramachandran, M. Kumar, Efficacy of combined proprioceptive exercises and conventional physiotherapy in patients with knee osteoarthritis: a double-blinded two-group pretest–posttest design, J. Orthop. Traumatol. Rehabil. 10 (2018) 94–97.

[17] M. Taglietti, L.F. Bela, J.M. Dias, et al., Postural sway, balance confidence, and fear of falling in women with knee osteoarthritis in comparison to matched controls, PM&R 9 (2017) 774–780.

[18] B.F. Mentiplay, L.G. Perraton, K.J. Bower, et al., Assessment of lower limb muscle strength and power using hand-held and fixed dynamometry: a reliability and validity study, PLoS ONE 10 (10) (2015).

[19] E.M. Roos, L.S. Lohmander, The knee injury and osteoarthritis outcome score (KOOS): from joint injury to osteoarthritis, Health Qual. Life Outcomes 1 (1) (2003) 64.

[20] S. Van Rossom, C.R. Smith, D.G. Thelen, B. Vanwanseele, D. Van Assche, I. Jonkers, Knee joint loading in healthy adults during functional exercises:

implications for rehabilitation guidelines, J. Orthopaedic Sports Phys. Ther. 48 (3) (2018) 162–173.

[21] U. Proske, S.C. Gandevia, The proprioceptive senses: their roles in signaling body shape, body position and movement, and muscle force, Physiol. Rev. 92 (4) (2012) 1651–1697.

[22] G. Panics, A. Tallay, A. Pavlik, I. Berkes, Effect of proprioception training on knee joint position sense in female team handball players, Br. J. Sports Med. 42 (6) (2008) 472–476.

[23] L.M. Croke, Treatment of knee osteoarthritis: a clinical practice guideline from the AAOS, Am. Fam. Physician 89 (11) (2014) 918–920.