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EMMATKA trial: the effects of mobilization with movement following total knee arthroplasty in women: a single-blind randomized controlled trial

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Abstract

Background Mobilization with Movement (MWM) is an examination and management approach for correcting the intra-articular translational and rotational movements to facilitate the active physiological movement. The study aimed to determine the effects of MWM on Total Knee Arthroplasty (TKA) using a randomized controlled trial (RCT) design.

Methods The trial is registered (ISRCTN ref: 13,028,992). A blinded examiner assessed patients at pre-surgical (before TKA), post-surgical (at 3-weeks post-TKA), 6-weeks and 6-months post-TKA. Participants were randomly assigned to receive MWM (six sessions, between 3 and 6 weeks post-TKA) plus standard rehabilitation (intervention group) or standard rehabilitation alone (control group) of outpatient rehabilitation including range of motion and strengthening exercises, cycling, gait and stair training. Outcome measures were range of motion (goniometer), pain (visual analogue scales), physical function (Timed Up and Go (TUG)), a 15-m walk test, and health status (Western Ontario and McMaster (WOMAC) Osteoarthritis Index). Change in outcome measures from post-surgical to 6 weeks and 6 months post-TKA were compared between groups. The primary outcome was change in knee flexion range of motion at 6 weeks.

Results 84 women scheduled for TKA were randomly allocated to intervention (n = 42) or control (n = 42); mean ± (SD) age 65.1 ± 7.4 and 66.8 ± 8.9 years, respectively. The intervention group demonstrated significantly greater increase in knee flexion at both 6 weeks (median (IQR) + 10.00^0 (20.00^0) compared with + 2.50^0 (6.25^0) in the control group) and 6 months (+ 12.50^0 (15.00^0) and + 5.00^0 (10.00^0) respectively) (both $p < 0.05$). There were no differences between groups in secondary outcomes.

Conclusion Introducing MWM for TKA rehabilitation has greater benefits for women post-TKA in increasing knee joint flexion range of motion than the standard rehabilitation programs in the short and medium-term. This evidence-based approach offers a promising adjunctive intervention for optimizing recovery and rehabilitation process following TKA in women. Clinicians should consider including MWM approach in post-TKA rehabilitation programs.

Level of Evidence: I

Keywords Rehabilitation, Knee arthroplasty, Surgery, Manual therapy, Range of motion, Mulligan approach

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Introduction

Knee osteoarthritis is the eleventh highest contributor to disability and is ranked the thirty-eighth for disability-adjusted life years globally [1]. With the increase in the global population's age, and with obesity on the rise, the demand for therapeutic approaches to knee osteoarthritis in health services is expected to increase [1–3]. In the advanced stage, conservative management may fail to control the symptoms, and total knee arthroplasty (TKA) could be required. TKA is a successful surgical procedure for resurfacing the damaged knee with artificial components, restoring joint function, and controlling the symptomatic manifestations [3,4]. The lifetime risk of primary TKA is 7.0% for men and 9.5% for women, where half of adults in the US diagnosed with knee osteoarthritis will undergo surgery for TKA [5]. Four million adults in the U.S currently live with TKA, representing 4.2% of the population [5]. The incidence of TKA is estimated to rise reaching 276% by 2030 with a total cost of 5.32 AUD billion [6]. By 2030, this economic burden will exceed 13 billion annually [7]. By 2050, the growth volume of TKA is expected to reach 855% [8]. For example, the annually performed TKA in the US has doubled exceeding 620,000 procedures and 97% of the TKAs were for managing osteoarthritis. [5]

Despite the significant improvements in joint pain, mobility and function post TKA, knee flexion range of motion (ROM) may not be fully restored, which could be related to pre-, intra- and post-operative factors [9–13]. To efficiently perform various activities, higher angles of knee flexion are required, which is associated with reduced functional performance [14–20]. Based on a systematic review and meta-analysis, the greatest mean angle reported for knee flexion post TKA was 108^0 12 months post-surgery, which is associated with reduced functional performance [14,15,17,19]. Other studies have reported a slightly higher knee flexion ROM of 113^0 while other studies have reported much higher angles and 139.5^0 with a TKA posterior-stabilized (PS) system [15,16]. A TKA reference chart for monitoring the recovery highlighted flexion ROM ranging from 109^0 to 122^0 3 months following TKA [19]. Yet, many daily activities require > 120^0 knee flexion, such as kneeling, squatting, and various functional activities [17–19].

Altered knee kinematics could explain the failure to regain knee flexion post TKA. Specifically, attaining maximal knee flexion requires synchronized intra-articular posterior translational and medial rotational movements at the tibio-femoral joint [17]. However, previous studies report significant changes in the translational and rotational movements at the knee joint post TKA. Paradoxical femoral condyle anterior translation was reported post TKA [20,22,23], which causes posterior edge impingement of the tibial component, consequently reducing knee flexion. Additionally, knee kinematics have been explored in various knee flexion angles in an in-vitro robotic study [17]. At 90^0 flexion, TKA showed significant reduction in posterior translation of the lateral femoral condyle compared to the intact knee; 6.7 (6.2) mm and 13.8 (7.0) mm, respectively [17]. At the same angle of 90^0, TKA showed a reduction in posterior translation of the medial femoral condyle compared to the intact knee; 2.6 (5.3) mm and 9.1 (6.8) mm, respectively [17]. At 30^0 and 60^0 of knee flexion, a significant reduction was also found in TKA tibial internal rotation. Biomechanical mechanisms that inhibit knee flexion in PS TKA were explored using a robotic experimental setup, where posterior femoral translation was reduced compared to the intact knee [15]. The anterior side of the tibial post showed wear and deformation, indicating a reduction in posterior femoral translation, and limiting maximum knee flexion to 112.5^0 [15]. Anterior femoral translation of the TKA was more pronounced at mid-flexion, and posterior translation was most limited at deep flexion [15]. Consequently, postoperative stiffness is reported in 4–16% of the patients, and adequate rehabilitation is recommended to reduce the limitation of knee flexion post TKA [24].

Mobilization with Movement (MWM) is an examination and management approach that follows a specified algorithm for correcting the deviation of the intra-articular translational and rotational movements to enhance physiological movement [25,26]. Particularly, in MWM a manual force is used to sustain translational or rotational intra-articular glides to facilitate the active physiological movement [25,26]. The algorithm of MWM is the only approach that follows the pain-free intra-articular glides and mobilizations as an indicator of the ultimate articular correction required to facilitate the physiological movement [25,26]. Such an approach could be effective in correcting the previously reported kinematic rotational and translational deviations post TKA, which could in turn maximize knee flexion angle. MWM has been found to be effective for the management of various musculoskeletal conditions, including frozen shoulder, impingement syndrome, knee osteoarthritis and ankle sprain [27–33]. However, the effectiveness of such an approach has not previously been explored for prosthetic kinematic correction, including TKA. Previous studies have investigated other mobilization approaches in TKA, and other advanced rehabilitation strategies such as motor imagery and telerehabilitation with no significant changes in ROM [12,34–36]. The MWM concept explored in the present investigation aims to correct the intra-articular position to enhance physiological movement, and thus could be more effective than the previously studied

approaches. Restoring knee kinematics post TKA could optimize functional capacity and performance, which could in turn enhance participation and quality of life. Therefore, the aim of this study was to determine the effect of MWM approach combined with standard rehabilitation in comparison to standard rehabilitation alone on knee flexion ROM, pain, function and participation following TKA using a randomized controlled trial (RCT) design. It is hypothesized that MWM is effective in increasing knee flexion ROM in patients with TKA.

Materials and methods (details can be accessed in the published protocol at Alsiri et al. 2021) [37]

Ethics and design

Ethical approval was granted by the Kuwait Ministry of Health Research Committee (ref:767/2018), the trial was registered on ISRCTN (ref:13,028,992) and funded by the Kuwait Foundation for the Advancement of Sciences (KFAS) (ref:PR19-13MM-05). Written informed consent was obtained from the participants, and privacy, confidentiality and right to withdraw were maintained according to the Declaration of Helsinki. Full methodological details are available in the published protocol [37]. The study has been reported according to Consolidated Standards of Reporting Trials (CONSORT) guidelines [38].

A single-blind parallel RCT design was used by randomly allocating patients to two groups intervention or control using an online randomizer with an equal allocation ratio of 1:1 [37]. The outcomes assessor was blinded from group allocation. Both groups received the conventional post-TKA rehabilitation program [37]. The intervention group additionally received MWM for six sessions twice per week over 3 weeks starting from week three post-surgery A decision was made to initiate the intervention at week three post-TKA to allow the surgical incision to heal, because MWM requires the application of over-pressure at the end of range. A previous study applied a different mobilization approach much earlier at 1 week post TKA and no adverse events were reported [37]. However, the level of the currently studied mobilization approach can be considered more intense, where the previously studied mobilization technique has no over-pressure element at the end of the reached range of knee flexion and has no combined movement element of both gliding while flexing and extending the knee simultaneously. Therefore, a pragmatic decision was undertaken to start the intervention at week three instead of week one post-TKA. The application of MWM techniques in TKA could be considered safe as the Mulligan concept includes the active participation of the patient and the elimination of pain during the procedure [41]. These characteristics ensure the procedure's safety, where no adverse effect has been previously reported for introducing mobilization techniques in the early stages post TKA [34,39].

Inclusion and exclusion criteria

Women who were admitted to Al-Razi Orthopedic Hospital for TKA and met the eligibility criteria were invited to take part in the study. Al-Razi Orthopedic Hospital is the main orthopedic hospital of the state of Kuwait, which serves the entire Kuwaiti population. The inclusion criteria were women aged 40–80 years and diagnosed with knee osteoarthritis by an orthopedic surgeon following the American College of Rheumatology criteria [40]. Patients older than 80 years old were not included due to the higher complication rates and prolonged recovery time [41]. Al-Razi Orthopedic hospital is a multi-building facility, where female and male wards and physiotherapy departments are in separate buildings, presenting practical challenges for research. A pragmatic decision was made to conduct the trial in the female facility due to convenience and accessibility. Previous studies suggest that mixed-gender studies might underestimate the biomechanical outcome of TKA for women, and standardized methods are needed for gender-specific studies to improve the outcome for patients who undergo TKA [42,43]. Exclusion criteria were secondary osteoarthritis, other inflammatory disorders, peripheral vascular disease, severe cardiac disease, neurological disorders, scheduled for bilateral TKA, and unable to comprehend in Arabic.

Sample size calculation

Reliability study was used for sample size calculation to identify the smallest difference for knee goniometer post-TKA which is 10^0 between raters, with differences smaller than 10^0 considered as measurement error [44]. The figure which could be also considered clinically important difference [45], and was used for sample size calculation are control group = $110.0^0 \pm 12.6^0$ and mobilization with movement group = $120.0^0 \pm 12.6^0$, assuming a minimum of 10^0 increase in flexion and a similar standard deviation [44]. An improvement of 3.8^0–6.4^0 is not clinically important in response to non-surgical interventions [46], however, accurately identifying changes of this magnitude using goniometer is doubtful and therefore 10^0 was used. Sample size was calculated on the basis of knee flexion ROM measured at 6-weeks post-TKA as the primary outcome measure. At least 35 participants per group is required to detect an effect size of 0.79 (two tailed hypothesis, $\alpha = 0.05$ and 90% power) [44]. Forty participants per group were targeted to account for 12.5% attrition rate.

Instrumentation and data collection:

The effectiveness of MWM was evaluated using outcome measures to reflect the International Classification of Functioning, Health, and Disability (ICF) of the World Health Organization (2001) (i.e. impairment, activity, and participation). Patients in both groups were examined four times: (1) 1–3 days pre-surgery, (2) post-surgical, 3-weeks post-TKA (before starting the intervention and their first rehabilitation session), (3) 6-weeks post-TKA (after the intervention group had received six sessions of MWM; patients attended a separate assessment within 1 week of intervention completion), and (4) 6-months post-TKA as a medium-term follow-up. Pre-TKA status was measured as an important indicator for the success of the surgery which could be a confounding factor for the success of the MWM approach. Additionally, pre-TKA status is an essential predictor for post-TKA outcome measures to help in results understanding and interpretation and provide a comprehensive overview of the participants' condition. An anterior approach was used for TKA using a PS system which anticipated knee flexion of $113.2^0 \pm 13.6^0$ [16]. In terms of impairment, visual analogue scales (VASs) were used to evaluate the intensity of knee pain during rest and on movement during performing daily activities such as walking, goniometry was used to measure knee flexion and extension ROM. A 10 cm VAS scales were used where 0 indicates "no pain" and 10 indicates "worst possible pain [47–50]. In terms of activity, the Timed Up and Go test (TUG-test), and 15-m walk test were administered. The Western Ontario, and MacMaster Universities Osteoarthritis Index Questionnaire (WOMAC) was used to assess physical function of the ability to perform daily activities including walking, climbing stairs and sitting which can indirectly assess the participation level. The instruments employed have strong psychometric properties, and the examination procedures were standardized [37]. The goniometer shows the least measurement error compared to sequential magnetic resonance imaging and two-dimensional motion analysis and this measurement error of less than 10^0 makes the goniometer appropriate for use as an examination tool [45,47]. The inter-rater and intra-rater reliabilities of the goniometer for measuring knee flexion are high of 0.996 and 0.993 ICCs, respectively. [45] The VAS, TUG-test, 15-m walk test and the WOMAC were found as highly valid, reliable, and sensitive [47–52]. For goniometry measurement, a 12-inch hand-held universal goniometer was used (JTECH Medical, United States). The lateral femoral epicondyle was the measurement center led by the lateral malleolus and greater trochanter (Fig. 1). In supine position, the heel of the operated limb was placed on a 12-cm diameter bolster. The contralateral limb was in full extension, and the examiner applied pressure to the extended knee. The patient was asked to actively flex the knee then the examiner applied mild pressure to reach the maximum available range. Two measurements were recorded, and the mean was used for knee flexion and extension. The goniometer is a clinically applicable tool and shows the least measurement error in comparison with much more technically intensive methods of sequential magnetic resonance imaging and two-dimensional motion analysis [47]. It was intended to report mechanical alignment of the knee, as described in the study protocol [37]. However, following an update to the organization's radiological system, images were irretrievably deleted. It was therefore not possible to report these data.

Fig. 1 The landmarks for goniometer application; axis at the lateral femoral epicondyle, stationary arm aligned with the greater trochanter and moving arm aligned with the lateral malleolus

Intervention

Template for intervention description and replication (TIDeR) is reported in Appendix I. [53] Both groups received a standardized post-TKA rehabilitation program starting from day two post-surgery for a period of 3 months [39]. As per hospital protocol, patients received individualized post-surgical rehabilitation daily for 1 week until discharge, including circulatory and ROM exercises and gait training. After discharge, all patients continued with the post-TKA rehabilitation program twice per week for 3 months in the physiotherapy outpatient department. The program includes ROM and strengthening exercises, cycling, gait and stair training, as detailed in the protocol [37]. The intervention group additionally received six sessions of MWM by a certified Mulligan practitioner, following a Mulligan examination algorithm to decide the required correctional approach to maximize knee flexion during open chain movement. [37] The adherence and completion rates were reported

in the results and by using the Consolidated Standards of Reporting Trials (CONSORT) follow-up diagram at week three and week six. Reaching the full ROM was considered as the criterion for not requiring the entire six sessions of MWM, which was based using goniometer measurement of reaching 130^0 of active knee flexion without pain or compensatory movement. [54]

Following Mulligan's guidelines, the 'faulty' position of the knee was determined with the mobilization technique for each patient individually by one of two Mulligan certified physiotherapists. Flexion restriction is normally associated with reduced femoral posterior translation, however, mechanical correction requirement is multifactorial and varies from patient to patient. So the Mulligan algorithm was used to decide the specific mobilization approach for each patient. The faulty position is conceptualized as mal-positioning of the joint articular surfaces which causes the symptoms of pain and reduction in ROM and is verified clinically by the successful resolution of the symptoms with correction [39]. The following MWM techniques were used according to the patient's faulty position determination: medial glide, lateral glide, medial rotation, lateral rotation or anterior–posterior. For all the techniques, the patient was in a supine position and a Mulligan belt (Mulligan Manual Therapy Concept™) was placed around the feet and held by the patient, who actively flexed the knee during MWMs and over-pressure was applied at the end of the range. For medial/lateral glide MWM, the practitioner medially/laterally glided the tibia; for rotational MWMs, the practitioner medially/laterally rotated the proximal part of the leg; and for anterior–posterior MWMs, anterior/posterior glide of the tibia was applied [25,55]. All glides were performed during active knee flexion and sustained through the movement and return to the starting position. Each mobilization technique was performed for three sets of ten times each (total 30 repetitions). The intervention for each patient was modified during the course of treatment where the physiotherapist re-determined the optimal technique before each session. Intervention details were recorded for each patient [25,55]. The intensity of MWM was selected according to the pain perception for each patient following MWM algorithm, where pain-free mobilization should be attained by applying the glides/rotation before the application of knee flexion movement. The target was to maximize knee flexion for each individual patient. A designated sheet was used to record patients' demographics and details, including age, height, weight and the examined outcome measures. Patients were followed for 6 months, which can be considered a sufficient period to evaluate the recovery of knee flexion ROM after the intervention [21]. Most knee flexion is regained within the first 40 days after surgery, followed by a gradual plateau. [21] Therefore, the 6 month follow-up period was considered sufficient.

Statistical analysis

The demographics were described using mean ± standard deviation (SD) and compared using independent samples t-tests as the data were normally distributed (Kolmogorov–Smirnov tests all $p > 0.05$). An intention to treat analysis was applied using the last-observation-carried-forward approach [56]. The majority of data for the primary and secondary outcomes (pain, ROM, TUG, 15-m walk test and WOMAC) were statistically significantly deviated from normality as suggested by the Kolmogorov–Smirnov tests ($p < 0.05$). Data transformations were attempted but the assumption of sphericity was not met after transformation. Therefore, a conservative decision was made to describe all primary and secondary outcome data using median (interquartile range, IQR), and non-parametric Mann–Whitney U tests were used for between-group comparisons. To account for small differences between groups at post-surgical, primary and secondary outcome data were converted to change scores (post-surgical scores minus 6 week or 6 month scores) and between-group analysis was performed on these change scores. This non-parametric analysis was a deviation from the published protocol [33], but was considered necessary due to the nature of the data generated. A p value of < 0.05 was considered as statistically significant. Friedman test was used for within group comparison as the non-parametric alternative for repeated measure ANOVA to assess the differences across the four examination points and reflect the overall statistical significane of change.

Results

One hundred and fifty-five patients were assessed for eligibility, with 71 patients excluded from the trial (Fig. 1). Accordingly, 84 patients underwent randomization. The flow diagram of the CONSORT demonstrates the enrolment of patients, randomization, allocation to groups, disposition status, and analysis (Fig. 2) [57]. The trial enrolled 42 patients to the intervention group and 42 patients to the control group mean ± (SD) age of 65.1 ± 7.4 and 66.8 ± 8.9 years old, respectively (Table 1). No differences were identified between the two groups in terms of age, height and weight (all $p > 0.05$) (Table 1). There were also no statistically significant differences between groups in the primary and secondary outcome measures at pre-surgical or post-surgical (Table 1). The summary statistics; mean (IQR) or mean ± SD for primary and secondary outcomes, present per protocol data (Table 2).

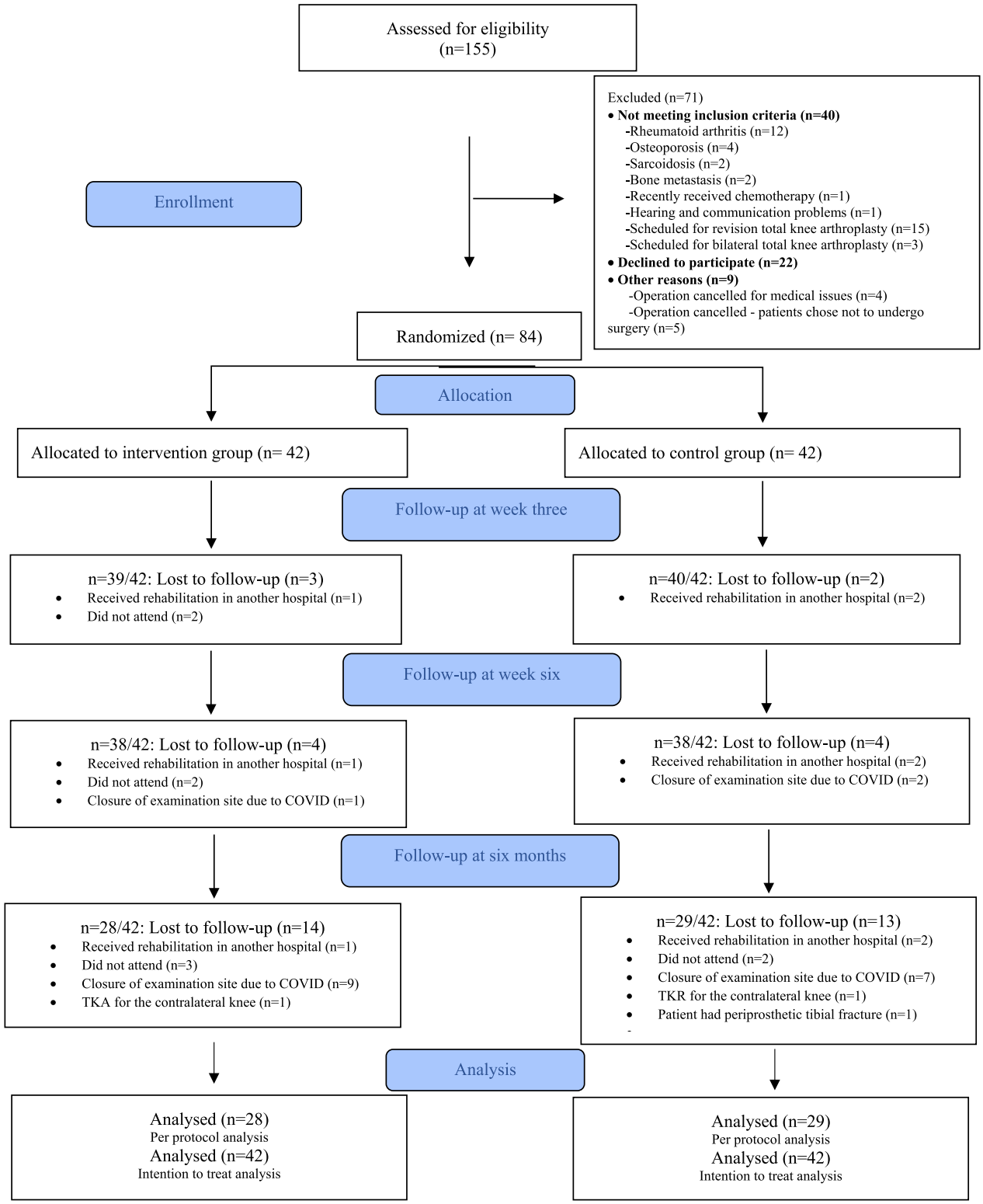

Fig. 2 The flow diagram of the Consolidated Standards of Reporting Trials (CONSORT) demonstrates the enrolment of patients, randomization, allocation to groups, disposition status, and analysis [57]

Table 1 Demographic characteristics, pre-surgical and post-surgical outcome measures of the intervention group compared to the control group

	Intervention group (n = 42)	Control group (n = 42)	*P* value
Demographic characteristics	Mean ± standard deviation	Mean ± standard deviation	
Age (years)	65.1 ± 7.4	66.8 ± 8.9	0.38
Height (cm)	155.0 ± 11.8	155.6 ± 12.1	0.85
Weight (kg)	81.0 ± 17.4	87.0 ± 20.3	0.21
Outcome measures	Pre-surgical		
	Median (IQR)	Median (IQR)	
Knee flexion range of motion (degrees)	110 (20)	110 (28)	0.32
Knee extension range of motion (degrees)	0 (10)	3 (15)	0.39
Pain intensity during rest (VAS, cm)	0.0 (6.0)	1.6 (5.3)	0.73
Pain intensity during movement (VAS, cm)	9.5 (3.8)	7.6 (4.5)	0.11
Timed up and go test (seconds)	15.0 (7.8)	15.2 (10.6)	0.71
15-m walk test (seconds)	19.7 (8.8)	20.7 (12.7)	0.65
The Western Ontario and McMaster Universities Arthritis Index (maximum score 96)	50.0 (31.7)	48.5 (27.5)	0.97
	Post-surgical		
Knee flexion range of motion (degrees)	100 (16)	95 (15)	0.18
Knee extension range of motion (degrees)	10 (15)	10 (16)	0.12
Pain intensity during rest (VAS, cm)	2.0 (6.2)	5.0 (7.0)	0.32
Pain intensity during movement (VAS, cm)	6.7 (7.3)	6.0 (5.50)	0.88
Timed up and go test (seconds)	19.8 (10.2)	22.0 (11.9)	0.27
15-m walk test (seconds)	27.3 (16.7)	28.1 (13.7)	0.59
The Western Ontario and McMaster Universities Arthritis Index (maximum score 96)	21.5 (28.0)	28.5 (25.7)	0.57

Means and standard deviations compared with independent sample t-tests, and median and Interquartile range (IQR) compared using Mann–Whitney U tests

The intention to treat analyses are reported in Table 3. There was a difference between groups in the primary outcome measure of change in knee flexion ROM at both 6 weeks and 6 months (both $p < 0.05$). These differences favored the intervention, with a median (Interquartile Range) increase of $+10^0$ (20^0) compared with $+3^0$ (6^0) in the control group at 6 weeks. At 6 months, the improvements were $+13^0$ (15^0) and $+5^0$ (10^0) respectively. The median difference was therefore 8^0 at both time points. The changes in secondary outcomes from post-surgical to 6 weeks and 6 months were not statistically significant, although there were trends in the majority of outcomes towards greater median improvements in the intervention group (with the exception of pain at rest) (Table 3).

Based on Mulligan's examination algorithm to increase knee flexion, various approaches were required (Table 4). For the five sessions, the most frequently used approach was MWM knee flexion with internal rotation at 36.8%, 31.5%, 42.1%, 35.2%, and 38.4%, respectively (Fig. 3). For the sixth session, MWM knee flexion with lateral glide was the most frequently used approach required at 64.2% (Fig. 3). All the patients required the first three sessions of MWM, 10.5% of the patients did not require the fourth session, 31.5% did not require the fifth session, and 63.1% did not require the final session (Fig. 3).

Discussion

The study demonstrated short/medium-term statistically significant improvements in the primary outcome of knee joint flexion ROM. The current trial provided a novel approach of knee mobilization following MWM's examination and management algorithm to optimize TKA post-surgical rehabilitation in women. No previous study has introduced an approach for correcting the intra-articular joint positioning with physiological movement optimization for TKA. The current trial showed that introducing knee mobilization via MWM could improve knee flexion ROM post TKA in both the short and medium term. This could be related to correcting the paradoxical femoral condyle anterior translation and rotation [17,20,22]. The approach of MWM for knee mobilization followed the correctional algorithm of the required accessory movement to maximize knee flexion. Such a correctional algorithm has been shown to be effective in the current trial. Particularly, the trial showed that the most frequently used correctional intra-articular approach

Table 2 Within group and between group comparisons of the Mulligans' Mobilization with Movement group and the control group in terms of pain intensity, knee range of motion of flexion and extension, timed up and go test, 15-m walk test and Western Ontario and McMaster University Arthritis Index; measured at baseline pre total knee replacement surgery, 3 weeks post-surgery, 6 weeks post-surgery when the intervention started for the intervention group, and six months post-surgery

Examination timeframe	Baseline	3 weeks	6 weeks	6 months	Within group *p* value
Pain intensity measured with Visual Analogue Scales (VAS)					
VAS during rest					
Intervention group	0.0 ± 5.5	0.0 ± 6.0	0.0 ± 1.0	0.0 ± 0.0	0.001*
Control group	1.6 ± 4.9	2.0 ± 6.7	1.4 ± 4.6	0.0 ± 0.0	0.000*
Between group *p* value	0.73	0.50	0.02*	0.74	
VAS during movement					
Intervention group	8.2 ± 3.8	5.0 ± 8.5	2.0 ± 3.0	0.0 ± 1.0	0.000*
Control group	7.6 ± 4.5	5.4 ± 6.4	4.0 ± 5.0	0.0 ± 2.0	0.000*
Between group *p* value	0.11	0.91	0.001*	0.76	
Knee range of motion (degrees)					
Knee flexion					
Intervention group	115 ± 20	100 ± 20	115 ± 15	115 ± 10	0.000*
Control group	110 ± 26	93 ± 14	100 ± 18	100 ± 15	0.000*
Between group *p* value	0.32	0.21	0.001*	0.001*	
Knee extension					
Intervention group	0.0 ± 15.0	10.0 ± 15.0	0.0 ± 10.0	0.0 ± 0.0	0.003*
Control group	2.5 ± 14.3	10.0 ± 15.0	7.5 ± 13.7	2.5 ± 10.0	0.003*
Between group *p* value	0.39	0.25	0.02*	0.01*	
Timed up and go test (s)					
Intervention group	14.9 ± 7.7	19.4 ± 9.9	15.1 ± 5.3	14.1 ± 4.4	0.000*
Control group	15.6 ± 10.4	22.7 ± 11.2	18.0 ± 8.9	15.3 ± 8.6	0.000*
Between group *p* value	0.71	0.21	0.05	0.04*	
15-m walk test (s)					
Intervention group	19.6 ± 7.1	26.0 ± 15.0	20.0 ± 8.2	18.2 ± 5.9	0.000*
Control group	23.1 ± 13.1	28.7 ± 14.2	28.0 ± 14.4	20.7 ± 14.1	0.000*
Between group *p* value	0.65	0.56	0.02*	0.03*	
The Western Ontario and McMaster Universities Arthritis Index					
Intervention group	47.0 ± 31.0	20.0 ± 19.0	11.0 ± 16.0	8.0 ± 15.4	0.000*
Control group	52.0 ± 25.7	30.0 ± 32.2	16.0 ± 23.7	8.0 ± 12.2	0.000*
Between group *p* value	0.97	0.57	0.12	0.36	

Data are presented with Median ± IQR and per protocol analysis is applied

* Indicated statistically significant difference at p value < 0.05

was internal rotation, which is in line with the previously reported biomechanical limitation post TKA [15]. The statistically significant improvement in knee flexion ROM reported by the current study could be also considered clinically significant. Small improvement in knee flexion post TKA equivalent to $5–7^0$ showed significant enhancement in daily activities including sitting, walking and stair climbing [46,58]. The current study showed smaller knee flexion ROM compared to previous studies which could be related to cultural and gender differences. Such factors support that even small improvement in knee flexion ROM in the current study would be a meaningful change [15,16,21].

A meta-analysis estimated the Minimal Clinically Important Change (MCIC) of knee flexion using relationships between change in flexion with change in pain and function [44]. The identified overall point estimate of knee flexion MCIC ranged from 3.8^0 to 6.4^0 but there

Table 3 An intention to treat between group comparison of the intervention group (n = 42) and the control group (n = 42) in terms of changes in pain intensity, knee range of motion of flexion and extension, timed up and go test, 15-m walk test and Western Ontario and McMaster University Arthritis Index. Values are expressed as change from post-surgical (when the intervention started) to 6 weeks post-surgery (when the intervention ended), and to 6 months post-surgery

Examination timeframe	Actual difference between week 3 and week 6	Actual difference between week 3 and month 6
Knee flexion range of motion (degrees)		
Intervention group	10 (20)	13 (15)
Control group	3 (6)	5 (10)
Between group *p* value	< 0.001*	< 0.001*
Knee extension range of motion (degrees)		
Intervention group	0 (10)	− 5 (10)
Control group	0 (6)	0 (10)
Between group p value	0.540	0.454
Pain intensity during rest (VAS, cm)		
Intervention group	0.0 (5.0)	0.0 (5.5)
Control group	− 0.9 (3.2)	− 1.3 (6.3)
Between group *p* value	0.985	0.513
Pain intensity during movement (VAS, cm)		
Intervention group	− 3.0 (15.0)	− 4.0 (7.7)
Control group	− 0.70 (3.0)	− 2.8 (5.3)
Between group p value	0.084	0.545
Timed up and go test (seconds)		
Intervention group	− 3.5 (4.8)	− 4.3 (6.4)
Control group	− 2.1 (4.9)	− 2.7 (6.8)
Between group p value	0.295	0.271
15-m walk test (seconds)		
Intervention group	− 4.6 (4.5)	− 5.5 (6.5)
Control group	− 2.7 (7.4)	− 3.5 (9.5)
Between group p value	0.181	0.140
The Western Ontario and McMaster Universities Arthritis Index (maximum score 96)		
Intervention group	− 7.0 (11.5)	− 7.0 (14.0)
Control group	− 7.0 (14.5)	− 8.5 (20.7)
Between group p value	0.875	0.402

Data are presented with median ± (IQR) and intention to treat analysis is applied

*Indicates statistically significant difference between groups (Mann–Whitney U test) at $p < 0.05$

were still no sufficient studies to draw strong conclusions due to missing data as stated by Silva et al., (2024) [46]. Knee flexion was measured in supine position in the current study and Silva et al., (2024) specifically identified that the MCIC of pooled-supine flexion ranged from 1.7^0 to 11.3^0 with a total range of 90% Credible Interval − 0.5 to 20.1^0. [46] The statistically significant difference highlighted by the current study for knee flexion between the intervention group and the control group is 7^0; third week compared to sixth week, and 8^0; third week compared to sixth month. Therefore, the statistically significant difference identified by the current study can be also considered clinically important. Previous studies showed that knee flexion ROM may not be fully restored post-TKA and range limitation was associated with reduced functional performance where many essential daily activities require high angles of knee flexion. [9–11,14–19] Moreover, the current study's descriptive statistics showed potential effectiveness of most of the secondary outcome measures, which could also support the clinical significance of the reported change in knee flexion.

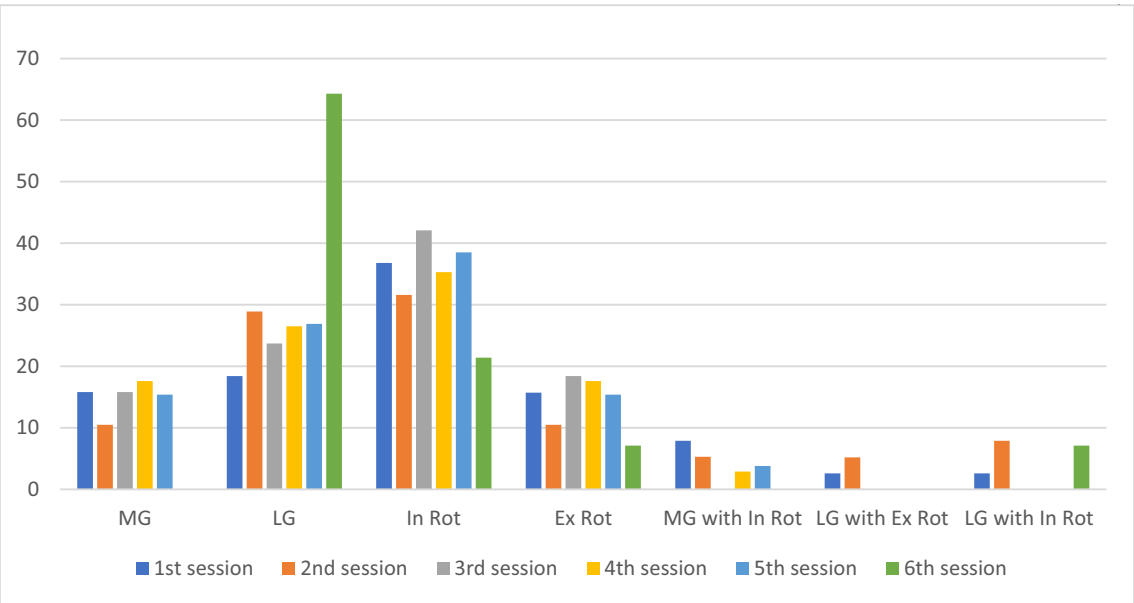

Fig. 3 The frequency of the used Mulligan Mobilization with Movement approach with knee flexion for the intervention group

Despite the various explorations of potential factors to enhance TKA outcomes, postoperative pain remains a substantial clinical challenge [59,60]. Pain intensity was measured during both rest and movement as differences were expected of more pain intensity during movement and to avoid patients from conflating the two types of pain when responding to a single question. Specifically, at 6 months post TKA no pain was reported for pain during rest, while pain during movement was reported as 0.0 ± 1.0 for the intervention group and 0.0 ± 2.0 for the control group (Median ± IQR). IQRs of 1 and 2 of pain intensity highlight the pain range during movement. The increase of pain intensity during movement in comparison to rest is consistent with the previous studies. A systematic review highlighted that pain post TKA at rest is different than pain during movement where pain during movement is the pain which may persist due to factors related to muscle weakness, joint stiffness, and soft tissue healing [61]. Moreover, preoperative pain is a predictor for post operative pain [62,63]. The sample of the current study reported high pain intensity during movement pre surgery while pain during rest was minimal. Such preoperative difference explains the outcome in terms of pain, which is consistent with the previous studies. [63]

The current trial has therefore established the effectiveness of MWM for improving knee flexion ROM both the short and medium term post TKA in women in Kuwait, and has also showed potential effectiveness of the MWM algorithm for TKA post-surgical rehabilitation in women in most of the secondary outcome measures. However, the observed impact did not reach statistical significance when change scores were used for analyses for the secondary outcome measures because the study might not have been powered to detect differences for these secondary outcomes. These observations need to be verified with a future larger sample size study, where the current study has calculated the sample size for the primary outcome measure of knee flexion and the secondary outcome measures were not considered in the calculation. An example was knee extension, with the descriptive statistics suggesting that the intervention group attained higher knee extension. Yet, this observation did not reach statistical significance for the change scores, a potential type II error. Maximizing knee extension is essential for proper joint biomechanics, avoiding biomechanical strain and ensuring equal leg length required for symmetrical walking pattern. More importantly, attaining full knee extension is necessary to allow sufficient intra-articular force distribution during the stance phase of walking, which could have a direct impact on prosthetic age. Particularly, some gait biomechanical limitations post TKA, including reduced knee extension, alter knee joint moments of intra-articular force maldistribution and are related to TKA component loosening [64–66]. This

observation should be confirmed with a larger sample size study in future research. Improvements in knee flexion showed potential to impact on the intensity of knee pain in the short-term period during both rest and movement. Persistent pain post TKA is common, reaching 21% at 6 months and 16% at 12 months. [67] The highlighted observation of the current trial could be used to support future research of larger sample size to determine the effectiveness of introducing MWM to control TKA post operative pain. Facilitating normative knee kinematics at the early stage post-TKA could be effective in reducing post-operative pain [68]. Such an impact could be valuable in terms of maximizing the patient's ability to adhere to the demands of a rehabilitation program. Moreover, trends were also observed for potential impact of the intervention on the functional performance of the TUG and 15-m walk tests. The current trial has therefore established the effectiveness of MWM for improving knee flexion ROM in both the short and medium term, and has also identified potential trends in secondary outcomes to support future research aiming to maximize the outcome of TKA via effective rehabilitation regimes.

This is the first trial to introduce the concept of knee mobilization for post-surgical rehabilitation. Therefore, comparison with previous studies is difficult. MWM has been studied in relation to knee osteoarthritis, where it has been considered as a promising intervention in reducing pain and improving function [33,69]. In terms of knee flexion ROM, a previous study showed that MWM is effective in improving knee flexion in subacute knee osteoarthritis which is in line with the findings of the current study [69]. Moreover, knee flexion ROM, pain and function were found to be improved in the long term in patients with knee osteoarthritis [16]. A systematic review and meta-analysis suggested that MWM is a promising intervention for patients with knee osteoarthritis in terms of pain and function [33]. However, the pooled analysis suggested no effectiveness of MWM in knee osteoarthritis in relation to knee flexion [33]. Such differences could be related to degenerative changes in the articular surfaces in knee osteoarthritis which limits the ability of the Mulligan approach to improve knee mobility. Moreover, the heterogeneity of subchondral bone and inflammatory phenotypes in knee osteoarthritis is a major research challenge, where more precise population is required for research purposes considering the phenotypes [59]. The articular resurfacing of the degenerative changes in TKA could explain the significant impact of MWM in improving knee flexion in the current study.

There are various strengths in the current study. The randomization of the current trial successfully generated homogenous groups. The current study has used the International Classification of Functioning, Health and Disability to assess the effectiveness of the intervention, following the WHO recommendation, which could be considered a strength; pain and ROM reflected the impairment level, TUG and 15 m walk tests reflected the activity level, and WOMAC reflected the participation level. The sample size was calculated for the primary outcome measure to ensure sufficient power to detect change in knee flexion, however, it seems that the study was not powered for the secondary outcome measures. A larger sample size study is needed to confirm the observations from the secondary outcome measures. Participants in the current study were women and the findings could not be generalized to men. Moreover, the prevalence of knee OA is higher in women compared to men [69]. Loss of follow up should be also considered a limitation of the current study which has exceeded the expected attrition rate. Future studies should consider larger attrition rate and target larger sample size. ITT analysis was used to maintain the benefit of randomization and reflect real world applicability of the intervention. This was decided to avoid bias from selective dropout. High attrition rate was mitigated with implementing imputation to strengthen the robustness of the ITT analysis. Per protocol comparison was not performed due to the concern of bias introduced by post randomization drop out. However, the descriptive statistics for per protocol are presented in Table 2. MWM could be considered a successful approach to enhance the outcome of post-surgery rehabilitation and could be introduced at the acute stage post TKA. Future research should consider using a larger sample size to explore the impact of MWM on activity and participation in the short and long-term, and should include men and consider the significant advancements in surgical approaches such as robot-assisted TKA [71]. Moreover, the impact of MWM could be studied in other joints including total shoulder, total elbow, and total ankle arthroplasties to optimize the outcome of post-surgery rehabilitation.

In conclusion, the findings of the current trial strongly support the addition of MWM into the post-rehabilitation program for TKA in women to maximize knee ROM following an MWM algorithm. The findings of the current trial support the addition of MWM into the post-rehabilitation program for TKA in women to maximize knee ROM and can be introduced at the acute stage post TKA.

Appendix

Authors-use N/A if an item is not applicable for the intervention being described. **Reviewers – use '?' if information

The TIDieR (Template for Intervention Description and Replication) Checklist*:
Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Mulligan Mobilization with Movement	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Introduction paragraph 3	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Methods: intervention	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Methods: intervention	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Mulligan certified physiotherapists	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Face-to-face	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Physical therapy department at central orthopaedic hospital	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Started at week three post op-TKA, twice/ Table for three weeks (Table 4)	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	The required articular mobilization (medial or lateral glide, internal or external rotation or combined glide with rotation were personalized according to patients needs using the Mulligan algorithm	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_NA___	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Assessed by the PI by thorough practice before the trial and frequent meetings and direct observations of sessions during the trial	

about the element is not reported/not sufficiently reported.

†If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

*We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

*The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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Authors contributions
N.A study design, writing the protocol, ethical submission, research supervision and coordination, fund application, statistical analysis and writing the manuscript and approving the final version of the manuscript. S.A data collection and approving the final version of the manuscript. M.A Intervention application and approving the final version of the manuscript. R.B Intervention application and approving the final version of the manuscript. F.F data collection and approving the final version of the manuscript. S.P Study design, research consultant, statistical analysis and reviewing the manuscript and approving the final version of the manuscript.

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Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was approved by the Kuwait Ministry of Health Research Committee (ref:767/2018). Written informed consent was obtained from participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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