CHAPTER 7

DISCUSSION

The key finding of the study is that the validated structured rehabilitation program for TKR was found to be effective in improving primary outcomes and it is safe to implement in patients undergoing primary TKR. The results of the present study confirm the effectiveness of structured rehabilitation program in promoting enhanced quality of life and functional outcome at short term follow up for KDJD.

The strength of the present study was noted to be its large sample size almost distributed in three zones of south India and one zone from north India and the protocol was specifically designed to meet the postoperative demands following TKR.

The study participants were distributed across three major zones of south India namely from Tamilnadu, Kerala, Andra Pradesh and one zone from north India (West Bengal). The percentages of distribution were as follows: Tamilnadu (72%), Andra Pradesh (16%), Kerala (6%), and West Bengal (6%).
The high incidence of Osteoarthritis in Asian population particularly in female population are attributed to the anatomy of knee joint and excessive loading characteristics of joint in functional activities. Asians usually do high flexion activities as like squatting, kneeling and cross leg sitting and also possess high coronal alignment (varus-looking) in knee joint.

In specific to Indian population there is always a need for higher knee flexion ranges to meet the cultural needs of cross leg sitting and squatting. Moreover, the high patient satisfaction index after replacement surgery in Indian population is expected to achieve better knee flexion mobility to perform functional activities. Hence the surgical approach, prosthetic mechanics and structured rehabilitation protocol are specifically designed to meet the cultural needs of Indian population.

Basically TKR procedure involves a biomechanical correction on the mechanical alignment of the joint. Proper alignment of knee joint is the most influencing factor in determining the long term outcomes following TKR. There exists a strong association between greater quadriceps angle (Q angle) with changes in tibiofemoral alignment. The present study was evident in exhibiting greater Q angle in preoperative phase in both groups predicting the presence of
deformity/ altered tibiofemoral alignment. Moreover postoperatively, there is a significant reduction in angle which signifies deformity correction in both groups serving the purpose of the surgical procedure. The present study was first of its kind in reporting the clinical significance of quadriceps angle in TKR population. Hence the realigned joint requires a specific rehabilitation to meet the demands.

The randomized controlled trial has attempted in all possible ways to increase participant’s adherence, the need for intent to treat analysis was not felt essential as the study has fulfilled the required sample size and the dropout rate was within the prescribed limit. Periodic reminders by telephone were given to prevent missing follow up assessment. Despite attempts to improve adherence, around 18 participants data were missed at 3 months follow up. Even though the study was able to meet the required sample size of 200, remaining missed data of 18 samples were used to analyze the impact of missing data on conclusions.

Following intent to treat analysis, there was not much difference in mean values of primary outcomes in both groups. Hence the study results discussed below are purely based on the estimated sample size of TKR population (n=201).
Moreover the final analysis was restricted to the participants, who fulfilled the inclusion criteria, randomly allotted for interventions and followed up as per the allotment. The adherence and compliance of participants were good and no single study participant crossed over groups, the participants were termed as per protocol population and analysis of the population was termed as per protocol analysis.

### 7.1 The Structured TKR Rehabilitation Protocol in Indian population

The procedure of validation got initiated with a 32 item protocol for face and content validity. Moreover the process of validation was done on a stepwise and stage wise manner with experts reaching consensus on all three stages. The face validity report from four experts revealed that the sequence of program was more appropriate with required contents but doubted the role of CPM and emphasized to monitor the adverse effects of early balance training.

The report on phase I/inpatient phase required a thorough supervision of Physiotherapist with maximal agreement on the content of exercises and strong emphasis for conducting early balance training within parallel bars. Phase II was reported to be partially inpatient and partially home based with supervision of
trained physiotherapist. Moreover the report strongly recommended on reporting incidents on the adverse events of balance training and closed chain activities. The panel of experts agreed and identified Phase III to be a continuum of phase II with exercise progression requiring minimal supervision. After final validation, the structured protocol underwent a pilot study with 10 samples and based on the results, structured rehabilitation program for primary TKR for osteoarthritis was implemented.

The validators agreed for incorporating early balance training and closed chain activities in TKR rehabilitation which facilitated symmetrical weight bearing, erect stance with minimal support and early independent walking. The early return of independent walking facilitated for measuring six minute walk test at approximately 2 weeks for the experimental group. Most participants in control group used assistive device (walker, tripod) to accomplish 6MWT and was observed during initial postoperative assessment.

The individual items of content validation index (I-CVI) guided the researcher to a greater extent which resulted in revision and substitution of items leading to a 26 item final protocol. The I-CVI of muscle activation program (except VMO
activation), strengthening program, basic balance training and functional training scored 100% for its relevance and feasibility of performance. These components were considered as the crucial steps for an early recovery in TKR population.

The other crucial component of the protocol was the mobility training comprising soft tissue flexibility and joint mobility. The joint mobility program has been addressed from initial postoperative days till follow up period. Continuous passive motion was considered to be an early intervention following TKR, despite various controversies of its use, experts agreed the relevance of using CPM but not the feasibility of performance in acute postoperative care.

Hence, the use of CPM is left out to be optional for clinical practice and this finding is in accordance to a present evidence (Nikolaou et al. 2014) stating that there are no high quality studies in CPM and its use need to be reconsidered. Thus the use of CPM in structured rehabilitation program was not considered, so the initial flexion mobility training was designed to be performed in supine lying, side lying, high sitting and later prone lying.
The training was further progressed in functional positions, closed chain activities and use of stationary bicycle was advocated. Incorporating early functional training as like forward step up, lateral step up, mini squat, VMO training in standing, wall slides and functional balance training have had positive impact on joint flexion mobility. The protocol was designed to meet the demands of achieving optimal knee flexion mobility for functional activities.

The staging of balance training was yet again the most significant step in structured rehabilitation program. Presently there is a lack in literature for specific balance training methods in TKR population, the protocol was proposed to comprise forward and diagonal reaches in standing, use of vision in training, use of stable surface, foam pad surface and unstable surface training. Finally functional activities of obstacle walking, figure of 8 walk, tandem walking and shuttle walking was proposed to meet the balance requirements in functional tasks were considered.

The contents of structured rehabilitation program were supported by Pozzi et al. (2013) in a systematic review of controlled trials recommending strengthening; intense functional exercise and balance training to be optimally included in
outpatient Physiotherapy protocol. Moreover Pozzi’s recommendation on application of FIT principles (dosage, frequency and duration) and criteria for progression of exercises was thoroughly implemented in the present study.

The validated protocol was applicable from initial postoperative days and lasted till 12 weeks with greater application of therapeutics within initial four weeks following replacement surgery. The present literature also states that early starting of rehabilitation program (within first postoperative month) was one among the factors for successful outcome in TKR (Bade et al. 2011).

A similar RCT under process titled targeted rehabilitation to improve outcome (TRIO) after TKR (Simpson et al. 2014) was proposed based on the evidences of functional rehabilitation comprising range of motions, strengthening, proprioception and balance. Thus the contents of structured protocol were in accordance to the recent evidences and practice.

The protocol’s effectiveness was measured through outcomes at every stage in alignment with the goals of intervention. The outcomes used can be classified as
early measures (pain severity, joint mobility), intermediate measures (muscle strength, functional performance test), functional outcome measures (KOOS) and overall quality of life (SF-36). A longitudinal analysis of outcomes by Mizner et al. (2011) reported outcomes to be performance based rather just being patient report measures in other words, use of self reported measures alone being dictated by pain should not be considered.

In a systematic review (Pozzi et al. 2013); the most recommended outcome measure is the Quadriceps muscle strength as it is highly related to functional performance and to protocols addressing muscle impairments. One among the major concern for patients and surgeons is to achieve optimal range of motion (ROM) outcome in specific to knee flexion (Bade et al. 2010). Dobson et al. 2013 in Osteoarthritis Research Society International strongly recommends the use of 6MWT for studies related to osteoarthritis and TKR.

The World Health Organization’s (WHO) International classification of Functioning, Disability and Health (ICF) has framed to evaluate functions in three domains namely body functions and structures, activity limitations and participation restrictions. The measurement of pain severity, joint mobility and
muscle strength signifies body functions, measurement of 6MWT encompass the activity limitation and use of SF-36 and KOOS scale measures the participation restrictions in TKR participants.

7.2 Effectiveness of Structured Rehabilitation Program on the QOL in TKR

The findings of the present study prove that the 12 week structured rehabilitation program for TKR in Indian population has produced significant improvements in quality of life at three months than the standard care. The greater mean differences from baseline values were observed in physical functioning (25 points) and role physical (26.26 points) domains.

In the experimental group, the mean scores of general health and bodily pain reached to a maximum of 88 points. The domains of role emotional and mental health showed 19 points in mean difference from its baseline values in the experimental group. The above mentioned observations were in accordance to a very recent study by Huber et al. (2015) depicting maximal changes in physical functioning (29.0), role physical (31.2) and bodily pain (27.9) at 3 months postoperatively.
The Minimal Clinical Difference (MCD) observed in SF36 domains is 10 points (Escobar et al. 2007) and all domains reached the proposed MCD values in the experimental group. In the control group, the domains of physical functioning, bodily pain and general health attained the proposed MCD score at 3 months but none of the mental domains reached it. Most studies using SF36 have analyzed scores at 6 months with MCD scores, whereas in the present study the obtained improvement was observed at 3 months.

In the present study’s results, the mental domains also showed to improve greater than 10 points in the experimental group (Escobar et al. 2007). Based on study results by Escober, he further proposed MCD of 3-11 points in mental domains and 11-16 points in physical domains at 6 months following TKR. Further in the present study, the physical and mental domains were above the proposed MCD points citing greater QOL improvements in the experimental group.

The present study results goes in accordance to a study by Peterson et al. (2010) stating PCS and MCS were found to improve at 3 months following a progressive strengthening protocol. Moreover, PCS (52.71) was noted to be far ahead from the other study results and MCS (56.76) nearly matches the other study findings.
The percentage of change from baseline to 3 months in experimental group was 31% for PCS and 28% for MCS and overall MCS far bettered PCS. This finding is in accordance to a study by Peterson et al. (2010) at three intervals reveals MCS bettered PCS but percentage of change from baseline to 3 months was 51% for PCS and 13% for MCS. The percentage of change at 3 months in mental summary scores in TKR Indian population was well ahead than the other study findings.

The multidisciplinary rehabilitation program for 10 days by Kaupila et al. (2011) reported that HRQOL did not improve more than the conventional care but clinical improvements of > 20 points was noted in three physical domains of physical functioning, role physical and bodily pain.

In the present study, the weakest baseline scores were noted in physical functioning and role physical domain which exhibited improvements with maximal mean differences at three months. Similar to previous study findings (Ethgen et al., 2014), the physical domain scales of RP and PF gained better improvements when compared with its baseline scores. This also goes in accordance to a statement by Fortin et al. (1999) that low level preoperative functions will improve greater after
TKR. It was observed that lowest baseline scores of certain QOL domains showed maximal improvements at 3 months.

The structured rehabilitation program has exhibited greater improvements in pain and improved functions (KOOS subscales and other secondary outcomes) predicting an improvement in QOL (Robson et al. 2014; Andy Judge et al. 2012). It is more significant to note that physical functions are the major factor in contributing to patient’s satisfaction index in TKR and in turn mental health too has its impact on TKR outcomes (Qi et al. 2016).

It is observed from the present study that there exists an inverse relationship between age and PCS scores, with increasing in age there is a decline in PCS scores at all points of measurement. The maximum PCS score of 55.32 was observed in the experimental group with age ranging 45-49 and proving that younger individuals gets the maximum benefit from rehabilitation (Ethgen et al. 2004).
Males exhibited maximum PCS scores and females scored better in MCS at all points of measurement and the finding was in agreement with Kaupilla et al. (2010). A report on a recent analysis of international TKR patient’s states preoperative mental health scores was a predictor of physical functions postoperatively (Escobar et al. 2007). Those who had lower mental summary scores before surgery were less likely to improve physically and many studies have reported that women had less recovery in physical functions than men.

The gender differences in PCS scores (males scored better than females) in the present study attributes to the above said finding that baseline MCS scores was found to be better in males than females.

The decline in PCS scores with increase in BMI ranges was yet another observation of the present study. This observation is consistent with a research reporting that higher BMI is associated with physical functions among TKR individuals as reported by Mizner et al. (2005). Despite participants in overweight and obese category, the rehabilitation program had a positive impact on Physical summary scores at 3 months.
Overall the postoperative BMI (control=29.58±6.71, experimental=27.69±5.26) measured at 3 months showed not much of difference from its baseline measurements. The mean PCS scores of overweight and obese categories showed similar improvements as with the normal and underweight categories at 3 months. This finding clearly highlights the significant change of cumulative quality of life scores evenly in all BMI categories which is attributed to the impact of the structured rehabilitation program.

The factors noted to influence the scores of health related QOL are age, gender, BMI and baseline scores of MCS. It is observed from the present study that females showed less mean PCS scores than their male counterparts at all intervals (Papakostidou et al. 2012). With the advancing age, it was observed that there was a decline in PCS and MCS scores reducing the opportunity to reach adequate QOL scores (Kauppila et al. 2011).

The impact of BMI on baseline scores of PCS was more evident in obese than overweight category. It was in congruent to the previous finding that obesity has a negative influence on the initial assessment and at follow up and predicted poorer QOL scores (Nunez et al. 2009).
Overall all domains improved significantly at three months when compared with its baseline scores (Huber et al. 2015). Baseline MCS scores of less than 42 indicated depressive disorders (Ware et al. 1994) and predicted poor outcomes postoperatively with a specificity of 81% and sensitivity of 74%. The baseline scores of MCS in both groups were noted above 42, predicting better quality of life at follow up.

The possible cited reasons for enhanced quality of life is achieved through effective implementation of supervised structured rehabilitation program, all participants were monitored and motivated all throughout the program. The early return of functional activity, ambulation and reaching the community at the earliest boosted the mental morale of individuals in the experimental group. Thus the structured rehabilitation program has profound effects on quality of life in Indian population at three months.

### 7.3 Effects of Structured Rehabilitation Program on the functional Outcome in TKR

The validated structured program has shown significant improvements in four subscales of KOOS. The maximal mean scores were observed in KOOS-symptoms
and ADL, which signifies that symptom reduction, is required for recovery of ADL following TKR.

A very recent study by Abdulemir et al. (2016) revealed improvement in all subscales of KOOS at 3 months with greater improvement noted in KOOS-pain and ADL subscales. Moreover in the present study, the mean scores of pain, ADL and Symptoms were ranging between 68 and 70 points at 3 months (Minns Lowe et al. 2012).

KOOS₄ is a method of summing all subscale scores except sports and recreation, as the subscale has a lesser role in TKR population. The KOOS₄ in the control group averaged to 46.24 points and 67.40 in the experimental group and a similar observation was observed in a very recent study by Soren et al. (2015). The study reported KOOS₄ showed greater improvements (67-69 points) at three months than the non-surgical management.

The subscale exhibiting maximal mean difference with 37.54 points (122% improvement) was KOOS-ADL subscale spearheading a study by Peterson et al.
2010 reported 42\% improvement at 3 months and 51\% improvement at 1 year of follow up.

As the KOOS scoring being an ordinal data, subscale scores are analyzed for its inter-quartile range. The shift of KOOS scores from lower quartile to upper quartile range signifies clinical improvement. In the present study the KOOS-pain subscale was analyzed based on its baseline score quartiles (< 28, 29-36, 37-50, >51) and KOOS-ADL was based on (< 32, 33-39, 40-49, >50) as proposed by Nilsdotter et al. (2009).

The baseline scores of KOOS-pain and ADL were in lower quartiles in both groups and only experimental group reached > 51 at POST-1 and at three months. Moreover the present study findings of all subscales except quality of life reaching the upper quartile (75) was also noted in a 5 year prospective study (Nilsdotter et al. 2009) at 6 and 12 months.

The MCID in specific to TKR population has not been established; however it is suggested by the primary author of KOOS to be 8-10 points. The smallest
detectable change for clinical improvement in subscales of pain and ADL is 10 points (Roos, et al. 2003).

Applying it to the present study, the subscales of KOOS showed better outcome at 3 months with difference of 30 points in the experimental group. The present study also highlights the clinical improvement in functions after TKR was evident with postoperative KOOS scores in the experimental group.

A very few study findings have reported positive outcomes in functional outcomes with a huge effect size in mean KOOS scores were noted consistently on all subscales from three months to 12 months (Collins et al; 2015 and Huber et al; 2015). One of them being the neuromuscular training in TKR by Huber et al; which identified significant differences in KOOS-ADL, pain and QOL subscales at 3 months. But the present study has found a clear positive outcome, the reason that it has additionally employed self management strategies of patient education and thus incorporating functional rehabilitation has paved for early functional recovery in TKR population.
7.4 Effectiveness of Structured Rehabilitation Program on Pain Severity in TKR

The study includes pain severity measurement in three possible ways namely NPRS, KOOS-pain and QOL domains. The surgical incision/dissection and intra-operative procedures were the cited reasons for postoperative pain. As the reason being multidimensional, pain has been treated through medical management in inpatient rehabilitation. The protocol advocates the use of cold packs as and when required for exercise induced pain.

The study reported significant decrease in pain intensity between groups at discharge (2 weeks) and at 3 months (12 weeks) in the experimental group. The within group analysis reveals that the reduction in pain severity was observed at all three intervals in the experimental group only.

The MCID was reported to be 2 points (Farrar et al. 2001) in NPRS and a difference of 3.51 points was noted to exhibit clinically important differences. Moreover Harmer et al. (2009) revealed the difference of pain intensity to be 3.2 points at 26 weeks and 0.4 -0.5 points at 12 weeks.
In the present study the results of the experimental group reported a mean difference of 3.51 points in pain intensity at 12 weeks as reported by Piqueras et al. (2013) with a mean difference of (-2.30) from its baseline values, highlighting the benefits of therapeutic exercise on pain reduction.

The overall success of structured rehabilitation program attributes to the 88% of reduction in pain severity (0.46±0.70) being observed in the experimental group at 3 months spearheading a study finding by Fung et al. (2002) reporting 32.5% reduction of pain severity using NPRS as a measure.

The role of therapeutic exercise on pain control is a phenomenon called as Exercise Induced Hypoalgesia (EIH) which is found to reduce pain and increase pain threshold after exercise (Koltyn, et al. 2014). The therapeutic exercise induces serum endocannabinoids and involvement of non opioid mechanism for reduction of pain intensity. The central opioid system was being activated by the increase discharges from the mechano-sensitive afferent nerve fibers from skeletal muscle following rhythmic muscle contractions in exercises. Moreover it is believed that therapeutic exercise has shown to increase blood beta-endorphin concentrations.
The hypoalgesic effects were reported in aerobic form/endurance mode and in resistance/strength type of training. The structured rehabilitation program comprising all forms of training with defined parameters (frequency, intensity, duration) was found to achieve desired effects of hypoalgesia.

7.5 Effects of Structured Rehabilitation Program on the Knee Joint Mobility in TKR

The process of knee replacement surgery includes deformity correction, release of tightened structures, removal of capsule-ligamentous structures, balancing of soft tissues and prosthetic implantation of femoral end and tibia tray. All participants were operated with either of the two surgical approaches using posterior stabilized prosthesis without resurfacing of patella. The kinematics of replaced joint was the key factor deciding the flexion mobility of the replaced knee joint.

The structured program was found to improve knee flexion mobility of 101 degrees and nearing zero degree of extension mobility at three months following TKR. In both groups, reduction of knee mobility was observed at discharge (2 weeks) as being an acute postoperative phase.
In the present study, the mean flexion range at 3 months was 100.98 degrees which was also reported by Kramer et al. (2003) and Chaudhary et al. (2008) with mean flexion range of 100 degrees. Evgeniadis et al. (2008) concluded postoperative physiotherapy has a greater impact on knee flexion ROM but no study group averaged greater than 100 degrees of knee flexion after 14 weeks.

A study by Rajan et al. (2004) analyzing the effects of outpatient physiotherapy following TKR reported 95 degrees of knee flexion at 3 months. It is also postulated from a meta-analysis that knee flexion mobility will increase particularly after 6 to 12 months and limited number of studies measured the mobility outcome (Neil Artz et al. 2015). The functional range /maximal range of knee flexion achieved in replaced knee joint were 110 degrees as proposed by Michael Bade et al. (2010).

The structured protocol was designed to meet the social and cultural demands of Indian population, thus the experimental group was able to accomplish 92% of the prescribed knee flexion mobility. The mean extension range (extensor lag) was analyzed based on the individual’s ability to extend knee joint completely to zero degree without lag in Quadriceps muscle. The mean extension range of 0.28° at
three months in the experimental group was remarkable as it reached near normal ranges. The significant improvement in extensor lag (knee extension range) favoring intervention was studied by Codine, et al. (2004).

Moreover studies analyzing knee extension ranges are very scarce; a study by Levine et al. (2013) has reported that following neuromuscular electrical stimulation (NMES) to Quadriceps muscle exhibited 2.58 degrees of knee extension at six months.

A study by Peterson et al. (2010) on progressive strengthening interventions reported knee extension range of 1.8 degrees in exercise group and 2 degree in NMES group at three months. On comparing the various studies Mizner et al. (2 degree), Kumar et al. (3 degree), Chaudhary et al. (4 degree), the structured rehabilitation program effects on knee extension mobility was remarkable at 3 months.

Comparing the previous study results, the present study has achieved near normal ranges of knee extension. Moreover on a review from 2011 to 2015 (data
collection period), no study participants reported mobility deficits or stiff knee at later duration requiring manipulation under anesthesia.

The Centers for Disease Control and Prevention have enlisted normative ROM with age classifications. When comparing the present study results with age matched healthy individuals age ranging from 44-69, Knee extension mobility were within the prescribed range of 0.5 degree for males and 1.2 degree for females. The achieved knee flexion range was 76% of its age matched individuals from age ranging from 44 to 69 (Soucie, et al. 2010).

The Satisfactory knee flexion mobility achieved will favor to accomplish various activities of daily living as like gait (67 degree) required for swing phase, climbing up stairs(83 degree),climbing down(90 degree) and getting up from seated position (93 degree) as proposed by Farahini et al. in 2012.

The minimal detectable change (MDC) in knee joint mobility following TKR was reported by Paul Stratford et al. 2010. A change of 6.3 degrees or more in knee extension (present study finding-5.96 degrees) and a change of 9.6 degree in knee
flexion (present study finding-9.13 degrees) was observed. This finding almost matches the proposed MDC values signifying the clinical progress in knee mobility over time.

Thus mobility component of structured rehabilitation program was able to produce reasonable clinical differences in knee mobility in TKR population. Moreover this information will assist physiotherapists as a point of reference for patient’s progress and for employing appropriate treatment strategies as and when required.

7.6 Effects of Structured Rehabilitation Program on the Knee Muscle Strength in TKR

Following replacement surgery, the major challenge in rehabilitating TKR is the optimal knee flexion mobility, good dynamic quadriceps control and maintaining Hamstring-Quadriceps ratio. The isometric strength of quadriceps was considered to be the strongest predictor in outcomes following TKR.
Despite its key importance, the role of antagonist (isometric strength of hamstrings) in providing joint stability is often neglected. A systematic review (Catherine, et al. 2007) commented that none of the studies have directly measured muscle strength and very less number of trials has studied isometric method of strength testing in TKR. Moreover the muscle dysfunctional state and recovery pattern is varied in TKR population.

Of these two musculature following TKR procedure, Hamstring musculature showed more dysfunctional state in acute postoperative period but early recovery (118% improvement) in quadriceps muscle performance was faster than hamstrings at later postoperative phase (Silva, et.al. 2003).

The methodology in measuring quadriceps muscle strength at 60-70 degrees was adopted by Silva et al. (2003), the study reported that postoperative muscle strength of Quadriceps was 93 N (equivalent to 9.4 Kg) and Hamstring strength was 45.9N (equivalent to 4.68 kg). This finding matches with the present study results reporting Quadriceps muscle strength of 9.04 kg and Hamstrings strength of 5.40 kg in the experimental group.
The effects of tele-rehabilitation (Piquerus et al. 2013) has brought out clinical differences in TKR individuals with a mean increase of 3 kg in Quadriceps strength and the present study reports with a difference of 4.91 kg from its baseline measurements. A study by Lorentzen et al. (1999) has reported decreased isometric muscle strength at three months following TKR. A very similar study by Jenifer et al. (2010) has analyzed isometric strength of Quadriceps (10.64 kg) and Hamstrings (5.81 kg) at three months. These findings more or less match the present study results of isometric Hamstrings muscle strength.

The Hamstring Quadriceps ratio (H: Q) is a measure of importance in muscle function assessment. The ratio is considered to measure knee muscle balance and it is linked to reduce stresses on joint. The mismatch in the ratio is anticipated in preoperative stage and at early postoperative phase. The HQ ratio is found to increase with less Quadriceps strength in TKR population. In the present study, the HQ ratio of 0.77 and 0.72 for the control and the experimental groups respectively was observed at baseline.

At 3 months the observed ratio was 0.59 for the experimental group, signifying improved quadriceps muscle strength and muscle balance but the ratio remained
the same in the control group. The recommended ratio of 0.60 was considered normal if tested isometrically with knee in 65 degree flexion (Nosse et al. 1982). The return of normal ratio in the experimental group clearly highlights the balancing of knee musculature which got regained at 3 months following TKR.

7.7 Effects of Structured Rehabilitation Program on the 6MWT in TKR

The most commonly used test to assess the functional recovery following TKR is the six minute walk test. Participants in structured rehabilitation program walked significantly longer distances in six minutes than did the subjects in control group at POST1 and POST2.

The present study 6MWD (386.85m) exhibited greater significant improvements between groups at 3 months. Mean differences of 230.76 meters of distance was noted in the experimental group and 32.06 meters in the control group from its baseline values. However Harmer et al. (2009) reported mean difference of 218m in six minute walk distance at 26 weeks following TKR. Extensive review shows that various studies have reported similar performance in 6MWT, Kramer et al.
(2003) - 320m, Moffet et al. (2004)- 380m on functional rehabilitation and Harmer et al., (2009)- 375 m on land based rehabilitation at 3 months.

The percentage of improvement was 148 % from its baseline scores in distance walked in six minutes attributes to the effects of functional training and balance training program. Based on reviews, a study by Peterson et al. (2010) on progressive strengthening program exhibited 535m at 3 months (33% of change) and 38% of change at one year from its baseline values. Hence the structured rehabilitation program has shown profound effects on the functional improvements.

The minimal clinical difference (MCD) value for 6MWT was reported as 61.34m by Deborah et al. (2005). Hence it was observed that the walking distance in six minutes was far ahead the proposed MCD value in the experimental group. The reliability of 6MWT after TKR analyzed by Thomas et al. (2012), states that 6MWT is the mandatory functional testing to be monitored till four months following TKR. The real clinical change in 6MWD in a group of patients is above 25.5m and for an individual it is 36.1m. Hence it is noted that there is a clinical
change noted in the control group and an excellent change in the experimental
group at three months.

The 6MWD in age matched healthy individuals for males is 523.36±88.73 and
470.61±71.4 in females in Indian population was reported by Ramanathan et al.
(2014). On comparing with age matched healthy counterparts, the experimental
group were able to fulfill 76% (mean distance= 399.96 meters) in males and 80 %
(mean distance= 378.60 meters) of performance in females.

Comparing the baseline values, there is no improvement in 6MWD at initial
assessment (2 weeks) but the walking distance has doubled after three months, a
similar finding by Bade et al. (2010) states that all functional measure activities
declines at one month and recovery of 6MWD to its preoperative levels takes over
by three months.

Thus the magnitude of structured rehabilitation program effect on the six minute
walk distance was excellent in terms of gained walking distance.
7.8 Comparative analysis of primary outcomes and quality of life between Medial Parapatellar and Midvastus approaches

The basic comparison between the two surgical approaches was analyzed with the early return of active Straight Leg Raise (SLR) test and the varied primary outcomes. The midvastus group showed early return of active SLR on the 6th postoperative day and the primary outcomes exhibited better improvements in midvastus approach than medial parapatellar approach (Michael et al. 2009).

The surgical reason cited for an early return of SLR is due to few lateral retinacular releases involved in midvastus approach (Aslam et al. 2017). This finding is in accordance with a study by Holger et al. (2005) and Shukla et al. (2016) stating that midvastus is advantageous over the standard procedure in early postoperative period. The key finding of significant improvements in isometric Quadriceps muscle strength at POST 1 and at three months further substantiates that midvastus is a muscle sparing approach in TKR procedure.

In present study, the maximum number of participants underwent medial parapatellar approach (79%) in the control and 60% in the experimental group. The mean extension range (degree of extensor lag) and the physical summary scores
(PCS) returned earliest in midvastus group than parapatellar approach in Indian population (Aslam et al. 2017).

The significant differences of extension mobility (return of extensor lag) and improved isometric Quadriceps muscle strength at two points of measurement were the strong predictors of 6MWD in midvastus group with a mean difference of 57.38m in 3 months. Thus the most popular midvastus approach was superior to the standard parapatellar approach in terms of Physical summary scores and primary joint specific outcomes.

7.9 Relationship between primary outcomes

The primary focus of a RCT is to compare the outcomes between treatment arms, but the present study has initiated to analyze the relationship between outcomes and very few RCT’s (< 1%) has reported about relation between outcomes. Moreover the present study has used multiple outcomes, which can depict the relationship (correlation, association) between outcomes.
The present study highlights the strong relationship between the isometric strength of Quadriceps and 6MWT. Studies by Yuri yoshida et al. (2008) and Mizner et al. (2005) have also reported significant association between them. Moreover the moderate positive association of knee flexion maximal peak torque force and a moderate positive relation of knee extensor strength with 6MWT were reported in a very recent study by Loannis et al. (2016).

These findings further advocate the need for knee flexors training as a component of structured rehabilitation program. The association between BMI and postoperative knee flexion mobility was also reported by Shoji, et al. (1990).

The relationship between the eight domains of SF-36 along with the summary scores (PCS and MCS) and 6MWT revealed a strong positive correlation between PCS and 6MWT. The physical summary scores has positive relationship with a physical performance measure of six minute walk distance in TKR population and this specific relationship was also reported in patients with pulmonary arterial dysfunction. Therefore PCS appears to have strong relationship with 6MWT and clinical usefulness in Indian population.
There exists an inverse association between BMI and knee flexion mobility. The association between BMI and knee flexion mobility is attributed to the fact that obesity is an important factor that increase the risk of mobility limitations (Lamb, et.al. 2000).

The relationship between knee extension mobility and quadriceps angle was more evident biomechanically. The method involved in measuring the action line of Quadriceps muscle requires zero degrees of knee extension either in standing or in supine lying. Hence an attitude of knee extension is basically required for measuring Q angle.

Thus the analyses of relationship between various sets of variables provide unique information which is most responsive to change and the results can be generalized to TKR individuals in specific to Indian population. However certain relationships between variables are established in various ethnic groups, the present study findings highlights the association between primary outcomes in specific to Indian population.
7.10 Interaction of primary outcomes of knee joint mobility, isometric muscle strength on the functional outcome of 6MWT.

The use of regression models in randomized controlled trial is to test for cause-effect relationship from the data collected in trial. Multiple regression model was used to reduce the complexity of relationships between variables. The regression analysis revealed few variables as like isometric extensor muscle strength (p<.000) and knee flexion range (p<.004) at 3 months to be the strong predictors of 6MWT.

The strongest predictor was the isometric strength of Quadriceps (B-23.83) as reported by Stephanie et al. (2009) and predicted a model establishing quadriceps strength, KOOS-pain score, knee extension ROM and knee flexion range for 6MWT at 12 months. Moreover the model shows 37 % variability in six minute walk performance at one year but the present study has showed 75% variability.

Commonly a predictor model for 6MWT in TKR is derived after six months or after a year but present study was able to propose a model for analyzing the effects at three months.
7.11 Interaction of preoperative variables and other confounding variables (age, gender, BMI) on the quality of life domains and interaction of QOL variables in predicting outcomes of six minute walk test

The backward regression model predicted age; preoperative scores of KOOS-symptoms subscale and isometric quadriceps muscle strength were the strong predictors of role physical in TKR at 3 months. This finding was reported by Escobar et al. (2007) and Yo Ko et al. (2011) that baseline/preoperative scores were the strongest predictors and determinants of SF-36 domains at 6 months.

The baseline scores of knee flexion mobility, symptoms scores of KOOS, Quadriceps muscle strength and age have influenced the QOL domains. The baseline scores of knee flexion ROM and Quadriceps muscle strength were considered to be the significant predictors of better functional ability in TKR (Lingard et al. 2004 and Mizner et al. 2005).

It is evident that symptoms subscale of KOOS was proved to predict two models of quality of life domain as because of maximal improvement in scores being reported between groups.
The highest baseline score was noted in mental health and general health and these domains were found to represent higher scores at three months. It is a general opinion that baseline mental health has influenced the individuals without depressive symptoms and dissatisfaction for enhanced mental health (Escobar et al. 2007; Lingard et al. 2004). Thus the baseline scores of mental health domain is considered to be the strongest predictor for the overall QOL at three months following TKR.

In most literature, advancing age is considered as barrier of HRQOL improvements. The present study indicates age is not a barrier (Escober et al. 2007) but it is found to be a predictor of role physical and social functioning domains at three months. The interaction of quality of life domains on the 6MWT at three months revealed significant influence in physical, general and a mental domains with a variability of 62%. Therefore it is clear and evident that to accomplish a functional activity measure, physical functions and mental functions along with general health of an individual is required.

The salient findings of this randomized controlled trial have key potential information for primary total knee replacement in specific to Indian population.
The salient findings include regaining normal HQ ratio, achieving 92% of prescribed functional knee flexion mobility, near normal knee extension mobility, efficient 6MWD with enhanced joint functions and quality of life. The faster locomotor recovery with the capability to perform ADL with ease and an enhanced physical and mental makeover contributed a more active lifestyle within 3 months following TKR. The active lifestyle could have been the determining factor in avoiding immobility and thereby preventing health related complications. Moreover, the above said findings facilitated early return to work at 1.5 months in the experimental group.

The higher scores of PCS and physical related domains of the SF-36 at three months after structured rehabilitation program also supports the positive impact of the intervention. This study has analyzed the relationship between primary outcomes and further facilitated in establishing these findings in Indian population. The predictor formula for 6MWT can be applicable in clinical setups in predicting the 6MWD at three months in TKR. Moreover the clinical parameters and preoperative factors influencing 6MWT and QOL are evident and applicable to Indian population. Thus the present study findings will provide an evidence base for reasoning and will help in the development of clinical practice guidelines in TKR rehabilitation.
7.12 Strength of the study:

To the best of my knowledge, this is one of largest randomized controlled trial in TKR rehabilitation conducted in India using multiple outcome measures as per the International Classification of Functions. Apart from the key findings, the study was able to predict relationship and interaction between variables in broader perspectives as applicable for Indian population. The derived predictor formula for measuring six minute walk distance can be applicable in all clinical setups practicing TKR rehabilitation as the predictors can be easily measured and it is cost effective.

7.13 Clinical implications

The results of the study revealed that structured exercise program has shown good improvements in outcomes at 3 months follow up. The validated protocol is a staged, safe tool which can be implemented in acute TKR rehabilitation. Incorporating early balance training was first of its kind proving early return of independent ambulation and faster recovery boosted the mental health amongst individuals. The dynamic control of quadriceps through staged training of quadriceps and functional training through closed chain activities resulted in improved functional performances.
Overall the structured program showed good improvement in functional outcomes and improved quality of life in TKR. The midvastus approach bettered in primary outcomes than the medial parapatellar approach further proving it to be a muscle sparing approach. The correlation analysis was useful in finding relationships between knee musculature strength and walking distance and further substantiating it for Indian population. The relationship between numerical and categorical variables was also useful in establishing its relationship in TKR in specific to Indian population. The regression analysis was useful to predict outcomes, especially the prediction formula of 6MWT at 3 months which can be utilized in clinical setup.

7.14 Limitations

Even though the details of co-morbidities were obtained, it was not considered as criteria for exclusion and so there is a possibility that it would have influenced the results. Moreover the influence of co morbidities on the functional outcome and quality of life was not analyzed.
The structured rehabilitation protocol has a component of balance training; outcome to measure in specific to balance skill (single leg stance time) was not implemented. Even though the exercise programs are dosed in structured rehabilitation program and standard care, there were chances of variations in exercise dosage in both groups.

7.15 Future scope:

The predictor model may be evaluated for its applicability and validity in clinical set up. Moreover use of advanced instrumentation (balance stability system) for balance training may be incorporated to the stages of structured rehabilitation protocol. The extensive three staged structured rehabilitation for primary TKR for osteoarthritis can be applicable for future research activities however a brief set of clinical tips from the program are proposed for effective clinical practice.

CLINICAL TIPS FROM STRUCTURED TKR REHABILITATION PROGRAM

- Baseline measurements of pain severity, knee flexion mobility, isometric Quadriceps muscle strength and functional capacity testing is required to predict outcomes.
- Preoperative counseling about postoperative plan of care
- Mobility training of knee joint in various positions of supine lying, side lying, prone lying and high sitting.
- Knee extension stretch and gentle manual overpressure to ensure knee extension.
- Mobility training of hip joint in all planes in standing and strengthening of hip abductors and extensors.
- Vastus medialis activation exercises in supine lying, high sitting and standing.
- Staged training of Quadriceps & hamstrings musculature
- Progressive strengthening program of hip and knee musculature.
- Balance training with stable, foam pad and unstable platforms with appropriate safety measures.
- Balance skill training in functional postures
- Closed kinetic chain exercises
- Functional training as like lateral and forward step up.
- Functional task specific training
- Aerobic training using stationary bicycle

Thus the key important clinical tips of the structured rehabilitation program may be time consuming, progressive and applicable for effective clinical practice.