

## Implementation, preliminary efficacy, and outcomes of TUCK exercise program in individuals with Knee Osteoarthritis: a feasibility pilot study

## Implementação, eficácia preliminar e resultados do programa de exercícios TUCK em indivíduos com osteoartrite de joelho: um estudo piloto de viabilidade

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**ABSTRACT | BACKGROUND:** Core strengthening exercises are recommended for the management of knee osteoarthritis (KOA). However, individualized, self-adjustable exercise programs may maximize benefits, improve adherence, and reduce risk. This pilot trial aimed to assess the feasibility of the TUCK core strengthening exercise programs and its preliminary clinical effectiveness on core strength, functional mobility, gait parameters, pain and function in adults with KOA. **METHODS:** In a preliminary randomized feasibility trial, 60 adults with unilateral or bilateral KOA were recruited from multiple centers and randomized into the TUCK exercise group or a standard physiotherapy group. Both interventions were delivered over 12 weeks, with assessments at baseline, week 6, and week 12. Feasibility was evaluated via recruitment, adherence and retention. Clinical effectiveness was assessed for core strength (ADIM and KLAT), functional mobility (TUG and 4-Meter Walk Test), gait parameters (stride length, double support time), pain (NPRS), and physical function (KOOS-PS). Statistical analysis included paired and independent-t-test for continuous variables, chi-square tests for categorical variables, and effect sizes (Cohen's d). Significance was set at  $P < 0.05$ , with 95% confidence intervals reported for between-group differences. **RESULT:** The TUCK was feasible, with more than 80% participants satisfaction and high adherence. The experimental group showed significant improvements in dynamic core strength (KLAT) compared with control: mean difference = 3.7mmHg, 95% CI [2.5, 5.2],  $P < 0.001$ , Cohen's  $d = 0.74$ . Both groups demonstrated significant within-group improvements in TUG, 4MWT, stride length, NPRS, and KOOS-PS ( $P < 0.05$ ). Between-group differences in functional mobility and gait were generally small to moderate, reflecting baseline variability. **CONCLUSION:** The TUCK exercise program is feasible, safe and demonstrates potential for effectiveness in improving core strength, functional mobility, gait, pain and physical function among adults with KOA. These findings support the rationale for a larger definitive randomized trial.

**KEYWORDS:** Knee Osteoarthritis. Core Stability. Exercise.

Trial registered on Clinical Trial Registry – India: CTRI/2024/09/073238.

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**RESUMO | CONTEXTO:** Exercícios de fortalecimento do core são recomendados para o tratamento da osteoartrite do joelho (OAJ). No entanto, programas de exercícios individualizados e autoajustáveis podem maximizar os benefícios, melhorar a adesão e reduzir os riscos. Este estudo piloto teve como objetivo avaliar a viabilidade do programa TUCK de fortalecimento do core e sua eficácia clínica preliminar na força do core, mobilidade funcional, parâmetros da marcha, dor e função em adultos com OAJ. **MÉTODOS:** Em um estudo preliminar randomizado de viabilidade, 60 adultos com osteoartrite de joelho unilateral ou bilateral foram recrutados em múltiplos centros e randomizados para o grupo de exercícios TUCK ou para um grupo de fisioterapia padrão. Ambas as intervenções foram realizadas ao longo de 12 semanas, com avaliações no início do estudo, na 6ª semana e na 12ª semana. A viabilidade foi avaliada por meio do recrutamento, adesão e retenção. A eficácia clínica foi avaliada quanto à força do core (ADIM e KLAT), mobilidade funcional (TUG e Teste de Caminhada de 4 Metros), parâmetros da marcha (comprimento da passada, tempo de duplo apoio), dor (NPRS) e função física (KOOS-PS). A análise estatística incluiu testes t pareados e independentes para variáveis contínuas, testes qui-quadrado para variáveis categóricas e tamanho do efeito (d de Cohen). A significância foi definida em  $P < 0,05$ , com intervalos de confiança de 95% relatados para as diferenças entre os grupos. **RESULTADO:** O programa TUCK mostrou-se viável, com mais de 80% de satisfação dos participantes e alta adesão. O grupo experimental apresentou melhorias significativas na força dinâmica do core (KLAT) em comparação com o grupo controle: diferença média = 3,7 mmHg, IC 95% [2,5, 5,2],  $P < 0,001$ , d de Cohen = 0,74. Ambos os grupos demonstraram melhorias significativas intragrupo no TUG, 4MWT, comprimento da passada, NPRS e KOOS-PS ( $P < 0,05$ ). As diferenças intergrupos na mobilidade funcional e na marcha foram geralmente pequenas a moderadas, refletindo a variabilidade basal. **CONCLUSÃO:** O programa de exercícios TUCK é viável, seguro e demonstra potencial de eficácia na melhoria da força do core, mobilidade funcional, marcha, dor e função física em adultos com osteoartrite do joelho. Esses achados corroboram a necessidade de um ensaio clínico randomizado definitivo de maior porte.

**PALAVRAS-CHAVE:** Osteoartrite do Joelho. Estabilidade do Core. Exercício.

Ensaio registrado no Clinical Trial Registry – Índia: CTRI/2024/09/073238.

## 1. Introduction

In India, Knee Osteoarthritis (KOA) poses a significant public health challenge<sup>1</sup>, with prevalence estimates indicating that approximately 22-39% of the population is affected<sup>2</sup>. The disease burden is influenced by varied socio-geographical factors, with different studies<sup>3,4</sup> reporting prevalence variations between urban and rural settings. Significant risk factors for KOA in India include advancing age, female sex, and obesity, while factors like sedentary work and prolonged squatting have also been implicated<sup>5</sup>. With India's elderly population growing<sup>6</sup>, the prevalence of KOA is expected to increase further<sup>7</sup>, compounding the existing challenges faced by a low-resource public health system. Given its progressive nature, absence of a definitive cure, and significant impact on quality of life, KOA remains a critically important joint disease by biomechanical stress and structural variations.

The knee joint subjected to high mechanical stress from load-bearing and body weight, possesses a relatively limited adaptive capacity compared to other joints. This inherent vulnerability makes its tissues susceptible to disruption during ageing and with increased body weight, contributing to the pathogenesis of KOA<sup>8</sup> while KOA is often viewed as a localized condition, clinical evidence reveals that patients frequently present with associated, systemic functional impairments. These include weakened core muscles, improper gait and loss of dynamic balance, which is prevalent within the patient community<sup>9,10</sup>. A key physiological link exists here, as the core muscles are known to activate in anticipation of or concurrently with lower limb movement<sup>11</sup>. Maintaining good core strength is therefore critical for enhancing overall limb stability, especially around the knee joint<sup>12</sup>.

The role of the core is multifaceted. The transverse abdominis, a crucial deep core muscle, is responsible for spinal stability and indirectly helps control the load on the lower extremities<sup>13</sup>. Age-related muscle weakness not only contributes to core instability but also negatively impacts walking speed and trunk rotation<sup>14</sup>. Recognizing the importance of these factors, reports have consistently suggested that gait is a major function that requires focused rehabilitation in KOA patients, with a need to accurate assessment of spatial-temporal parameters<sup>15</sup>. Additionally, research shows that perturbation of the trunk is directly related to gait speed, with core muscle imbalances increasing the risk of imbalance and falls<sup>16</sup>. Consequently, strengthening the core has been shown to directly improve walking speed<sup>17</sup>. Another critical factor is the postural stability required for patients to perform their day-to-day activities in a coordinated manner without losing balance<sup>18</sup>.

Very few studies<sup>17,19</sup> had reported the effect of core strength in relation to gait and balance among KOA patients. Previous studies mainly analyzed core strength but did not specify the exercise patterns used. Despite the established connection between core strength and functional outcomes, review of existing literature reveals a scarcity of specific, evidence-based exercise protocols designed for improving core strength, gait, and balance, specifically in KOA patients<sup>19,20</sup>.

In response to this clear gap in the therapeutic options, we developed and investigated the TUCK (Transverse Abdominis, Upper body, Core, Knee) exercise protocol. This program was chosen over kinesiotherapies for its targeted and progressive 12-week design, tailored to address the unique deficits of KOA patients in a systematic and phased manner. Unlike more generic exercise regimens, TUCK is built upon the principle of first establishing foundational core control using stable positions (weeks 0–3), before gradually advancing to more challenging dynamic stabilizations (weeks 4–8), and finally to functional core strengthening (weeks 9–12). This low impact, minimal-equipment approach not only minimizes the risk of exacerbating knee symptoms but also promotes higher patient adherence, making it a more accessible and sustainable therapeutic option.

By systematically addressing the underlying core deficits that compromise stability and balance, the TUCK protocol is directed toward achieving potential therapeutic gains, including spinal and pelvic stability, enhanced walking speed, and greater dynamic balance in the KOA population.

This research aims to analyze the viability of the TUCK exercise regimen for KOA participants and determine its preliminary efficacy. The primary objective is to evaluate the feasibility of the program by assessing participant recruitment, adherence, and retention. As secondary objectives, the study aims to determine the program's preliminary effectiveness in improving core strength, gait, balance, and disability. The authors hypothesized that the TUCK exercise program would be feasible and potentially effective in improving these outcomes among KOA patients.

## 2. Methods

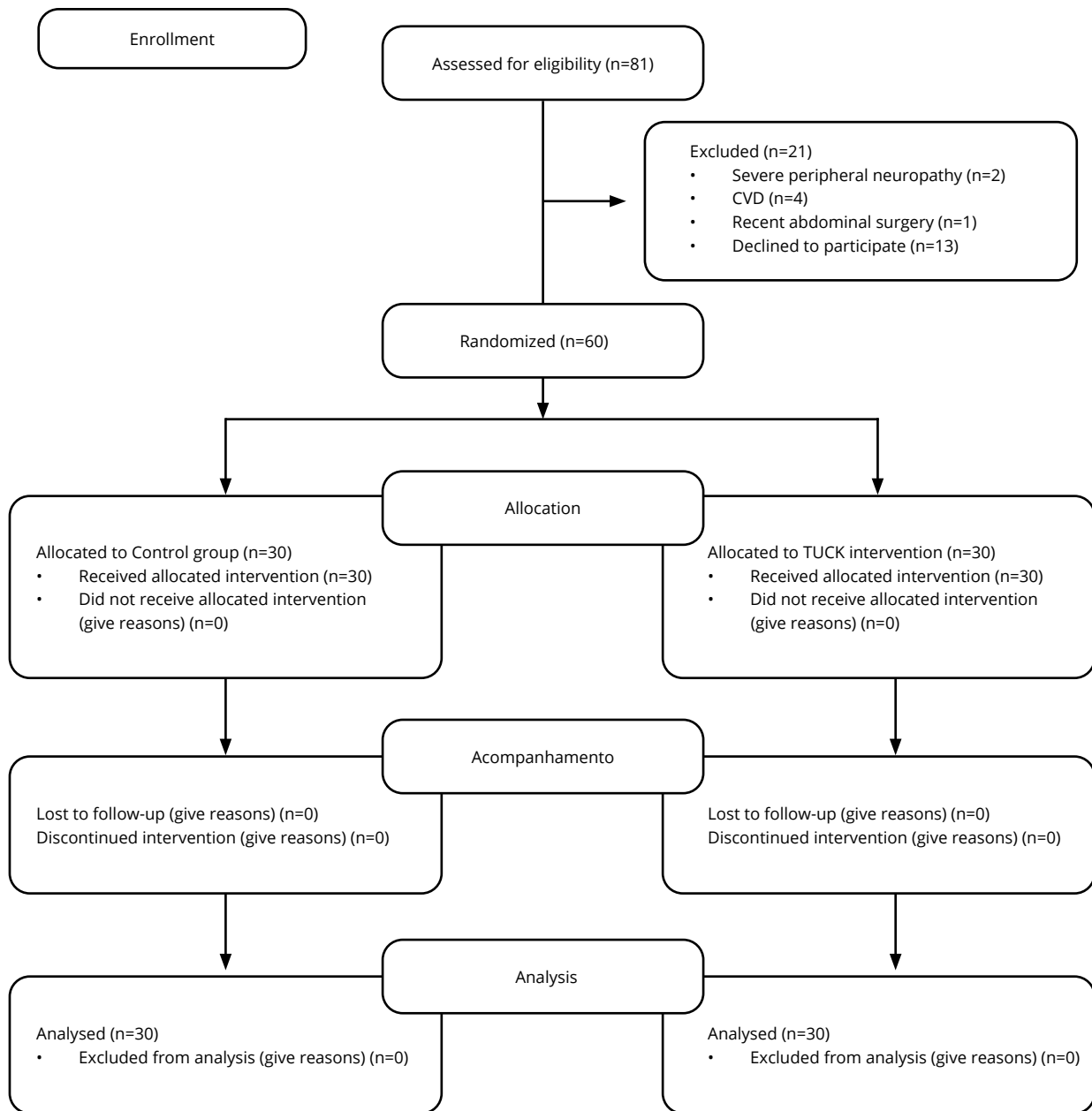
### 2.1 Trial registration

The TUCK exercise trial received support from the Institutional Ethical Committee of SRM Medical College Hospitals and Research Centre (Ethical clearance reference number: 8501/IEC/2023, dated 25/01/2023) and was prospectively registered with the Clinical Trial Registry of India (CTRI/2024/09/073238).

### 2.2 Trial design

A pilot randomized controlled trial employing a 1:1 allocation and parallel design was implemented to evaluate the study objectives. The TUCK trial's design, execution, and reporting conformed to the consolidated standards of reporting trials (CONSORT) (Figure 1). We utilized the extension for pilot and feasibility studies version of the CONSORT reporting guidelines ([appendix A](#)). The Pragmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2)<sup>21</sup> tool was used to guide the design and assess the pragmatic nature of this feasibility trial ([appendix B](#)). As an extension of the CONSORT 2010 and SPIRIT 2013 statements ([appendix C](#)), the Template for Intervention Description and Replication (TIDieR)<sup>22</sup> checklist was used to report the details of the intervention ([appendix D](#)).

**Figure 1.** The CONSORT diagram depicts the flow of participants through each step of a randomized experiment

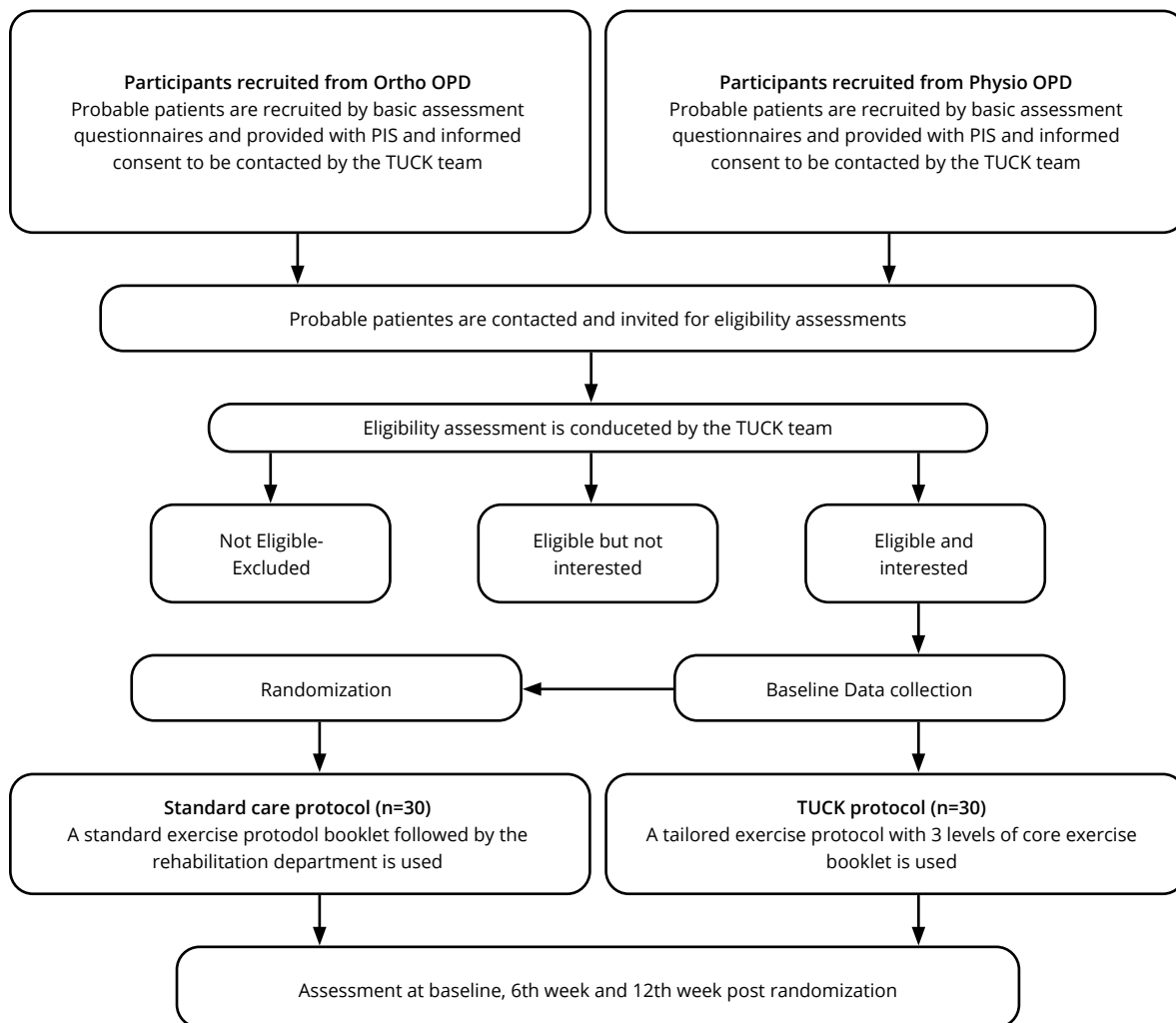


### 2.3 Participants

Sixty men and women over 18 years old were recruited for this pilot study, with participants meeting the 1986 ACR clinical criteria for KOA<sup>23</sup>. Inclusion criteria further specified that participants must have radiological changes of grades 1 or 2 on the Kellgren and Lawrence scale and have low core strength (a pressure bio-feedback reading of + 40 mmHg). Participants were recruited from SUPRESSED based on a matched-pair design, ensuring they were of a similar age category and had a comparable history of knee pain. Exclusion criteria included any condition that could increase the risk of injury during the intervention, such as total knee replacement, a known history of cardiovascular disease, severe peripheral neuropathy, a known hypertensive condition, a chronic foot ulcer, or any neurological disorder affecting lower extremity function. Additionally, individuals with a core strength reading between 38 – 42 mmHg were excluded.

Before the trial began, all the participants provided informed consent form. A random selection strategy with a block size of six was used to enroll participants into the experimental and control groups. Subjects underwent baseline assessments for core stability assessment using a pressure bio-feedback unit, physical function via the KOOS-PS questionnaire, gait speed with the four meter walk test and physical performance using TUG test. These assessments were repeated at three-time points baseline, six weeks, and 12 weeks (Figure 2).

**Figure 2.** Flow chart of explanation of study



## 2.4 Allocation concealment, blinding and randomization

Following the baseline data collection, patients were randomly allocated in a 1:1 ratio to either experimental group (n=30) receiving the TUCK protocol or the control group (n=30) receiving the standard care protocol. The randomization process was performed using a simple random sampling method. This study was single blinded study (assessor blinded), and it is not possible to blind the physiotherapist providing the intervention.

## 2.5 Sample size estimation

The sample size for this feasibility trial was estimated based on the recommendation for pilot studies outlined by Bell et al. in 2018<sup>24</sup>. The calculation assumed a 5% margin of error (alpha level 0.05), a medium effect size and a statistical power of 90%. Based on these assumptions, the estimated sample size was determined to be 30 participants for each group.

## 2.6 Intervention procedure

The experimental group (n=30) received the TUCK protocol, a structured 12-week exercise program designed to improve core strength. This regimen, "Treat Your Core – Kinetic exercises" was provided to participants with exercises progressing through three distinct levels: Core control (weeks 0-4) Core stabilization (weeks 5-8) and Core strengthening (weeks 9-12). The initial phase involved 1-3 sets of 10-15 repetitions performed at a slow pace, while the subsequent phases progressed to 2-3 sets of 8-12 repetition at a medium pace. Each session began with a warmup, and participants were instructed to rate the quality of their exercise performance using a weekly assessment table provided in their booklets. Notably, all the participants in both the experimental and control group received standard physiotherapy care for KOA with the TUCK protocol serving as an additional, specific intervention for the experimental group (appendix B and E).

## 2.7 Control group (standard care protocol)

The standard care protocol was provided to the control group. The program began with a 10-minute warm-up session, which included walking, jogging, or cycling. The main strengthening exercises were graded according to the severity of the participant's KOA: individuals with Grade 1 or 2 lesions performed 2 sets of 8–12 repetitions over 15 minutes, while those with Grade 3 lesions performed 3 sets of 8–12 repetitions for the same duration. The protocol concluded with a 10-minute stretching session. Participants in the control group followed this standardized exercise protocol consistently for 12 weeks. Minor self-modifications, such as reducing exercise intensity, were permitted based on individual tolerance, and adherence was monitored similarly to the TUCK group.

## 2.8 Outcome variables

The outcomes assessed were mobility and balance, core strength, gait parameters, pain and functional status. To assess mobility and balance, TUG and 4-MWT were used. For assessing core strength pressure, bio-feedback unit is used at two different positions such as ADIM and KLAT.

Gait parameters were assessed using Double limb support time, and stride length. NPRS is used for pain and KOOS-PS is used for functional assessment. All these outcomes are valid and reliable<sup>25-29</sup>.

## 2.9 Procedure

An assessor qualified and experienced in musculoskeletal physiotherapy conducted the core strength, TUG, 4-MWT, gait parameter, pain and functional assessment in individuals with KOA. Before commencing the tests, the participants were briefly described about the test procedures. Demographic data such as age, occupation, BMI and details regarding KOA were collected.

### 2.9.1 TUG

TUG is a tool which is used to assess static and dynamic balance, which is a component of physical performance. The TUG can be administered anywhere in a community or other settings because it doesn't require any specialized equipment. This test requires a standard chair with armrests (seat height: 46 cm; armrest height 63-65 cm), a stopwatch and a measuring tape to delineate a clear, unobstructed 3-meter path. Assessment was conducted using an obstacle-free, linear 3-meter path. With the chair stabilized at the starting point, participants were briefed on the TUG parameters to ensure consistency across trials. Participants were instructed to walk at their typical pace to avoid bias. The timer measures the duration required for the participant to rise from the chair, walk to the designated line, turn and return to sit down. The measurements are recorded in seconds. The patient is required to perform the test three times, with sufficient rest intervals between each trial to mitigate bias<sup>30</sup>.

### 2.9.2 4-meter walk test

To measure gait speed, a stopwatch and a defined walkway are used. Participants were instructed to walk the 4-meter pathway at their normal pace. Timing is measured once the participant crosses the 4-meter mark. To increase accuracy, the procedure is repeated three times with suitable breaks between the distances covered (4 meters). The average of trials is considered for final score<sup>31</sup>.

### 2.9.3 Core strength - pressure bio-feedback unit

The subject was asked to lie down in a crook-lying position with palms facing downward, face facing the ceiling, feet approximately shoulder-width apart, and knees bent to a comfortable, pain-free position. The Pressure Bio-feedback Unit was placed horizontally, in the center of the lumbar spine, and inflated with a cuff to 40 mmHg. It was then allowed to stabilize. An optimal fluctuation range of 2 mm Hg on either side of the 40mmHg reference point (38 – 42 mmHg) was considered. All participants were instructed to breathe normally while contracting their abdominal muscles without moving the pelvis. The instructions were given to breathe in and out and then keep the spinal position steady. During this test, the investigator carefully monitored for any trick movements. This was repeated three times to get an average reading, with a one-minute rest period between each measurement. The verbal commands for the voluntary contraction of the transverse abdominis were standardized and repeated for all participants in the same way. The three-compartment PBU device was positioned in the middle of the lumbar spine, between the last rib and the posterior superior iliac spine, in an open horizontal position. The measurement was taken in two different positions the Abdominal Drawing-in Maneuver (ADIM) and the Knee Lift Abdominal Test (KLAT)<sup>31</sup>.

### 2.9.4 Gait parameters

Key temporal and spatial gait parameters were measured. Double limb support time was quantified as the total time (in seconds) that both feet were in simultaneous contact with the ground during the gait cycle. Spatial characteristics were captured by measuring stride length, the distance (in centimeters) between consecutive ground contacts of the same foot. Patients were considered to have successfully completed the intervention if they participated in 80% or more of the scheduled sessions.

### 2.9.5 NPRS and KOOS-PS

NPRS is an 11-point scale to measure pain intensity. Individuals rate their pain from 0 (no pain) to 10 (worst pain). KOOS Physical Function Questionnaire is a 7-item questionnaire covering common daily physical

activities like getting up from bed and wearing and removing slippers. These items were analyzed, with scores from 0 – 4 added for a total of 28. The scores were then converted to a 100-point scale, where the lowest score indicated functional inability, as reported by a previous study.

### 2.10 Data analysis

We utilized IBM software of SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA) to complete the analysis. We used chi-square and independent sample t-tests to look at the baseline and socio-demographic clinical features. We utilized the Shapiro-Wilk test ( $p > 0.05$ ) and looked at normal Q-Q plots, histograms, and Levene's test to see if the assumption of homogeneity was true. The statistical tests were assumed to be significant at  $p$  less than 0.05 with a 95 percent CI-confidence interval, interaction at a 0.05 a priori alpha ( $\alpha$ ) level. Paired and unpaired t test was conducted to estimate an association between  $T_0$  (baseline)  $T_1$  (12 weeks) and the results were expressed as unadjusted means, standard deviation, mean difference, and 95% confidence interval of mean difference. The actual effect size of TUCK intervention was estimated using Cohen's D effect size. An effect size of 0.3, 0.5 and 0.8 were considered small effect, moderate effect and large effect respectively<sup>32</sup>. The feasibility aspects like satisfaction, adherence, difficulty, and retention rate of the TUCK exercise program were expressed as proportion and percentage.

## 3. Results

### 3.1 Demographic characteristics

The mean age of the overall participants was 44.82  $\pm$  9.1 and the distribution of gender did not differ significantly between groups ( $P > 0.05$ ), indicating homogeneity of baseline characteristics. The mean BMI of the all the participants ( $n = 60$ ) was higher than the normal BMI cut-off point, at 28.70  $\pm$  3.99 kg/m<sup>2</sup>. Among the participants, most of them were in grade 2 stage of OA, and right-side OA was the common presentation in the included sample (30%) (Table 1).

**Table 1.** Baseline demographic and clinical characteristics of patients with KOA in the TUCK pilot trial (n=60, 1:1 allocation into two groups)

Variables	All samples (n=60)
Age (years) (mean $\pm$ SD)	44.82 $\pm$ 9.1
<b><sup>a</sup>Gender, n (%)</b>	
Male	31 (51.7)
Female	29 (48.3)
Height (cm), mean $\pm$ SD	161 $\pm$ 7.3
Weight (kg), mean $\pm$ SD	74.43 $\pm$ 11.4
<sup>a</sup> BMI kg/m <sup>2</sup> , mean $\pm$ SD	28.7 $\pm$ 3.9
<sup>a</sup> Chronicity of knee OA (months), mean $\pm$ SD	17.58 $\pm$ 10.1
<b><sup>a</sup>Occupation n (%)</b>	
Business/self-employed	10 (16.7)
Clerical	6 (10)
Homemakers	6 (10)
Labour	10 (16.7)
Professional	27 (45)
Not willing to disclose	1 (1.7)
<b><sup>a</sup>OA grade n (%)</b>	
Grade 1	25 (41.7)
Grade 2	35 (58.3)
<b>Side involved n(%)</b>	
Right	27 (45)
Left	15 (25)
Both	18 (30)
<b>Outcome measures (mean <math>\pm</math> SD)</b>	
4-meter walk test	0.49 $\pm$ 0.1
Core strength-ADIM,	39.43 $\pm$ 5.8
Core strength-KLAT, mean $\pm$ SD	49.03 $\pm$ 7.5
NPRS (0 - 10), mean $\pm$ SD	5.43 $\pm$ 2.0
TUG test, mean $\pm$ SD	11.52 $\pm$ 1.6
KOOS score, mean $\pm$ SD	55.75 $\pm$ 8.4
Stride length, mean $\pm$ SD	63.54 $\pm$ 3.7
Double support time, mean $\pm$ SD	0.365 $\pm$ 0.0

### 3.1.1 Chronicity of OA

The mean duration of KOA symptoms was  $19.67 \pm 12.3$  months in the control group and  $15.50 \pm 6.6$  months in the experimental group. The pooled mean chronicity across participants was  $17.58 \pm 10.1$  months, indicating that individuals had been experiencing symptoms for over 1.5 years on average, highlighting the chronic nature of the condition (Table 3). Although the experimental group demonstrated a slightly shorter symptom duration, the difference between groups was not statistically significant ( $P=0.11$ ). With respect to disease severity, a majority of participants presented with moderate OA (Grade 2: 58.3%), while 41.7% had mild OA (Grade 1), with no cases of severe OA (Grades 3 or 4). Regarding the side involved, unilateral KOA (70%) was more common than the bilateral involvement (30%), a pattern consistent with previous studies reporting that unilateral presentation predominates in the early stages. Collectively, these findings suggest that the study population predominantly represented the early-to-moderate stage of KOA, making them appropriate candidates for conservative physiotherapy-based interventions, lifestyle modification, and exercise therapy such as the TUCK exercise protocol.

### 3.1.2 Occupation

Participants in the study represented a diverse occupational background. In the control group, 3 participants (10%) were business or self-employed, 3 (10%) were clerical workers, 4 (13.3%) were homemakers, 7 (23.3%) were laborers, 1 (3.3%) was a professional, and 12 (40%) chose not to disclose their occupation. In the experimental group, 7 participants (23.3%) were business or self-employed, 3 (10%) were clerical workers, 2 (6.7%) were homemakers, 3 (10%) were laborers, and 15 (50%) opted not to disclose their occupation. The occupational distribution did not differ significantly between the two groups ( $P=0.392$ ), indicating that participants from both groups were comparable in terms of work-related physical activity levels and lifestyle factors. This occupational variability reflects a typical community-based distribution and supports the generalizability

of the study findings to adults with KOA engaged in varied daily activities.

### 3.1.3 Pain and functional score

At baseline, the mean NPRS score was  $4.90 + 2.1$  in the control group and  $5.97 + 1.7$  in the experimental group, showing a statistically significant difference (0.04). Despite this, the overall pain levels in both groups indicated moderate pain intensity, suggesting comparable symptom burden at the start of the study. The baseline KOOS values were  $56.97 + 9.7$  for the control group and  $54.54 + 6.4$  in the experimental group, with no significant difference ( $P=0.27$ ) between groups. This indicates similar baseline functional status and symptom severity before the intervention. Overall, these findings suggest that although the experimental group reported slightly higher pain levels at baseline, both groups were functionally comparable, allowing for valid comparisons of intervention effects in subsequent analysis.

### 3.1.4 Functional performance

At baseline, the mean TUG time was  $11.90 + 3.2$  in the control group and  $11.15 + 1.7$  seconds in the experimental group, with no significant difference ( $P=0.27$ ) between groups, indicating comparable mobility levels prior to intervention. Similarly, the 4MWT scores were  $0.51 + 0.1$  m/s and  $0.47 + 0.1$  m/s for the control and experimental groups, respectively ( $P=0.09$ ), reflecting similar walking speeds across groups. However, significant group differences were observed in certain gait parameters. Stride length was slightly greater in the control group ( $65.01 + 3.5$  cm) compared to the ( $62.06 + 3.3$  cm), while double support time was higher in the experimental group ( $0.39 + 0.6$  seconds) than in the control group ( $0.33 + 0.9$ ). These findings indicate that both groups demonstrated comparable functional mobility and gait performance at baseline, with only minor but statistically significant variations in stride length and support time that are unlikely to be clinically meaningful. This suggests a well-balanced distribution of baseline characteristics, supporting the validity of between-group comparisons in later analyses (Table 2).

**Table 2.** Comparison of baseline demographic data and clinical characteristics of control and experimental group of KOA knee patients in the TUCK pilot trial (n=60, 1:1 allocation into two groups)

Variables	Control (n=30)	Experimental (n=30)	p value
Age (years) (mean ± SD)	46.03 ± 11.6	43.6 ± 5.66	< 0.001**
<b><sup>a</sup>Gender, n (%)</b>			
Male	15 (50)	16 (53.3)	0.65
Female	15 (50)	14 (46.7)	
Height (cm), mean ± SD	161.60 ± 8.37	160.40 ± 6.3	0.52
Weight (kg), mean ± SD	75.00 ± 11.7	73.87 ± 11.2	0.71
<sup>a</sup> BMI kg/m <sup>2</sup> , mean ± SD	28.70 ± 4.2	28.63 ± 3.8	0.89
<sup>a</sup> Chronicity of knee OA (months), mean ± SD	19.67 ± 12.3	15.50 ± 6.6	0.11
<b><sup>a</sup>Occupation n (%)</b>			
Business/self-employed	3 (10)	7 (23.3)	0.392
Clerical	3 (10)	3 (10)	
Homemakers	4 (13.3)	2 (6.7)	
Labour	7 (23.3)	3 (10)	
Professional	1 (3.3)	0 (0)	
Not willing to disclose	12 (40)	15 (50)	
<b><sup>a</sup>OA grade n (%)</b>			
Grade 1	14 (46.7)	11 (36.7)	0.601
Grade 2	16 (53.3)	19 (63.3)	
<b>Side involved n (%)</b>			
Right	15 (50)	12 (40)	0.627
Left	6 (20)	9 (30)	
Both	9 (30)	9 (30)	
<b>Outcome measures (Mean ± SD)</b>			
4-meter walk test	0.51 ± 0.1	0.475 ± .0948	.092
Core strength-ADIM,	40.36 ± 5.1	39.66 ± 2.57	0.27
Core strength-KLAT, mean ± SD	45.53 ± 5.9	49.23 ± 3.82	0.003**
NPRS (0 - 10), mean ± SD	4.90 ± 2.1	5.97 ± 1.732	0.04*
TUG test, mean ± SD	10.167 ± 3.2	9.913 ± 1.611	0.27
KOOS score, mean ± SD	56.97 ± 9.7	54.54 ± 6.4	0.27
Stride length, mean ± SD	65.01 ± 3.5	62.06 ± 3.3	0.001**
Double support time, mean ± SD	0.33 ± 0.8	0.39 ± 0.6	0.009**
Lost to follow up	0	0	NA

Significant if  $P < 0.05$ .

### 3.2 Feasibility and adherence outcomes

Adherence to the TUCK program varied across age groups, with younger participants (< 45 years) showing good adherence, as 65% completed  $\geq 80\%$  of the sessions, and 35% had <80% adherence. Among middle-aged participants (45–55 years), adherence was more variable, with only half achieving  $\geq 80\%$  completion and the remaining half below 80%. In contrast, all older participants (>55 years) maintained  $\geq 80\%$  adherence, with half completing all sessions, indicating that the program is feasible and acceptable across age groups, particularly among older adults. Regarding perceived difficulty, half of the younger participants reported no difficulty, while most of the remaining participants found the exercises somewhat challenging. In the 45–55 years group, the majority reported somewhat difficulty, with small proportions indicating difficulty or very difficult. All participants >55 years perceived the exercises as somewhat difficult, suggesting moderate challenge without excessive strain. Overall, these findings indicate that the TUCK program is well-tolerated and feasible across age groups, with a generally high adherence and difficulty ratings reflecting manageable levels of challenge.

**Table 3.** Age group-wise distribution of feasibility (adherence rate and difficulty rating) of KOA participants in the TUCK pilot trial at 12 weeks post-intervention

Variables	Experimental (TUCK intervention) group		
	< 45 years	45 - 55 years	> 55 years
Age groups (years)	< 45 years	45 - 55 years	> 55 years
<b>Adherence, n (%)</b>			
100	7 (35%)	2 (25%)	1 (50%)
> 80	6 (30%)	2 (25%)	1 (50%)
< 80	7 (35%)	4 (50%)	0 (0%)
<b>Difficulty rating, n (%)</b>			
'0' No difficulty	10 (50%)	2 (25%)	0 (0%)
'1' Somewhat difficulty	9 (45%)	4 (50%)	2 (100%)
'2' Difficulty	0 (0%)	1 (12.5%)	0 (0%)
'3' Very difficulty	1 (5%)	1 (12.5%)	0 (0%)

### 3.3 Clinical findings

#### 3.3.1 Core strength improvements

In the control group (Table 4), no significant change was observed in ADIM ( $p=0.819$ ) or KLAT ( $P=0.240$ ), whereas the experimental group (Table 5) showed significant improvement in both ADIM ( $P<0.001$ ) and KLAT ( $P<0.001$ ). Between groups, the experimental group achieved significantly higher KLAT scores post-intervention ( $P<0.001$ , Cohen's  $d=0.74$ ), indicating a large effect size and superior gains in dynamic core endurance. The ADIM scores, however, did not differ significantly ( $P=0.002$ , Cohen's  $d=0.17$ ), suggesting comparable static core activation ability between groups at post-test (Table 6).

**Table 4.** Paired t-test values of control for TUCK Pilot trial (n=60, 1:1 allocation)

Control	Variable	Mean $\pm$ SD		t-teste	P value
		Pre	Post		
	Core Strength-ADIM	40.26 $\pm$ 7.2	40.36 $\pm$ 5.1	-.231	.819
	Core Strength-KLAT	46.23 $\pm$ 8.8	45.53 $\pm$ 5.9	1.199	.240
	TUG	11.90 $\pm$ 3.28	10.167 $\pm$ 3.280	10.933	<.000**
	4MWT	0.51 $\pm$ 0.1	0.60 $\pm$ 0.1	- 6.551	<.000**
	DLS	0.33 $\pm$ 0.8	0.32 $\pm$ 0.9	2.363	.025*
	Stride Length	65.01 $\pm$ 3.5	65.98 $\pm$ 3.1	-4.409	<.000**
	NPRS	4.90 $\pm$ 2.1	4.43 $\pm$ 2.1	5.037	<.000**
	KOOS_PS	56.97 $\pm$ 9.7	59.60 $\pm$ 10.3	-7.076	<.000**

\* Significant if  $P<0.05$ .

#### 3.3.2 Mobility and functional outcomes

The control group demonstrated a highly significant improvement in TUG time ( $p<0.001$ ), indicating better functional mobility after intervention. In contrast, the experimental group showed a numerical reduction in mean TUG time (from 11.15 to 9.91 seconds), but this change was not statistically significant ( $P=0.338$ ). The between-group comparison ( $P=0.003$ ,  $d=0.097$ ) reached statistical significance but had a small effect size, implying the observed difference is not clinically meaningful.

In the 4-Meter Walk Test, both groups demonstrated significant within-group improvements in walking speed ( $p < 0.001$ ). The control group improved from  $0.51 \pm 0.10$  m/s to  $0.60 \pm 0.10$  m/s, and the experimental group from  $0.47 \pm 0.10$  m/s to  $0.54 \pm 0.10$  m/s. However, the between-group difference at post-test was not statistically significant ( $p = 0.124$ ), suggesting that both exercise programs were equally effective in enhancing short-distance mobility performance.

**Table 5.** Paired t-test values of experimental group for TUCK pilot trial (n=30, 1:1 allocation)

Experimental	Variable	Mean $\pm$ SD		t-test	P value
		Pre	Post		
	Core Strength-ADIM	38.60 $\pm$ 3.8	39.66 $\pm$ 2.5	-3.117	<.000
	Core Strength-KLAT	51.83 $\pm$ 4.5	49.23 $\pm$ 3.8	8.843	<.000**
	TUG	11.15 $\pm$ 1.7	9.91 $\pm$ 1.6	3.124	<.338
	4MWT	0.47 $\pm$ 0.1	0.54 $\pm$ 0.1	-7.800	<.000**
	DLS	0.39 $\pm$ 0.6	0.36 $\pm$ 0.7	1.773	<.988
	Stride Length	62.06 $\pm$ 3.3	65.37 $\pm$ 3.2	-4.062	<.702
	NPRS	5.97 $\pm$ 1.7	5.37 $\pm$ 1.5	3.844	<.000**
	KOOS_PS	54.54 $\pm$ 6.4	58.50 $\pm$ 6.5	-9.213	<.000**

\* Significant if  $P < 0.05$ .

### 3.3.3 Gait parameters

Analysis of gait parameters revealed significant improvements in the control group, with a reduction in double limb support time ( $P = 0.025$ ) and an increase in stride length ( $P < 0.001$ ), indicating enhanced walking stability and step efficiency. In contrast, the experimental group showed improvements in both parameters, but these changes were statistically insignificant ( $P = 0.988$  and  $P = 0.702$ , respectively). Between-group comparisons at post-test revealed no significant differences in either double limb support time ( $P = 0.213$ ) or stride length ( $P = 0.889$ ), with small effect sizes (Cohen's  $d = 0.43$  and  $0.19$ ). This suggests that both interventions produced comparable gait performance outcomes, with only marginal differences that are not clinically meaningful.

### 3.3.4 Pain and functional outcomes

Both groups showed significant reductions in pain on the NPRS following intervention ( $P < 0.001$ ), indicating that both exercise regimens were effective in alleviating discomfort associated with KOA. Although the control group reported slightly lower pain scores at post-test ( $4.43 \pm 2.1$ ) compared with the experimental group ( $5.37 \pm 1.5$ ), this difference was small ( $P = 0.03$ , Cohen's  $d = 0.51$ ) and likely not clinically meaningful. Significant improvements were observed within both groups ( $p < 0.001$ ), reflecting better physical function and reduced activity limitation in KOOS. The between-group comparison revealed no clinically relevant difference at post-test ( $p = 0.007$ ,  $d = 0.13$ ), suggesting comparable benefits from both exercise protocols in improving knee-related function.

**Table 6.** Unadjusted means, standard deviations, mean difference, and 95% CI of the mean difference, Cohen's d effect size, Post intervention comparison of continuous outcome measure for experimental and control group (n=60, 1:1 allocation)

Outcome measures	Experiment group Mean ± SD T1 (n=30)	Control Mean ± SD T1 (n=30)	Mean diff (95% CI)	p-value	Cohen's d effect size
Core strength ADIM	39.66 ± 2.5	40.36±5.1	0.70	.002*	0.171
Core strength KLAT	49.23 ± 3.8	45.53 ± 5.9	3.70	<.000**	0.740
TUG	9.91 ± 1.6	10.16 ± 3.2	0.25	.003	0.097
4 MWT	0.54 ± 0.1	0.60± 0.1	0.05	0.124	0.403
Double support time	0.32 ± 0.9	0.36 ± 0.7	0.35	.213	0.429
Stride length	65.37 ± 3.2	65.98 ± 3.1	0.60	.889	0.191
NPRS	5.37 ± 1.5	4.43 ± 2.1	0.93	.030	0.507
KOOS-PS	58.50 ± 6.5	59.60 ±10.3	1.09	.007	0.126

\* Significant if  $P < 0.05$ .

## 4. Discussion

The primary objective of this feasibility pilot trial was to examine the safety, adherence, and practicality of the 12-week TUCK exercise protocol in adults with KOA. Consistent with the aims of feasibility research, analyses of clinical outcomes were exploratory and intended to identify potential signals of benefit rather than establish definitive clinical efficacy. Overall, the TUCK program demonstrated high acceptability, excellent adherence, and no safety concerns, supporting its suitability for evaluation in a future fully powered randomized controlled trial.

Given the pilot nature of this study, all secondary clinical outcomes including core strength, mobility, gait parameters, pain, and functional status should be interpreted as preliminary and hypothesis-generating. The study was not powered to detect small or moderate between-group differences and observed effects should therefore be viewed as indicative of potential trends rather than confirmatory evidence of clinical effectiveness.

### 4.1 Core strength improvement and mechanistic insights

The TUCK program was associated with a promising improvement in dynamic core strength in the experimental group, while static core activation remained similar between groups, suggesting that dynamic core endurance may be more responsive to the sequential, progressive exercises employed in TUCK. Core musculature plays a critical role in stabilizing the trunk and pelvis, which can influence knee joint loading during weight-bearing tasks, and strengthening the proximal kinetic chain is theorized to improve distal joint function, reduce compressive forces on the knee, and potentially mitigate pain while enhancing functional mobility<sup>33</sup>. These findings are consistent with previous research by Almansoor et al.<sup>34</sup> which reported that core stabilization exercises improved trunk and lower limb function in older adults with KOA, leading to enhanced postural control and reduced pain, while Esteban-García et al.<sup>35</sup> reported that a 12-week core exercise program increased trunk muscle endurance and reduced knee adduction moments during gait, indirectly supporting joint health. Unlike these prior studies, the TUCK protocol incorporates a Pressure Bio-feedback Unit, enabling real-time monitoring of transverse abdominis activation and promoting safe, personalized exercise intensity, which may further enhance adherence and training effectiveness. However, these findings should be interpreted cautiously due to the exploratory nature of the analysis and baseline group differences.

## 4.2 Functional mobility and gait outcomes

Improvements in functional mobility and gait parameters were observed in both groups; however, between-group differences were generally small and inconsistent. These findings suggest that while both interventions were acceptable and safe, the present study does not provide conclusive evidence of superiority of the TUCK protocol for gait or mobility outcomes. Instead, the results highlight areas of potential benefit that should be explored in a larger, adequately powered trial. These findings align with previous research, by Ding et al.<sup>36</sup>, which reported that lower-limb strengthening exercises improved gait speed and functional mobility in individuals with knee osteoarthritis, consistent with the improvements observed in both groups in this study. The modest between-group differences in our trial may be attributed to baseline disparities, including higher pain levels and greater KLAT scores in the experimental group, as well as the small sample size, which limited statistical power and the ability to detect clinically meaningful differences.

Several outcome variables, including dynamic core strength, pain intensity, and selected gait parameters, demonstrated statistically significant differences at baseline between the intervention and control groups. Although randomization was used, these imbalances are not uncommon in feasibility and pilot trials with relatively small sample sizes. The experimental group presented with higher baseline pain and dynamic core strength, along with less favorable gait characteristics, which may have influenced the magnitude and direction of post-intervention between-group comparisons. Consequently, some observed differences may reflect regression to the mean or baseline variability rather than true intervention effects. Overall, the small and inconsistent between-group differences observed in mobility and gait parameters suggest that these findings represent preliminary trends rather than evidence of superior clinical effectiveness of the TUCK protocol.

## 4.3 Pain and functional outcomes

Both groups demonstrated reductions in pain, as measured by the NPRS, and improvements in physical function, reflected in KOOS-PS scores, although between-group differences were small to moderate.

The experimental group had slightly higher baseline pain, which may have attenuated the magnitude of post-intervention changes. These findings suggest that while core strengthening may support functional improvements, it may not independently produce substantial pain relief over a 12-week period. Similar results have been reported by Thomas et al.<sup>37</sup>, who observed moderate reductions in pain following core and lower-limb exercise programs in individuals with knee osteoarthritis, indicating that proximal strengthening can contribute to symptom alleviation. These changes should be interpreted as exploratory findings rather than definitive treatment effects attributable to the TUCK protocol. However, unlike some prior studies<sup>38,39</sup>, our trial did not control NSAID or analgesic use, which could have influenced the observed pain outcomes, representing an important limitation that warrants attention in future definitive trials.

The results of this study indicate that the TUCK program demonstrates good feasibility and acceptability across different age groups, with adherence generally high and difficulty levels perceived as manageable. Younger participants (<45 years) showed good adherence, with the majority completing at least 80% of the sessions, and reported lower difficulty, suggesting that the program aligns well with their baseline physical capacity and lifestyle flexibility. In contrast, adherence among middle-aged participants (45–55 years) was more variable, likely reflecting competing occupational, familial, or social responsibilities that may interfere with consistent exercise participation. Notably, older participants (>55 years) maintained high adherence, with all completing at least 80% of sessions, and reported moderate difficulty, indicating that the program is appropriately challenging without being overly strenuous. The perception of moderate difficulty among older adults may also suggest that the exercises are effective in engaging core musculature while remaining safe, which is essential for promoting long-term adherence. These findings are consistent with previous studies<sup>40,41</sup> highlighting that home-based, self-regulated interventions with clear instructions and progressive intensity can achieve high adherence and are well-tolerated across age groups. Clinically, the TUCK program appears suitable for integration into daily routines, particularly for older adults who may benefit from structured core-strengthening exercises to support functional mobility and musculoskeletal health.

Several outcome variables, including dynamic core strength, pain intensity, and selected gait parameters (stride length and double support time), demonstrated statistically significant differences at baseline between the intervention and control groups. Although randomization was used, these imbalances are not uncommon in feasibility and pilot trials with relatively small sample sizes. The experimental group presented with higher baseline pain and dynamic core strength, along with less favorable gait characteristics, which may have influenced the magnitude and direction of post-intervention between-group comparisons. Consequently, some observed differences may reflect regression to the mean or baseline variability rather than true intervention effects.

This trial has few limitations. First, the study lacked control over participants' use of NSAIDs or other analgesics. Since pain was a primary outcome and directly affects functional performance, the absence of this information may have confounded observed improvements in pain, mobility, and KOOS scores. Second, this study did not employ adjusted statistical analyses to account for baseline imbalances between groups. Between-group comparisons were based on unadjusted post-intervention means and change scores, and no covariate-adjusted methods such as analysis of covariance (ANCOVA) or mixed-effects modeling were performed. As a result, residual confounding due to baseline differences in KLAT, NPRS, and gait parameters cannot be ruled out, which limits causal inference regarding the comparative effectiveness of the TUCK program relative to standard physiotherapy care. Third, several baseline differences existed between groups, including NPRS, KLAT, stride length, and double support time. The experimental group had higher baseline pain and KLAT scores, shorter stride length, and longer double support time, which could have influenced post-intervention outcomes. Fourth, the study did not monitor fluctuations in participants' physical activity levels, which may have further impacted on the results and limits the generalizability to clinical practice. As a feasibility pilot study, this trial was not designed to establish clinical efficacy, and all secondary outcome findings should be interpreted cautiously as hypothesis-generating. Future definitive trials should systematically record analgesic use, monitor physical

activity, and consider stratified randomization or statistical adjustment for baseline differences to ensure a more accurate evaluation of the TUCK protocol's efficacy. Nevertheless, this feasibility trial evaluated a novel intervention design that may help patients incorporate core strengthening exercises into their activities of daily living, providing a critical foundation for future large-scale trials.

#### **4.4 Feasibility and clinical relevance**

The study confirms that the TUCK program is safe, feasible, and its home-based, self-regulated design supports adherence, allowing integration of core-strengthening exercises into daily routines. Participants demonstrated preliminary gains in dynamic core strength and functional mobility, suggesting potential benefits for lower extremity stability and knee joint load management. These findings align with the kinetic chain theory, which posits that proximal stabilization can influence distal joint function, highlighting the potential clinical value of incorporating core-focused exercises into KOA rehabilitation programs. The TUCK protocol also provides objective feedback via Personal Use Bottom Time (PBU), enabling patients to perform exercises safely and effectively, which may enhance self-efficacy and adherence over time. Given that participants were allowed to modify the sequences of the TUCK exercises, it is important that future trials establish a feasible method to track such variations, as they could significantly influence study findings. Systematic monitoring of exercise fidelity in definitive trials will help ensure accurate assessment of program efficacy and improve interpretation of outcomes.

## **5. Conclusion**

This feasibility pilot study demonstrates that the 12-week TUCK exercise protocol is safe, acceptable, and highly feasible for adults with knee osteoarthritis, with excellent adherence and no loss to follow-up. Exploratory analyses identified promising trends toward improvement in dynamic core strength and functional outcomes; however, between-group differences were small to moderate and should

not be interpreted as definitive evidence of clinical effectiveness. These findings support the feasibility of conducting a fully powered randomized controlled trial with improved baseline balance, appropriate adjustment for confounding factors, and sufficient statistical power to rigorously evaluate the clinical effectiveness of the TUCK protocol on pain, gait, and functional outcomes in individuals with KOA.

### Authors' contributions

The authors declared that they have made substantial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the study.

### Competing interests

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

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# Appendix A

**Table A1.** CONSORT checklist of information to include when reporting a pilot trial\* (to be continued)

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
<b>Title and abstract</b>			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	Pg.No-1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Pg.No-2
<b>Introduction</b>			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pg.No-4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	Pg.No-4
<b>Methods</b>			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Pg.No-4
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Pg.No-4
Participants:			
4a	Eligibility criteria for participants		Pg.No-4
4b	Settings and locations where the data were collected		Pg.No-4
4c		How participants were identified and consented	Pg.No-5
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		Pg.No-7
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Pg.No-9
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	-
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	--
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	Pg.No-6

**Table A1.** CONSORT checklist of information to include when reporting a pilot trial\* (continuation)

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	Pg.No.11
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	
<b>Results</b>			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Pg.No-5
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Pg.No-12,13,14
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Pg.No-16,17
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Pg.No-17
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	

**Table A1.** CONSORT checklist of information to include when reporting a pilot trial\* (conclusion)

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		
19a		If relevant, other important unintended consequences	
<b>Discussion</b>			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	
Generalizability:			
21	Generalizability (external validity, applicability) of the trial findings	Generalizability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pg.No- 17,18,19,20
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
<b>Other information</b>			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	Pg.No-4
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	Yes
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		
26		Ethical approval or approval by research review committee, confirmed with reference number	Pg.No-4

\*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.

# Appendix B

## TUCK Exercise Protocol

Core muscles are a chain connecting upper and lower body. Whether the cation is hitting a tennis ball or mopping the floor, the necessary motions either originate in core or move through it. A strong core also enhances balance and stability.

### About the manual:

This manual serves one purpose: to make healthy exercise possible for everyone. It provides exercises and health promoters with tools, resources, and support to guide safe, effective exercises program with minimal or no equipment. All routines, forms and information can be downloaded, free of charge.

The program has been designed by Qualified Physiotherapist and emphasizes exercise safety.

A complete training manual workout that is not only suitable for beginners but introduces them to strengthen and exercise ever so subtly. This exercise plan will help to improve your bodily muscle health.

**\*\*Note\*\*** Please do not hold your breath while doing exercise. Follow a normal rhythmic breathing pattern. Do an open mouth pursed lip breathing during exercising.

### To the respondents

Thank you for your contribution to the TUC-K exercise Trial. During the following 12 weeks, you will be under our guidance for this exercise program, which has 3 levels to complete within the stipulated time.

## STRUCTURED 3 MONTHS EXERCISE PROTOCOL FOR CORE STRENGTH

1st Level - CORE CONTROL EXERCISES (0—4 WEEKS)

2nd Level - CORE STABILISATION EXERCISES (5—8 WEEKS)

3rd Level - CORE STRENGTHENING EXERCISES (9—12 WEEKS)

Disclaimer: This manual is intended as a guide only. Please undergo a medical clearance before you start to do any exercises. Some exercises will not be appropriate for all participants and should be modified at your discretion.








### Exercise Highlights:

This workout plan is four days weekly routine, while 3 days go to muscle recovery. The recovery time is essential to let the muscles heal and grow in strength and size. One-minute rest between regular sets and at the end of all exercises.







**\*\*Note\*\*** It is mandatory to drink 2-3 liters of water per day according to WHO 2009. Do not hold your breath during your entire exercise session. Don't exercise if you are not feeling well. Talk to your doctor if you have chest pain, increased palpitations, balance problems, nausea, dizziness, or trouble breathing while exercising. Keep track of your diabetes and blood pressure levels, especially while doing this program.

**TIPS BEFORE STARTING:** Before you begin, please keep in mind that you should wear comfortable clothes and footwear and prepare a safe space with good lighting and no tripping hazards. Don't forget to use a safe support like a sturdy chair, kitchen worktop, table or windowsill, if needed.




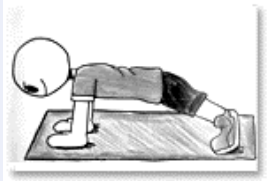
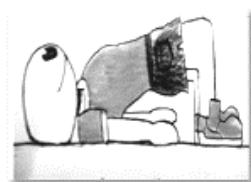
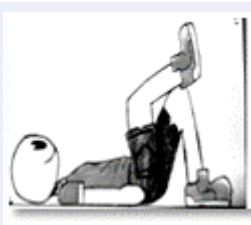

**Table B1.** TUCK Exercise Protocol (to be continued)

S.No	Exercises	Position
<b>Warm up exercises each Exercise 10-15 Repetitions</b>		
1	<p>Heel raise</p> <ul style="list-style-type: none"> <li>• Hold on to support</li> <li>• Lift heel up and down Slowly</li> </ul>	Standing
		
2	<p>Toe raise</p> <ul style="list-style-type: none"> <li>• Hold on to support</li> <li>• Lift Toes up and down slowly</li> </ul>	Standing
		
3	<p>Spot marching</p> <ul style="list-style-type: none"> <li>• Lift your knee up and down alternatively as if you are marching with rhythmic hand movements</li> </ul>	Standing
		
4	<p>Arm swings</p> <ul style="list-style-type: none"> <li>• Stand with wide legs</li> <li>• Swing your arms front and back slowly</li> </ul>	Standing
		
<b>Core control exercises-0-3 weeks 1-3 sets (10-15 repetitions per set) at a slow tempo</b>		
5	<p>Transverse Abdominis (TA) activation</p> <ul style="list-style-type: none"> <li>• Pull in the lower tummy slowly while breathing out</li> <li>• Hold on to tucked tummy for 5 seconds and relax</li> </ul>	Chair sitting
		
6	<p>Seated side bends</p> <ul style="list-style-type: none"> <li>• Sit with an arm less chair with back straight</li> <li>• Now TUCK your tummy</li> <li>• Keep right hand behind the neck and left hand hanging by the side</li> <li>• Now bend towards the hanging arm by keeping your core tight. And return to starting position</li> <li>• Repeat on one side and move to opposite side</li> </ul>	Chair sitting
		
7	<p>Seated twisting</p> <ul style="list-style-type: none"> <li>• Sit with an arm less chair with back straight</li> <li>• Now TUCK your tummy</li> <li>• Keep both arms folded in front of chest</li> <li>• Now twist your upper body towards right and left alternatively</li> </ul>	Chair sitting
		




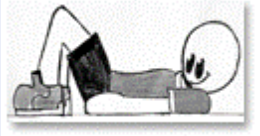


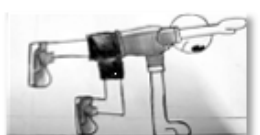

**Table B1.** TUCK Exercise Protocol (continuation)

S.No	Exercises	Position
8	<p>Sitting cross crunches</p> <ul style="list-style-type: none"> <li>• Sit with an arm less chair with back straight</li> <li>• Now TUCK your tummy</li> <li>• Keep both hands behind the neck without locking</li> <li>• Now lift right knee and bring left arm close to the knee</li> <li>• Repeat it with opposite hand and leg</li> </ul>	<p>Chair sitting</p> 
9	<p>Seated wood chop</p> <ul style="list-style-type: none"> <li>• Sit with an arm less chair with back straight</li> <li>• Now TUCK your tummy</li> <li>• Keep both hands clasped with elbows straight in front of chest</li> <li>• Now lift it diagonally above the right side and move it diagonally down to left</li> <li>• Repeat the same procedure on left side</li> </ul>	<p>Chair sitting</p> 
10	<p>Seated march</p> <ul style="list-style-type: none"> <li>• Sit with an arm less chair with back straight</li> <li>• Now TUCK your tummy</li> <li>• Keep both the hands rested on seat</li> <li>• Now lift one knee up to reach the chest level and bring it down</li> <li>• Now repeat it with other knee like marching</li> </ul>	<p>Chair sitting</p> 
11	<p>Wall plank with straight elbow</p> <ul style="list-style-type: none"> <li>• Start in a standing position</li> <li>• Now place the hands on the wall straight to shoulder level and move back both feet away from wall like leaning</li> <li>• Now TUCK your tummy</li> <li>• Now straighten the legs behind, keeping your feet hip-width apart</li> <li>• Hold this position for 10 seconds</li> <li>• Repeat 8-12 times</li> </ul>	<p>Standing</p> 
<p><b>Core stabilization exercises- 4-8 weeks</b>  <b>2-3 sets (8-12 repetitions per set) at a medium tempo</b></p>		
12	<p>Standing side reach</p> <ul style="list-style-type: none"> <li>• Stand with shoulder width wide legs</li> <li>• TUCK your tummy and raise one hand above shoulder and start bending to one side and repeat the same on other side</li> </ul>	<p>Standing</p> 
13	<p>Twisting in Standing</p> <ul style="list-style-type: none"> <li>• Stand with shoulder width wide legs</li> <li>• Now TUCK your tummy</li> <li>• Keep both hands clasped with elbows straight in front of chest</li> <li>• Now twist your upper body towards right and left alternatively keeping your core tight</li> </ul>	<p>Standing</p> 

**Table B1.** TUCK Exercise Protocol (continuation)

S.No	Exercises	Position
14	<p>Standing cross crunches</p> <ul style="list-style-type: none"> <li>• Stand with shoulder width wide legs</li> <li>• Now TUCK your tummy</li> <li>• Keep both hands behind the neck without locking</li> <li>• Now lift right knee and bring left arm close to the knee</li> <li>• Repeat the same with opposite side alternatively</li> </ul>	<p>Standing</p> 
15	<p>Dog bird—standing</p> <ul style="list-style-type: none"> <li>• Stand straight with hands by the side.</li> <li>• Now TUCK your tummy</li> <li>• Then lift right knee and left arm straight up and down together</li> <li>• Now repeat the same with left knee and right arm</li> <li>• ** Make sure you are having balance while doing this exercise</li> </ul>	<p>Standing</p> 
16	<p>Standing wood chop</p> <ul style="list-style-type: none"> <li>• Stand with shoulder width wide legs</li> <li>• Now TUCK your tummy</li> <li>• Keep both hands clasped with elbows straight in front of chest</li> <li>• Now lift arm diagonally above the right side and move it diagonally down to left</li> <li>• Repeat the same procedure on left side</li> <li>• Finish of one side then move on to the other side</li> </ul>	<p>Standing</p> 
17	<p>Plank with straight elbow</p> <ul style="list-style-type: none"> <li>• Start on all fours position</li> <li>• Now TUCK your tummy</li> <li>• Place hands below your shoulders and knees below your hips.</li> <li>• Now straighten the legs behind, keeping your feet hip-width apart</li> <li>• Tighten your core</li> <li>• Hold for 10 seconds</li> <li>• Repeat 8-12 times</li> </ul>	<p>Four legs</p> 
18	<p>Pelvic bridging</p> <ul style="list-style-type: none"> <li>• Lie down straight with hands by the side</li> <li>• Now TUCK your tummy</li> <li>• Keep both leg bent with foot firm on floor</li> <li>• Now lift the whole hip up and hold it for 10 seconds and relax</li> <li>• Now repeat it for 8-12 times</li> </ul>	<p>Supine lying</p> 
19	<p>Knee to chest in lying</p> <ul style="list-style-type: none"> <li>• Lie down straight with hands by the side or placed behind the lower back and keep your knees bent foot resting on floor</li> <li>• Now TUCK your tummy</li> <li>• Keep both leg bent with foot firm on floor</li> <li>• Now lift one of the knee up and down to touch the floor and come back</li> <li>• Now repeat the same with other leg</li> </ul>	<p>Supine lying</p> 
<p><b>Core strengthening exercises-9-12 weeks</b>  <b>2-3 sets of 8-12 repetitions at a medium tempo</b></p>		
20	<p>Pelvic tilt in lying</p> <ul style="list-style-type: none"> <li>• Lie down straight with hands by the side or placed behind the lower back and keep your knees bent foot resting on floor</li> <li>• Now pull the tummy in and slowly tilt your pelvic bone backward as if to touch the floor</li> <li>• Hold this position for 10 seconds and relax</li> <li>• Repeat for 8-12 times</li> </ul>	<p>Crack lying</p> 

**Table B1.** TUCK Exercise Protocol (conclusion)

S.No	Exercises	Position
21	<p>Straight leg raises—lying</p> <ul style="list-style-type: none"> <li>• Lie down straight with hands by the side or placed behind the lower back</li> <li>• Now TUCK your tummy</li> <li>• Raise your right leg to a maximum of 70 degree or a minimum of 50</li> <li>• Then return to starting position</li> <li>• Now Repeat it with the other leg</li> </ul>	Supine lying 
22	<p>Long arm crunches</p> <ul style="list-style-type: none"> <li>• Lie down on your back with knees bent and feet flat on the floor. Extend the arms overhead, keep the arms straight throughout the movement</li> <li>• Now TUCK your tummy</li> <li>• Then, lift the shoulders off the ground while maintaining a steady and controlled motion. Exhale as you crunch up</li> </ul>	Crook lying 
23	<p>Double leg lifts</p> <ul style="list-style-type: none"> <li>• Lie down flat with hands by the side</li> <li>• Now TUCK your tummy</li> <li>• Now lift both the legs up by bending knees with foot together and bring both the knee to chest</li> <li>• Repeat this movement</li> </ul>	Supine lying 
24	<p>Heel touch</p> <ul style="list-style-type: none"> <li>• Lie down on a flat surface with hands by the side and knees bent placing foot on floor</li> <li>• Now TUCK your tummy</li> <li>• Now lift the shoulder blades off the floor facing the ceiling and try to touch your heel with fingers on alternative sides</li> <li>• Return to your starting position</li> </ul>	Crook lying 
25	<p>Cross crunches</p> <ul style="list-style-type: none"> <li>• Lie down on a flat surface with hands behind the neck and bend one of the knee and place the other feet on the floor</li> <li>• Now TUCK your tummy</li> <li>• Now lift the shoulder blades off the floor and twist your upper body to reach the bent knee with your elbow</li> <li>• Return to your starting position</li> <li>• Now repeat the same on the other side</li> </ul>	Crook lying 
26	<p>Dead bug</p> <ul style="list-style-type: none"> <li>• Lie down flat with arms facing ceiling and legs lifted to 90 degree with knees bent</li> <li>• Now TUCK your tummy</li> <li>• Now stretch your left leg and lower your right arm behind you until both are just above the ground, then return to the starting position</li> <li>• Repeat with the opposite arm and leg</li> </ul>	Supine lying 
27	<p>Dog bird—four legs</p> <ul style="list-style-type: none"> <li>• Kneel down on floor or any firm surface placing your hands on the surface (on all four)</li> <li>• Now TUCK your tummy</li> <li>• Now lift right arm up and leg up straight with out bending the knee or elbow</li> <li>• Hold this position for 10 seconds and relax</li> <li>• Repeat for 8-12 times</li> <li>• Now repeat the same on other side</li> </ul>	Four legs 
28	<p>Plank</p> <ul style="list-style-type: none"> <li>• Start on all fours position</li> <li>• Now TUCK your tummy</li> <li>• Place elbow below your shoulders and knees below your hips</li> <li>• Now straighten the legs behind, keeping your feet hip-width apart</li> <li>• Tighten your cor</li> <li>• Hold for 10 seconds</li> <li>• Repeat 8-12 times</li> </ul>	Four legs 

**Stretches**

Table B2. Quality performance ratings (to be continued)

Days/ week	0-1 week Yes/No	Rate your quality of performance	1-2 week Yes/No	Rate your quality of performance	2-3 week Yes/No	Rate your quality of performance	3-4 week Yes/No	Rate your quality of performance
Day-1								
Day-2								
Day-3								
Day-4								
Day-5								

Table B2. Quality performance ratings (continuation)

Days/ week	4-5 week Yes/No	Rate your quality of performance	5-6 week Yes/No	Rate your quality of performance	6-7 week Yes/No	Rate your quality of performance	7-8 week Yes/No	Rate your quality of performance
Day-1								
Day-2								
Day-3								
Day-4								
Day-5								

Table B2. Quality performance ratings (conclusion)

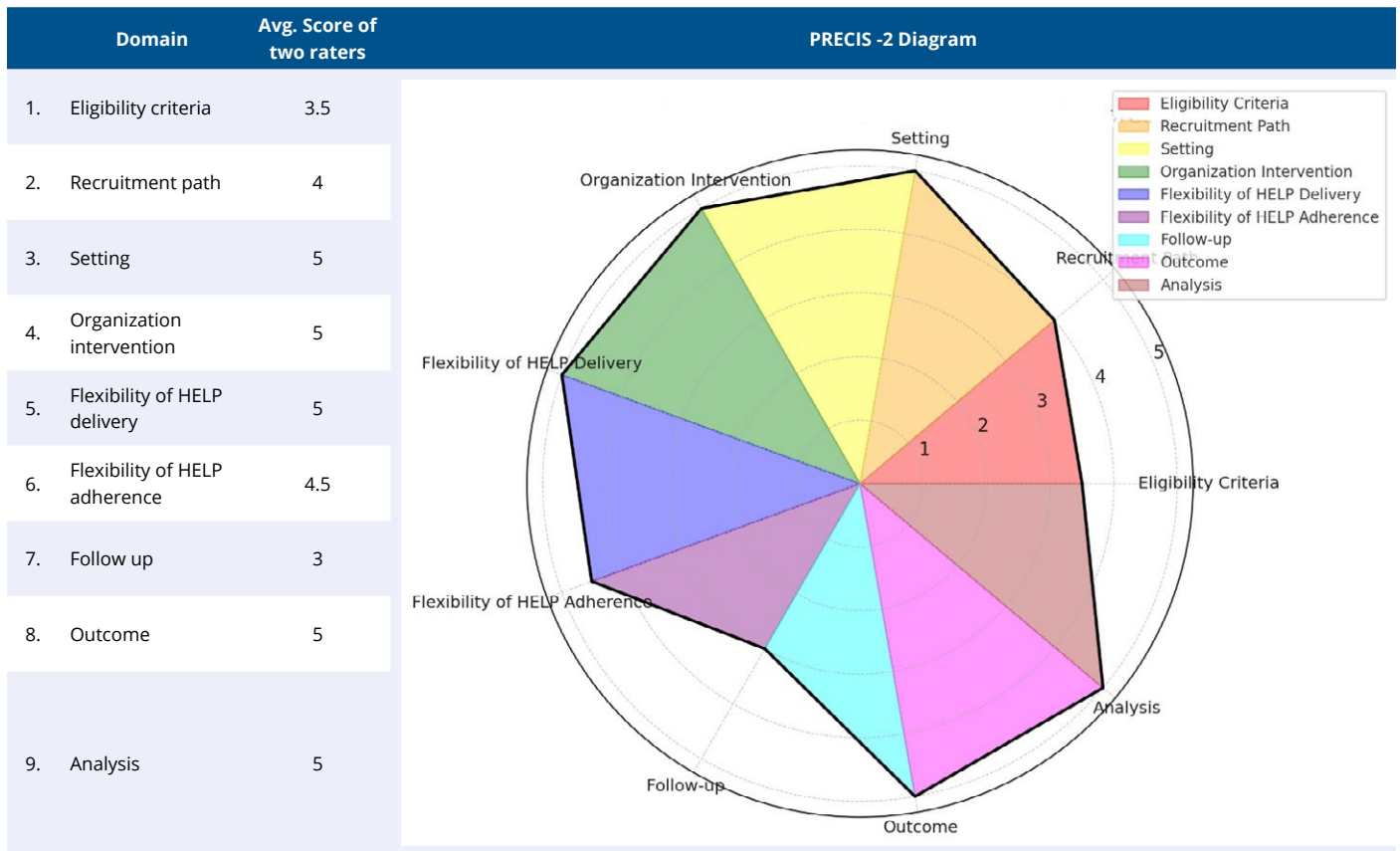
Days/ week	8-9 week Yes/No	Rate your quality of performance	9-10 week Yes/No	Rate your quality of performance	10-11 week Yes/No	Rate your quality of performance	11-12 week Yes/No	Rate your quality of performance
Day-1								
Day-2								
Day-3								
Day-4								
Day-5								

# Appendix C

## PRECIS-2

The pragmatic design assessment of the study highlights the application of the TUCK exercise protocol in the clinical practice. Through the utilization of PRECIS-2, the development of the pragmatic study outcomes is given a greater amount of focus. This evaluation of TUCK exercise protocol according to the rating grid as proposed by PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) guidelines, scores each item covering overall treatment and assessment outcomes (Table C1). Table C2 - PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) scoring for HELP with rationale. The average score among PRECIS domain is 4.44, which assigns this study a rather pragmatic design.

**Table C1.** Average of PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) scoring for TUCK exercise protocol



**Table C2.** PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) scoring for HELP with rationale

	Domain	Avg. Score of two raters	Rationale of Rater-1	Rationale of Rater-2
1	Eligibility criteria	3.5	P: inclusion of patients with OA knee and weak core muscles	P: inclusion of patients with low back pain and with smart phone E: focus recuing low back pain through exercise adherence
2	Recruitment path	4	P: Referral from different departments of SRM MCH and RC E: Checklist to assess eligibility	P: Recruitment of participant from SRM OPD units E: Checklist to assess eligibility
3	Setting	5	P: Outpatient unit is the ideal catchment area for OA knee	P: Catchment area is OPD
4	Organization intervention	5	P: Delivery of care for both the groups	P: Resource, expertise, and delivery of care in both the arm are similar
5	Flexibility of HELP delivery	5	P: Identical flexibility to routine care given	P: Identical flexibility to routine care given
6	Flexibility of HELP adherence	4.5	P: Weekly monitoring of exercise diary by the therapist	P: usual encouragement to adhere to routine PT
7	Follow up	3	P: Support calls for assistance till 12th week	P: Follow up through calls and assessment done
8	Outcome	5	P: Outcomes are important predictors of exercise adherence and improvement of symptoms	P: Outcomes are important predictors of exercise adherence and improvement of symptoms
9	Analysis	5	P: intention-to-treat analysis with all available data	P: intention-to-treat analysis with all available data

# Appendix D

**Table D1.** Schedule of enrolment, interventions and assessments for TUCK protocol

Trial type	STUDY PERIOD			
	Pre randomization	Base line assessment	Intervention period 0-6 weeks	Intervention period 6-12 weeks
	Feasibility trial			N A
	Definitive trial			
TIMEPOINTS**	0	T0	T1	T2
<b>ENROLMENT</b>				
Potential participant identification and screening	X			
Eligibility screening	X			
Informed consent	X			
Provision of PIS	X			
Core strength $\pm$ 40 mmHg	X			
Allocation				
<b>ASSESSMENTS</b>				
Demographic data		X		
Grade of OA		X		
Side involved		X		
Chronicity of OA		X		
<b>Outcome variables</b>				
Core strength ADIM		X	X	X
Core strength KLAT		X	X	X
4 Minute walk test		X	X	X
Timed Up and Go test		X	X	X
KOOS- PS		X	X	X
Double limb support time		X	X	X
Stride length		X	X	X
NPRS		X	X	X
<b>INTERVENTIONS</b>				
Standard care protocol		X		
TUCK protocol		X		

\*Recommended content can be displayed using various schematic formats. See SPIRIT 2013 Explanation and Elaboration for examples from protocols.

\*\*List specific timepoints in this row.

# Appendix E

**Table E1.** The TIDieR (Template for Intervention Description and Replication) Checklist for TUCK exercise protocol

1	BRIEF NAME	TUCK – Exercise protocol
2	WHY	Self-administered core rehabilitation intervention based on scheduled, progressive, repetitive, and goal-specific practice
3	WHAT	Materials - Exercise manual booklet will be provided to the participants, Pressure biofeedback unit to assess the core strength and KOOS-PS self-administered questionnaire Procedures: <ul style="list-style-type: none"> <li>• The program consisted of providing TUCK booklet to the participants to be done at home.</li> <li>• The schedule of progression of exercises consists of three sets of exercise each set lasting for about 30 mins, with warm up and cool down sessions are mentioned in the booklet.</li> </ul>
4.	WHO PROVIDED	The primary assessors and two to three volunteers were involved in categorising, assessing as well as training the participants and follow up for their home-based TUCK exercise protocol.
5.	HOW	The primary assessors were involved in categorising the participants based on inclusion criteria. The other assessors were along with the primary assessors were involved in training the home based TUCK exercise manual. They were also involved in assessing the participants during their 6th and 12th week of assessment. The primary assessors were involved in follow-up of the participants by phone calls.
6.	WHERE	The training was given once when they visit the department for the first time for treatment. Later they were given the exercise booklet and follow-up was done over phone calls.
7.	WHEN and HOW MUCH	One day training was given at the department for the first-time remaining sessions were done as a home-based exercise. No fees were collected for the training session
8.	TAILORING	The TUCK intervention was given for a total of 12 weeks where the first training session was given at the department on their visit and they were asked to continue the exercises at home by using the booklet as a guide. They were followed up through phone calls and were asked to report to the department on their 6th and 12th week. They were instructed to do exercise for 5 days a week with each session lasting for about 30 minutes. Participants were asked to report to the department whenever they feel any discomfort in doing the exercises.
9.	MODIFICATIONS	Participants were allowed to do exercise for 5 days in a week and also, they were allowed to do the exercise whenever they want to do it in a day. The TUCK exercises were given such that they increase the intensity slowly from the basic to advanced core training.
10.	HOW WELL	N / A
11.	Planned: If intervention adherence was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	The participants were assessed at three time points as T0 – baseline; T1- 6th week; T2 – 12th week. They were assessed for core strength, TUG, 4MWT, KOOS-PS, NPRS, double limb support time and stride length.