BMJ Open

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061648
Article Type:	Original research
Date Submitted by the Author:	11-Mar-2022
Complete List of Authors:	McNamara, Iain; Norfolk and Norwich University Hospital; University of East Anglia Pomeroy, Valerie; University of East Anglia Clark, Allan; University of East Anglia, Norwich Medical School Creelman, Graham; Mental Health Act Review Panels, Whitehouse, Celia; Norfolk and Norwich University Hospital Wells, J.; University of East Anglia Harry, B; University of Cambridge, Department of clinical neurosciences Smith, Toby; University of East Anglia, Faculty of Medicine and Health Sciences High, Juliet; norwich clinical trials unit Swart, Ann Marie; University of East Anglia; University of East Anglia, Health Sciences Clarke, Celia; University of East Anglia
Keywords:	HEALTH ECONOMICS, Knee < ORTHOPAEDIC & TRAUMA SURGERY, Clinical trials < THERAPEUTICS

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

TITLE PAGE

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility randomised controlled trial

Authors with affiliations, ORCID IDs and twitter handles

McNamara, I. Consultant Orthopaedic Surgeon Norfolk and Norwich University Hospital NHS foundation trust and Honorary Professor, University of East Anglia. ORCID ID: https://orcid.org/0000-0002-2051-8451

Pomeroy, V M. Professor of Neurorehabilitation, School of Health Sciences, University of East Anglia. ORCID ID: https://orcid.org/0000-0003-4487-823X

Clark, A. B. Associate Professor in Medical Statistics, Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia ORCID ID: https://orcid.org/0000-0003-2965-8941

Creelman, G. Chair, Mental Health Act Review Panels, Norfolk and Suffolk, NHS Foundation Trust; Visiting Professor of Media, Norwich University of the Arts.

Whitehouse, C.E., Orthopaedic Clinical Trials Research Nurse, Norfolk and Norwich University Hospital NHS Foundation trust

Wells, J. Researcher, School of Health Sciences, University of East Anglia. ORCID ID: 0000-0002-6752-762X.

Harry, B. Clinical Trials Project Coordinator, Department of Clinical Neurosciences, University of Cambridge. ORCID ID: https://orcid.org/0000-0002-6938-567X

Smith, T,O. Associate Professor in Physiotherapy, School of Health Sciences, University of East Anglia. ORCID ID: 0000-0003-1673-2954

High, J. Senior Trials Manager, Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia. ORCID ID: https://orcid.org/0000-0003-2555-2349

Swart, A M. Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia

Clarke, C. Lecturer in School of Health Sciences, University of East Anglia. ORCID ID: https://orcid.org/0000-0001-6584-9601

Corresponding author: Iain McNamara

Department of Trauma and Orthopaedics

Norfolk and Norwich University Hospital NHS Foundation Trust

Norwich

NR4 7UY

Iain.mcnamara@nnuh.nhs.uk

Word count: 4,229

ABSTRACT (300 words)

Objectives: To determine if a newer design of TKR (Journey II BCS) produces superior patient reported outcomes scores and biomechanical outcomes than the older, more established design (Genesis II).

Setting: Patients were recruited from an NHS University Hospital between July 2018 and October 2019 with surgery at two sites. Biomechanical and functional capacity measurements were at a University Movement and Exercise Laboratory.

Participants: 80 participants undergoing single-stage TKR.

Interventions: Patients either received the Journey II BCS or Genesis II TKR

Primary and secondary outcome measures: Primary outcome was the Oxford Knee Score (OKS), at six months. Secondary outcomes were: OKS Activity and Participation Questionnaire (OKS-APQ), EQ-5D-5L and UCLA Activity scores, Timed Up and Go Test (TUG), six-minute walk test (6MWT), lower limb kinematics and lower limb muscle activity during walking and balance.

Results: This study found no difference in the OKS between groups. The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20) respectively, adjusted effect size 0.35 (-2.01,2.71) p=0.771

In secondary outcome measures, the Genesis II group demonstrated a significantly greater walking range-of-movement (50.62 (7.33) versus 46.07 (7.71) degrees, adjusted effect size, 3.14 (0.61,5.68) p=0.02) and higher peak knee angular velocity during walking (mean (SD) 307.69 (38.96) versus 330.38 (41.40), adjusted effect size was 21.75 (4.54,38.96), p=0.01) and better postural control (smaller resultant centre of

path length) during quiet standing than the JII-BCS group (mean (SD) 158.14 (65.40) versus 235.48 (176.94) mm, adjusted effect size, 59.91 (-105.98,-13.85) p=0.01.).

Conclusions: In this study population, the findings do not support the hypothesis that the Journey II BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at six months after surgery. Newer designs of TKR do not necessary confer improved results when compared to older designs.

Trial registration: ISRCTN32315753, 12 December 2017.

Key words: Total knee replacement**,** Genesis II, Journey II BCS, PROMS, biomechanical analysis

Strengths and limitations

Strengths:

- This is a two arm, superiority, observer-blind, participant-blind and clinical staff-blind, randomised control trial
- It uses a wide variety of patient reported outcomes measures and biomechanical measurements to determine if one implant is superior to the other
- the required sample size was achieved with only one person lost to follow-up.

Weaknesses

- A potential limitation is the relatively large number of secondary outcomes.
- The surgeons all had a much greater familiarity with the implantations of Genesis II implants.

Summary boxes:

What is already known on this topic

Up to 34% of all patients following total knee replacement have poor functional outcomes. Rates of knee osteoarthritis are increasing worldwide on a yearly basis, and therefore the number of patients with intrusive symptoms after surgery is significant.

Multiple changes in knee replacement implant design have been introduced to try to improve patient outcomes. Newer implants are more costly and do not have patient outcomes or long term results to support their use. The Getting in Right First time (GIRFT) initiative is driving a rationalisation of implant device usage by cost and patient outcome data. Currently it is unclear whether the risks and costs of newer devices implant will translate to patient benefits.

What this study adds

This is a two arm, superiority, observer-blind, participant-blind and clinical staff-blind, randomised control trial to determine if an evolutionary design of TKR (Journey II BCS) produces superior patient reported outcomes scores and biomechanical outcomes than its predecessor, an older and more established design (Genesis II).

In this study population, the findings do not support the hypothesis that the Journey II BCS produces a better outcome than the Genesis II, for any of the primary or secondary outcomes at six months after surgery. This information is important for all stakeholders within the envelope of GIRFT when choosing an implant or planning a change from an older to a newer implant design. Such research should be undertaken before supporting widespread adoption of newer implants into use.

ORIGINAL PROTOCOL FOR THE STUDY UPLOADED AS A SUPPLEMENTAL FILE

INTRODUCTION

Despite total knee replacement (TKR) being an recommended surgical treatment for end-stage knee osteoarthritis[1], up to 34% of all patients following TKR have poor functional outcomes [2–6]. With estimates of osteoarthritis of the knee affecting one in eight people in the USA [7] and 250 million individuals worldwide [8] the number of patients with intrusive symptoms after surgery is significant.

Multiple changes in implant design have been introduced to try to improve patient outcomes and whilst some implant design alterations have led to improvements in patient-reported outcome measures (PROMS) [9–11] and kinematics [12,13] not all have led to differences [14–20].

The Genesis II (Smith & Nephew, Memphis, TN) TKR has been reported to have good survivorship and patient satisfaction [13,21] and commonly used in the UK [22] An evolutionary design, the Journey II BCS (JII-BCS; Smith & Nephew, Memphis, TN), also manufactured by Smith and Nephew, has been developed with the aim of improving kinematic outcome compared to the Genesis II by using a bicruciate design [23] This design change has been supported by encouraging fluoroscopic studies. However, to date, no randomised controlled trials have been conducted to assess if there is a difference in the outcome compared to its predicate design. [24].

The aim of this trial was to assess whether the JII-BCS would produce better patient reported and movement outcomes than the Genesis II.

The published protocol included the aims for investigating: the rotational profile around the native knee and following TKR; and patients' experiences and surgeons' experiences [25]. These findings will be reported in subsequent manuscripts.

METHODS

Trial design, randomisation, blinding to intervention allocation, ethics and registration

A two-arm, superiority randomised controlled trial (RCT) comparing the JII-BCS knee implant (experimental intervention) to the Genesis II knee implant (control intervention) was performed. The trial was observer-blind, participant-blind and clinical staff-blind. Only the operating surgeon and theatre team knew which implant was used for an individual participant.

Trial participants were assigned to either the JII-BCS or Genesis II group using a computer-generated, 1:1 randomisation schedule stratified by site and age (<60 years = younger; ≥60 years = older) [26,27]. Group allocation was revealed using REDCap [28,29], the interactive web-randomisation system, to a member of the research team who was not involved in either the clinical care or assessments of any participant. Allocation was concealed from the surgical team until after the pre-operation baseline measures were completed.

Ethical approval

Ethical approval was given by the East of England – Cambridge Central Research Ethics Committee (reference 16/EE/0230). All participants provided informed consent prior to enrolment.

Sample size

The sample size was calculated from the Oxford Knee Score (OKS, primary outcome measure) [30]. The RCT was powered at 80% with a 5% significance level to detect a minimally important clinical difference of five points [31,32] with a standard deviation of 7.4 points [33]. Accounting for an estimated attrition rate of 10% at six months post-surgery the estimated sample size was 80 participants (40 per group).

Participants, setting and recruitment

Full eligibility criteria are provided in the published protocol [25]. In brief, participants were aged at least 18 years and met the clinical and radiological criteria for a single-stage TKR. People were excluded if they: had a fixed-flexion deformity of at least 15º or non-correctable varus/valgus deformity of at least 15º; had inflammatory arthritis or previous septic arthritis; had previous surgery to the collateral ligaments of the affected knee; had a contralateral TKR implanted less than one year earlier; had severe co-morbidity that could present an unacceptable safety risk or were pregnant; were a private patient; were likely to be living outside the clinical centre catchment area at six months post-surgery; or were enrolled on another clinical trial.

Patients were recruited at a university teaching hospital with surgery conducted at two sites. Outpatient physiotherapy was conducted in a single hospital. The Movement and Exercise Laboratory at the associated University (MoveExLab) was the setting for measures of functional capacity and biomechanics.

Interventions

All participants received routine NHS care for people with TKR irrespective of the implant received. This included following a standard post-operative rehabilitation of out-patient physiotherapy centred on knee strength and range of motion exercises within the first six weeks after surgery.

Experimental intervention

Participants in the experimental group received the JII-BCS. The JII-BCS is a dual-cam post designed to substitute for both the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) to promote normal knee kinematics and increase anteroposterior (AP) stability throughout knee flexion.

Control intervention

Participants in the control group received the Genesis II (Smith and Nephew, Memphis TN), posterior stabilised (PS) TKR.

Surgical techniques

All four surgeons had extensive experience, at least five years, of the Genesis II implant. All undertook cadaveric training on the JII-BCS and declared that they were competent in the surgical technique having completed their operative learning curve before starting the trial. The surgical procedure followed the standard surgical approach and technique through a medial parapatellar approach in all cases. Patella resurfacing was used in both groups.

Data collection schedule

Data collection timepoints for the primary outcome measure were: at least one day before surgery (baseline), 7±2 days after surgery (one-week post-operatively), 6-8±2 weeks after surgery (two months), six months ±4 weeks after surgery (outcome, primary time point). Secondary outcomes were collected at baseline, two months and six months. Any differences from these timepoints are provided in the outcome measures section.

Outcome measures

Primary outcome measure

The Oxford Knee Score (OKS) was the primary outcome measure. This is a 12-question patient self-assessment of knee function and pain [30] with values ranging from 0 (worst outcome) to 48 (best outcome.

Secondary outcome measures

1. Patient reported outcome questionnaires

a. The OKS Activity and Participation Questionnaire (OKS-APQ) which complements the OKS by assessing everyday activity and social participation [34]. The overall score is from 12 to 60 with 12 being the best outcome.
b. The EQ-5D-5L is a self-report questionnaire consisting of five questions and a visual analogue scale (VAS). Higher values indicate better quality of life [35].
c. The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10 (participation in impact sport). .

2. Walking and balance function
    a. Timed Up and Go Test (TUG) – seconds to rise from chair, walk 3m and return to sitting; mean of three trials [36]. The reported minimal detectable change after TKR is 2.27 seconds [37]. A lower value indicates better function.
    b. Six-minute walk test - metres walked in six minutes around a 20-metre circuit [38,39]. The reported minimal detectable change from baseline after TKR is 26 metres [40]. A higher value indicates greater function.
    c. Modified Star-Excursion Test [41] (cm/leg length) where larger values indicate better balance.
3. Temporal-spatial gait parameters, lower limb kinetics, lower limb kinematics and lower limb muscle activity during walking and balance.

    For these simultaneous measures, participants wore shorts and were bare-footed. Reflective sensors were placed in accordance with the Plug-In Gait model (Vicon) for the lower limb and 3D motion data were collected, at 100 HZ, with eight wall-mounted infrared cameras (Vicon Motion System, Oxford UK). Three embedded force plates (BERTEC, Ohio, USA) were used to collect kinetic data at 2000Hz for walking tasks and 100hz for balance tasks. Surface electromyographic sensors (EMG, Delsys) were placed bilaterally on the Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Bicep Femoris and lateral head of the Gastrocnemius following SENIAM guidance. EMG data was collected at 2000 Hz.

For walking tasks, participants were asked to walk in a straight line along a 10-metre walkway at their self-selected speed. For double stance activities, participants were instructed to stand with their feet shoulder-width apart. For single stance activities, participants were instructed to stand on one leg in the centre of one force plate with hands-on-hips. Three trials of 10 seconds were recorded for each activity.

For the stair ambulation task, participants were asked to complete six ascents and six descents all unaided, leading with the operated limb for three trials and the non-operated limb for the remainder. The stairs had four steps. The first step was 16.5 cm and the others were 15 cm high. Handrails were available if participants needed support.

Motion data were processed in accordance with the Plug-in Gait Model. Raw EMG was filtered with pass bands at 10 and 500 Hz, rectified and low pass filtered using a 4th order Butterworth with a 10 Hz cut off. Walking data were normalised to 101 data points for the gait cycle. Three trials of tasks were used to create a mean for each measure per participant. Values were extracted using a purpose-built Matlab script.

a. Walking speed (meters/second). A higher value indicates better function.
b. Walking symmetry – step length ratio calculated as ((2xOp)/Op+NOP))-1); where Op is the step length of the operated leg and NOP is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.
c. Double stance support (% of gait cycle). A lower value indicates better performance
d. Cadence, (steps/min) step length (m), and stride length(m) were also provided from the Vicon data output. These values are provided in the online supplement (Table S1) for completeness only because there is measurement redundancy if all temporal-spatial measures of gait are analysed statistically.
e. Peak extension and flexion moments of operated knee during the gait cycle (Nm/kg). A higher value indicates better function.
f. Hip, knee, and ankle range-of-motion during walking. Higher values indicate better function

g. Peak knee angular velocity during walking (inadvertently omitted from the statistical analysis plan) and stepping up onto a stair. Higher value indicates better function.
h. Percentage of gait cycle for peak activation of Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Biceps Femoris and Lateral head of Gastrocnemius (% of gait cycle).
i. Single stance on the operated lower limb for 10 seconds with eyes open (yes/no) and duration maintained.
j. Resultant centre of pressure path length (COP cm) in double stance with eyes closed: lower path length indicates better balance ability.
k. Resultant COP velocity (cm/s) in double stance with eyes closed: lower velocity indicates better balance ability [42].

4. Protocolised secondary measures not reported
   a. the Forgotten Joint Score (FJS) is not reported because the score was incorrectly collected for 90% of participants making the data unusable for analysis.
   b. Maximal voluntary isometric contractions about the knee joint, using a Cybex Isokinetic Dynamometer were added for both the knee extensors and flexors to protocol version 2.3. Because this additional measure was added after the project had begun and there was a subsequent mechanical fault with the equipment, only 15 participants provided data at all three time points. These unrepresentative data are omitted from this report.
   c. Time-To-Boundary (TTB) [43] is not reported here because many participants were unable to balance for the full 10 seconds.
   d. Kinematic and kinetic data collection was planned for ascent/descent of a set of four steps. However, participants needed support rails to undertake the task and/or maintain safety. The rails prevented full sight of the Vicon markers. Consequently, there were large gaps in the raw trajectory data that compromised data integrity.

Clinical context and adverse events

Data on length of hospital stay and complications related to the surgery (e.g. anaesthesia-related problems, bleeding, morbidities) was collected from a notes review. At each visit, participants were asked about their pain medication and if they had received additional

treatment since their surgery/previous visit and what this entailed. Any need for revision surgery was recorded. All adverse events identified were tracked until resolution.

Analysis

The statistical analysis plan (SAP) was finalised and agreed prior to database lock and analysis was completed blinded to group allocation (Supplementary file). For all outcomes the hypothesis tests and 95% confidence intervals (CI) were two-sided; and a p-value of <0.05 was considered significant. An intention-to-treat analysis was conducted i.e., all randomised participants regardless of their eligibility or adherence were analysed according to the treatment they were randomised to receive. The analysis was undertaken by the Trial Statistician using Stata version 16.

The primary outcome, OKS at six months was analysed using a general linear model adjusting for site and age (<60years/≥60years). An adjusted analysis was conducted by adjusting for the OKS at baseline. The model assumptions were checked graphically and sensitivity analysis done using a non-parametric bootstrap.

The secondary outcomes were analysed separately at two months and six months using the same linear model used for the primary outcome measure. The exception was ability to balance for 10 seconds. This was analysed using a logistic regression model.

The walking function, temporal-spatial gait parameters, balance ability and lower limb kinematic values were compared between the control and the experimental group at each follow-up time-point separately using a general linear model.

Patient and public involvement

A patient representative, who had previously undergone knee replacement surgery, was involved in the protocol development, assessment of the burden of the intervention and time taken to participate in the research and oversight of the trial as a member the trial management group. The representative also contributed to the planning and writing of research dissemination materials.

RESULTS

Participants were recruited between July 2018 and October 2019. Last follow-up visits were in October 2020 with some impact and delayed visits due to COVID-19.

In the published protocol [25] the analysis plan included a per-protocol and safety analysis. This was not undertaken as the implants were used as intended so these populations would be the same as the intention-to-treat population.

Flow of participants through the trial

In total, 105 of 153 people screened were eligible to take part, 16 declined participation and eight were excluded for other reasons. Therefore, 81 of 153 people (53%) were recruited. All participants in the Genesis II group (n=40) received their allocated intervention. In the JII-BCS group (n=41) one participant withdrew prior to surgery (post-randomisation exclusion). Full details are in the CONSORT Flowchart (Figure I).

Participant characteristics

There were no discernible baseline differences between the groups. (Table 1 and online supplement) so a summary of key characteristics for all participants is provided here. Participants' age was a mean of 68.61 (SD 6.90) years, mean body mass index was 29.32 (SD 4.28) and 55% were female. Mean (SD) OKS was 19.65 (5.49) and median (IQR) score on the Pain Self-Efficacy-2 Questionnaire was 8.0 (4.0,10.0). EQ-5D mean (SD) scores were 0.49 (0.18) for utility and 55.54 (18.10) for the VAS. Mean (SD) walking speed was 0.94 (0.20) metres/second. Mean operated knee range-of-movement was 43.24 (SD 9.25) degrees.

Table 1. The baseline characteristics of participants

	JII-BCS (n=40)	Genesis II (n=40)
Age, mean (SD)	69.28 (7.50)	67.95 (6.28)
Sex, female, number (%)	24 (60.0%)	20 (50.0%)
Body Mass Index, mean (SD)	28.77 (4.25)	29.86 (4.29)
Operated knee, right, number (%)	23 (57.0%)	14 (35.0%)
Intraoperative Am Soc Anaesthesiologists		
Score 1, number (%)	4 (10%)	2 (5%)
Score 2, number (%)	35 (88%)	36 (90%)
Score 3, number (%)	1 (3%)	2 (5%)
Previous contralateral knee implant		
yes, number (%)	7 (17.5%)	6 (15.0%)
no, number (%)	26 (65.0%)	22 (55.0%)
Missing, number (%)	7 (17.5%)	12 (30.0%)
Previous hip surgery, yes, number (%)	5 (13.0%)	5 (13.0%)
Employment, retired, number (%)	25 (63.0%)	24 (60.0%)
Pain Self-Efficacy-2 Questionnaire, median (IQR)	8.0 (6.0,10.0)	6.0 (3.0,9.5)
Hospital Anxiety & Depression Scale		
Anxiety total, mean (SD)	6.32 (3.54)	7.43 (3.05)
Depression total, mean (SD)	6.03 (2.37)	8.05 (3.55)
Oxford Knee Score, mean (SD)	20.25 (5.69)	19.05 (5.28)
EQ-5D utility score, mean (SD)	0.52 (0.16)	0.47 (0.20)
EQ-5D visual analogue score, mean (SD)	59.78 (17.70)	51.30 (17.71)
Timed Up and Go time (seconds), mean (SD)	11.34 (3.40)	11.04 (3.33)
Six-minute walk distance (metres), mean (SD)	304.03 (79.75)	299.09 (85.69)

Walking speed, mean (SD)	0.95 (0.21)[a]	0.93 (0.20)
Step length ratio, mean (SD)	-0.00 (0.04)[a]	-0.00 (0.04)
Operated knee range-movement (degrees), mean (SD)	42.11 (9.90)[a]	44.35 (8.56)
Operated leg single stance eyes open (secs), mean (SD)	5.60 (3.44)[b]	5.58 (3.28)[b]

[a] = 39 participants; [b] = 38 participants.

EQ-5D is a measure of health-related quality of life, in the range of -0.109 (worst possible state) and 1.0 (perfect health), anchored at 0 (death).
EQ-VAS is a health state assessment ranging between 0 and 100, in which zero is worst imaginable health state and 100 is best imaginable health state.
OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).
Timed Up and Go Test (TUG) – seconds to rise from chair, walk 3m and return to sitting; mean of three trials. A lower value indicates better function.
Six-minute walk test - metres walked in six minutes around a 20-metre circuit A higher value indicates greater function.
The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10

Primary outcome comparison – six months post-operatively (Table 2)

The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20) respectively. There was no significant difference between the groups: adjusted effect size 0.35 (-2.01,2.71) p=0.771.

Post-operative clinical context and adverse events

There were no between-group significant differences for: length of stay, change in pain medication from randomisation or physiotherapy received (online supplement Tables S2 and S3).

Secondary outcome comparisons – six months post-operatively (Table 2)

Patient-reported outcome questionnaires

There was no difference between the two groups for OKS-APQ. The mean (SD) values for the JII-BCS and Genesis II groups were 70.83 (23.81) and 74.14 (25.46) respectively. The adjusted effect size was 3.31 (-8.05,14.67) p=0.56.

No difference between the groups was found for EQ-5D-5L. Utility score mean (SD) values for the JII-BCS and Genesis II groups were 0.90 (0.12) and 0.89 (0.13) respectively. The adjusted effect size was 0.00 (-0.06,0.05) p=0.95. For the VAS score the mean (SD) was 89.03 (9.44) for the JII-BCS group and 87.55 (12.75) for the Genesis II group. Adjusted effect size was -1.04 (-5.32,4.23) p=0.70.

For the UCLA there was no difference between the groups. Mean (SD) scores were 6.87 (1.38) for the JII-BCS group and 6.68 (1.44) for the Genesis II group. The adjusted effect size was 0.08 (-0.69,0.5).

Table 2. Oxford Knee Scores (OKS, primary outcome), OKS-APQ, EQ5D-5L and UCLA from baseline to six months after surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
OKS											
JII-BCS	20.25 (5.69) (n=40)	34.10 (7.10) (n=39)	42.97 (5.21) (n=39)	1.97 (-1.37,5.32)	0.24	2.5 (-0.71,5.71)	0.12	0.24 (-2.10,2.58)	0.84	0.35 (-2.01,2.71)	0.77
Genesis II	19.05 (5.28) (n=40)	36.00 (7.61) (n=40)	43.13 (5.20) (n=40)								
OKS-APQ											
JII-BCS	2.81 (6.63) (n=40)	36.09 (27.05) (n=40)	70.83 (23.81) (n=39)	11.63 (-1.87,25.14)	0.09	12.09 (-1.63,25.8)	0.08	3.66 (-7.53,14.84)	0.52	3.31 (-8.05,14.67)	0.56
Genesis II	1.41 (3.39) (n=40)	47.34 (32.50) (n=40)	74.14 (25.46) (n=40)								
EQ5D Utility											
JII-BCS	0.52 (0.16) (n=40)	0.74 (0.10) (n=40)	0.90 (0.12) (n=39)	0.05 (-0.01,0.1)	0.11	0.05 (0.00,0.11)	**0.05**	0.00 (-0.06,0.05)	0.89	0.00 (-0.06, 0.05)	0.95
Genesis II	0.47 (0.20) (n=40)	0.78 (0.14) (n=40)	0.89 (0.13) (n=40)								

EQ5D VAS										
JII-BCS	59.78 (17.70) (n=40)	77.85 (14.12) (n=40)	89.03 (9.44) (n=39)	0.65 (-6.18,7.48)	0.85	2.89 (-3.92,9.70)	0.40	-1.71 (-6.77,3.35)	0.50	-1.04 (-6.32,4.23)	0.70
Genesis II	51.30 (17.71) (n=40)	78.25 (16.11) (n=40	87.55 (12.75) (n=40)								
UCLA										
JII-BCS	1.10 (0.78) (n=40)	4.82 (1.62)[b] (n=40)	6.87 (1.38) N=38)	0.23 (-0.5,0.95)	0.53	0.25 (-0.48,0.98)	0.49	-0.13 (-0.74,0.48)	0.67	0.08 (-0.69,0.53)	0.79
Genesis II	3.00 (0.85) (n=40)	5.05 (1.60)[b] (n=40)	6.68 (1.44) (n=40)								

[a] adjusted for strata used in randomisation and for baseline scores, [b] median (IQR)

OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).

The OKS Activity and Participation Questionnaire (OKS-APQ) which complements the OKS by assessing everyday activity and social participation. The overall score is from 12 to 60 with 12 being the best outcome.

EQ-5D is a measure of health-related quality of life, in the range of -0.109 (worst possible state) and 1.0 (perfect health), anchored at 0 (death).

EQ-VAS is a health state assessment ranging between 0 and 100, in which zero is worst imaginable health state and 100 is best imaginable health state.

The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10 (participation in impact sport).

Walking function (Table 3)

There was no difference between the JII-BCS and Genesis II groups in the time to complete the TUG Test: mean (SD) for the JII-BCS group was 10.30 (2.90) seconds and for the Genesis II group was 9.76 (2.36) seconds. The adjusted effect size was –0.37 (-1.25,-0.50), p=0.40.

No statistically significant difference was found between groups for six-minute walk distance (p=0.07). Mean (SD) distance for JII-BCS was 343.41 (73.44) metres and for Genesis II was 363.39 (58.85) metres: adjusted effect size was 20.19 (-1.60,41.98), p=0.07.

Table 3. Walking function and temporal-spatial gait parameters from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	Unadjusted p-value	Adjusted[a] effect size (95% CI)	Adjusted[a] p-value	Unadjusted effect size (95% CI)	Unadjusted p-value	Adjusted[a] effect size (95% CI)	Adjusted[a] p-value
Walking function											
Timed Up & Go Test (secs)											
JII-BCS	11.34 (3.40) (n=40)	11.89 (3.92) (n=37)	10.30 (2.90) (n=35)	1.61 (-3.11,-0.1)	**0.04**	-1.32 (-2.48,-0.16)	**0.03**	-0.62 (-1.91,0.66)	0.34	-0.37 (-1.25,0.50)	0.40
Genesis II	11.04 (3.33) (n=40)	10.42 (2.45) (n=37)	9.76 (2.36) (n=34)								
6-minute walk test (metres)											
JII-BCS	304.03 (79.95) (n=40)	272.20 (71.51) (n=39)	343.41 (73.44) (n=35)	30.12 (-1.16,61.39	0.06	32.2 (5.74,58.65)	**0.02**	22.24 (-9.72,54.2)	0.17	20.19 (-1.60,41.98)	0.07
Genesis II	299.09 (85.69) (n=40)	298.87 (65.23) (n=37)	363.39 (58.85) (n=34)								
Temporal-spatial gait parameters											
Walk speed (metres per sec)											
JII-BCS	0.95 (0.21) (n=39)	0.90 (0.23) (n=37)	1.09 (0.22) (n=35)	0.08 (-0.02,0.17)	0.11	0.09 (0.01,0.17)	**0.03**	0.05 (-0.05,0.15)	0.34	0.03 (-0.04,0.09)	0.40
Genesis II	0.93 (0.20) (n=40)	0.97 (0.17) (n=37)	1.13 (0.18) (n=34)								

Step length ratio										
JII-BCS	-0.00 (0.04) (n=40)	0.03 (0.04) (n=37)	0.02 (0.04) (n=35)	-0.02 (-0.04,0.00)	**0.02**	-0.02 (-0.04,0.00)	**0.02**	-0.01 (-0.03,0.00)	0.10	-0.01 (-0.03,0.00)	**0.05**
Genesis II	-0.00 (0.04) (n=40)	0.01 (0.04) (n=37)	0.00 (0.04) (n=34)							
Double stance (% gait cycle)										
JII-BCS	0.30 (0.07) (n=39)	0.32 (0.11) (n=37)	0.25 (0.08) (n=35)	-0.02 (-0.06,0.02)	0.33	-0.03 (-0.07,0.00)	0.07	-0.01 (-0.04,0.02)	0.60	0.00 (-0.02,0.02)	0.69
Genesis II	0.32 (0.09) (n=40)	0.30 (0.07) (n=37)	0.25 (0.05) (n=34)							

[a] adjusted for strata used in randomisation and for baseline scores

Timed Up and Go Test (TUG) – seconds to rise from chair, walk 3m and return to sitting; mean of three trials. A lower value indicates better function.

Six-minute walk test - metres walked in six minutes around a 20-metre circuit. A higher value indicates greater function.

Walking speed (meters/second). A higher value indicates better function.

Walking symmetry – step length ratio calculated as ((2xOp)/Op+NOP))-1); where Op is the step length of the operated leg and NOP is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.

Double stance support (% of gait cycle). A lower value indicates better performance

Balance function and kinetics (Table 4)

There was no between-group difference for standing on operated leg only for 10 seconds with eyes open. The number (%) for the JII-BCS and Genesis II groups was 15/35 (42.9%) and 10/34 (29.4%) respectively. The adjusted effect size was 0.62 (0.17,2.28) p=0.471. Likewise, for seconds standing on the operated leg only with eyes open. Mean (SD) values were: JII-BCS 6.37 (3.36) seconds,

Genesis II 6.03 (3.23) seconds. Adjusted effect size was -0.41 (0.48) p=0.48. Data for the non-operated leg is provided for completeness in the online supplement (Table S4)

The Star-Excursion Test was attempted with participants but 59% of participants at baseline, 59% at follow up and 63% at outcome were unable to complete it. Therefore, collected data is provided in Table S4 of the online supplement.

The Genesis II group had a smaller COP path length than the JII-BCS group (p=0.001). The mean (SD) values for the Genesis II and JII-BCS groups were 158.14 (65.40) mm and 235.48 (176.94) mm, respectively. Adjusted effect size was -59.91 (-105.98,-13.85) p=0.01.

Because of measurement redundancy between COP path length and COP velocity the data for the latter are provided in Table S5 of the online supplement.

Table 4. Balance ability and operated lower limb knee kinetics from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Can stand for 10 secs only on operated leg, eyes open (number)											
JII-BCS	13/40 (32.5%)	13/39 (33.3%)	15/35 (42.9%)	0.92 (0.34,2.49)	0.88	1.17 (0.34,4.07)	0.80	0.56 (0.20,1.51)	0.249	0.62 (0.17,2.28)	0.47
Genesis II	10/40 (25.0%)	11/37 (29.7%)	10/34 (29.4%)								
Seconds standing only on operated leg, eyes open											
JII-BCS	5.60 (3.44) (n=38)	5.95 (3.56) (n=35)	6.67 (3.36) (n=33)	-0.09 (-1.73,1.55)	0.92	0.26 (-0.93,1.45)	0.66	-0.65 (-2.29,1.00)	0.43	-0.41 (-1.57,0.75)	0.48
Genesis II	5.58 (3.28)	5.78 (3.20)	6.03 (3.23)								

	(n=38)	(n=36)	(n=33)								
COP path length (mm) standing on both legs											
JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	235.48 (176.94) (n=35)	7.00 (-48.53,62.53)	0.80	23.72 (-10.93,58.37)	0.18	82.42 (-147.17,-17.67)	**0.01**	-59.91 (-105.98,-13.85)	**0.01**
Genesis II	188.25 (125.93) (n=40)	226.09 (137.15) (n= 36)	158.14 (65.40) (n=34)								
Peak extension moment operated knee during walking (Nm/Kg)											
JII-BCS	-0.34 (0.09) (n=37)	-0.30 (0.10) (n=38)	-0.41 (0.08) (n=34)	-0.03 (-0.08,0.01)	0.16	-0.03 (-0.07,0.02)	0.22	-0.02 (-0.05,0.02)	0.45	-0.02 (-0.05,0.02)	0.35
Genesis II	-0.32 (0.08) (n=40)	-0.33 (0.10) (n= 37)	-0.42 (0.08) (n=34)								
Peak flexion moment operated knee during walking (Nm/Kg)											
JII-BCS	0.52 (0.25) (n=37)	0.38 (0.22 (n=38)	0.55 (0.27) (n=34)	-0.06 (-0.16,0.04)	0.22	-0.06 (-0.15,0.04)	0.26	0.11 (-0.23,0.02)	0.10	-0.07 (-0.19,0.05)	0.22
Genesis II	0.44 (0.21) (n=40)	0.34 (0.21) (n=37)	0.45 (0.25) (n=34)								

[a] adjusted for strata used in randomisation and for baseline scores

Single stance on the operated lower limb for 10 seconds with eyes open (yes/no) and duration maintained.

Resultant centre of pressure path length (COP cm) in double stance with eyes closed: lower path length indicates better balance ability.

Peak extension and flexion moments of operated knee during the gait cycle (Nm/kg). A higher value indicates better function.

Temporal-spatial gait parameters (Table 3)

Mean (SD) walking speed was greater for the Genesis II group, 1.13 (0.18) metres/second, than the JII-BCS group, 1.09 (0.22) metres/second. However, the adjusted effect size was not statistically significant: 0.03 (-0.04,0.09), p=0.40.

Walking symmetry as assessed by step length ratio was not significantly different between groups. Mean (SD) for JII-BCS 0.03 (0.04), Genesis II 0.01 (0.04), adjusted effect size -0.01 (-0.03, 0.00), p=0.05.

Double stance support (% of gait cycle) was similar for groups. Mean (SD) values were: JII-BCS 0.25 (0.08)%, Genesis II 0.25 (0.05)%. Adjusted effect size was 0.00 (-0.02,0.02) p=0.69.

Operated lower limb kinetics (Table 4)

There was no difference between the groups for either operated knee extension or flexion moment (Table 4). The adjusted effect sizes for operated knee extension and flexion moments were -0.02 (-0.05,0.02) p=0.35 and -0.07 (-0.19,0,05) p=0.22 respectively.

Data for the non-operated lower limb are provided in Table S6 of the online supplement.

Operated lower limb kinematics (Table 5)

The Genesis II group had a greater range-of-movement of the knee joint during walking than the JII-BCS group: mean (SD) values were 50.62 (7.33) degrees and 46.07 (7.71) degrees respectively. The adjusted effect size was 3.14 (0.61,5.66) p=0.02 (Table 6).

For hip and ankle joint range-of-movement during walking there were no differences between the groups. For the ankle the adjusted effect size was 0.08 (-1.89,2.04) p=0.94. For the hip the adjusted effect size was 1.64 (-0.11,3.39) p=0.07.

Peak knee angular velocity (degrees/second) during walking was greater for the Genesis II than the JII-BCS group. For JII-BCS and Genesis II respectively, the mean (SD) values were 307.69 (38.96) and 330.38 (41.40). The adjusted effect size was 21.75 (4.54,38.96), p=0.01.

Data for the non-operated lower limb are provided in Table S7 of the online supplement.

Table 5. Lower limb kinematics from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Knee range-of-movement – walk (degrees)											
JII-BCS	42.11 (9.90) (n=39)	37.87 (7.73) (n=38)	46.07 (7.71) (n= 35)	4.51 (0.39,8.64)	**0.03**	3.42 (-0.41,7.24)	0.08	4.77 (1.11,8.43)	**0.01**	3.14 (0.61,5.68)	**0.02**
Genesis II	40.31 (5.93) (n=40)	42.25 (9.75) (n=38)	50.62)7.33) (n=34)								
Hip range-of-movement – walk (degrees)											
JII-BCS	40.00 (6.04) (n=39)	38.90 (5.44) (n=38)	41.56 (6.01) (n=35)	2.24 (-0.48,4.95)	0.11	1.93 (-0.20,4.06)	0.07	3.01 (0.20,5.82)	**0.04**	1.64 (-0.11,3.39)	0.07
Genesis II	40.31 (5.93) (n=40)	41.03 (6.15) (n=37)	44.44 (5.48) (n=34)								
Ankle range-of-movement – walk (degrees)											
JII-BCS	24.84 (6.57) (n=39)	21.69 (4.54) (n=38)	24.54 (6.63) (n=35)	0.75 (-1.21,2.71)	0.45	1.36 (0.22,2.94)	0.09	-1.37 (-4.21,1.28)	0.31	0.08 (-1.89,2.04)	0.94
Genesis II	23.10 (5.52) (n=40)	22.43 (3.76) (n=37)	23.22 (3.77) (n=34)								
Peak knee angular velocity – walking (degrees/second											
JII-BCS	283.10 (53.83) (n=39)	269.65 (36.75) (n=38)	307.69 (38.96) (n=35)	23.15 (-0.84,47.14)	0.06	16.47 (-6.21,39.14)	0.15	31.00 (10.34,51.66)	**0.01**	21.75 (4.54,38.96)	**0.01**
Genesis II	300.36 (55.56) (n=40)	321.65 (43.31) (n=38)	330.38 (41.40) (n=35)								
Peak knee angular velocity – stairs (degrees/second)											
JII-BCS	221.70 (88.35) (n=37)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31 (16.67,91.96)	**0.01**	51.63 (15.36,87.89)	**0.01**	49.01 (5.92,94.04)	**0.03**	35.15 (-3.09,73.39)	0.07

Genesis II	243.74 (84.05) (n=38)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)

[a] adjusted for strata used in randomisation and for baseline scores

Hip, knee, and ankle range-of-motion during walking. Higher values indicate better function

Peak knee angular velocity during walking and stair climbing. Higher value indicates better function.

Muscle activity, operated lower limb, during walking (Table 6)

No differences were found between the groups for the percentage of the gait cycle for peak activity of vastus medialis, vastus lateralis, tibialis anterior, biceps femoris or lateral head of gastrocnemius. Adjusted effect sizes ranged from -10.97(-25.69,4.74) p=0.17 for peak activation of biceps femoris to 6.06 (-2.14,14.26) p=0.14 for tibialis anterior.

Data for the non-operated lower limb are provided in Table S8 of the online supplement.

Table 6. Muscle activity during walking, operated lower limb, from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Peak activation Vastus Medialis (% of gait cycle)											
JII-BCS	28.62 (27.23) n=39	25.42 (24.93 n=38	23.20 (22.72) n=35	-1.22 (-12.1,9.65)	0.82	-1.13 (-11.98,9.72)	0.84	1.86 (-9.46,13.16)	0.74	1.4 (-9.43,12.22)	0.80
Genesis II	30.10 (27.73) n=40	23.18 (22.66) n=38	24.64 (24.94) n=33								

Peak activation Vastus Lateralis (% of gait cycle)										
JII-BCS	18.44 (12.15) n=39	17.29 (11.51) n=38	13.03 (5.61) n=35	1.20 (-5.67,8.07)	0.73	1.11 (-5.78,8.01)	0.75	4.59 (-1.92,12.71)	0.12	5.63 (-1.65,12.9)	0.13
Genesis II	20.23 (20.35) n=40	18.47 (17.46) n=38	18.79 (19.89) n=33								
Peak activation Tibialis Anterior (% of gait cycle)										
JII-BCS	23.46 (24.74) n=39	18.97 (20.91) n=38	15.20 (14.27) n=35	0.47 (-9.18,10.13)	0.92	0.54 (-9.21,10.28)	0.91	4.68 (-3.92,13.28)	0.28	6.06 (-2.14,14.26)	0.14
Genesis II	28.88 (27.88) n=40	19.82 (20.76) n=38	19.61 (20.32) n=33								
Peak activation Biceps Femoris (% of gait cycle)										
JII-BCS	25.03 (25.32) n=39	21.87 (21.34) n=38	35.77 (34.01) n=35	6.76 (-5.49,19.01)	0.28	5.71 (-6.42,17.84)	0.35	-2.78 (-25.03,5.76)	0.21	-10.97 (-26.69,4.74)	0.17
Genesis II	29.98 (28.00) n=40	29.16 (31.55) n=38	25.30 (28.86) n=33								
Peak activation Lateral head of Gastrocnemius (% of gait cycle)										
JII-BCS	24.67 (17.24) n=39	23.87 (19.34) n=38	20.66 (15.99) n=35	-1.18 (-8.9,6.53)	0.76	-1.01 (-8.55,6.52)	0.79	-1.84 (-8.61,4.93)	0.59	-1.89 (-8.79,5.01)	0.59
Genesis II	25.23 (22.36) n=40	23.39 (14.60) n=38	20.00 (13.80) n=33								

[a] adjusted for strata used in randomisation and for baseline scores

Percentage of gait cycle for peak activation of Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Biceps Femoris and Lateral head of Gastrocnemius (% of gait cycle).

Adverse events

One patient with a JII-BCS developed acute swelling and pain in the knee and was systemically unwell at 4 months post operatively. The joint aspiration demonstrated turbid fluid and an exchange of the polyethylene spacer and retention of the femoral and tibial components (Debridement And Implant Retention, (DAIR)) was performed with post operative antibiotic treatment. Subsequent

microbiology was negative so infection was never conclusively demonstrated. The numbers and type of complications are reported in Table S9.

DISCUSSION

The findings do not support the hypothesis that the JII-BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at six months after surgery. No differences between groups were also found for: other patient reported outcomes; measures of balance and walking function; hip and ankle range-of-motion; knee moments during walking; double support time during walking and percentage of gait cycle for peak muscle activation. However, significant advantages for the control group (Genesis II) were found for: operated knee range-of-movement and peak knee angular velocity during walking, and postural control (COP path length).

A potential limitation is the relatively large number of secondary outcomes. However, this is also a strength as it ensured comprehensive examination of the potential impact of TKR on functional ability, motor impairment and health-related quality of life. Another potential limitation is that the surgeons all had a much greater familiarity with the Genesis II implants. However, all surgeons received thorough training with the JII-BCS and the surgical technique and instrumentation are similar for both devices. A key strength of this trial is that the required sample size was achieved with only one person lost to follow-up. Other strengths include minimisation of selection bias through a robust randomisation procedure and use of double blinding to minimise interpretation bias.

It is interesting that differences between the two groups were found for some biomechanical measures of motor impairment but not for other biomechanical measures; patient-reported outcomes; and, walking and balance function. It is possible that knee range-of-movement during walking, walking symmetry, peak knee angular velocity during walking, and postural control (COP path length) are detecting motor impairment improvement for the Genesis II group and/or because statistical significance was a result of testing

multiple outcomes. The latter explanation is clearly possible but knee range-of-movement is greater for people reporting good outcome after knee replacement than for those reporting poor outcome [44]. Moreover, knee range-of-movement has been found to be the main biomechanical effect of TKR [45] and to improve over time whilst other biomechanical measures do not [45,46]. Likewise, postural control improves over time [47,48] and approaches healthy control values [47]. Importantly, gait symmetry is an indicator of walking control [49] and, whilst of borderline statistical significance (p=0.05) can possibly detect differences following insertion of different prostheses. Peak knee angular velocity during walking is also an indicator of walking control [50] and has been found to change beneficially after insertion of the Genesis II prosthesis [45]. These findings indicate that secondary, in-depth, analysis of the biomechanical data should be undertaken.

Whilst some investigators have demonstrated differences between generations of knee designs [12] not all modern generation TKR designs have demonstrated an improvement in outcomes when compared to their predecessors. [15–20,51]. One possible reason for this is that the predecessor is already producing good results and therefore is difficult to improve upon.

The lack of difference between implant designs is important for patients, surgeons, healthcare providers and implant companies. For the patient and surgeons, reassurance can be gained that older designs, with proven track record of function and survivorship, can provide the same patient reported and functional outcome as more modern designs. For the healthcare providers, older implants are often less expensive and, in the absence of clinical benefit with and demonstrable longevity, if the additional expenditure on more modern designs is avoided for the hundreds of thousands of patients undergoing surgery worldwide the cost savings are potentially significant. Finally, for the implant companies, it is more likely than not than implant design has reached a point when non-implant related factors play a more important role in patient outcome. The future of design and innovation may come in the form of more modern surgical techniques such as robotic assisted implantation. It is possible, only then in combination with modern surgical techniques, that improvements in patient outcomes can be realised but well-constructed surgical trials will need to answer such questions.

Conclusion

This study demonstrated comparable clinical results of the Genesis II and its successor the JII-BCS for patient reported outcome measures, walking function, temporal-spatial gait parameters, balance ability and lower limb kinematic results at 6 months follow up. However, significant advantages were seen in for the Genesis II in the operated knee range-of-movement, peak knee angular velocity during walking, and postural control. This information is important for all stakeholders when choosing an implant or planning a change from an older to a newer implant design.

FUNDING STATEMENT

This work was supported by an investigator initiated grant from Smith and Nephew, with both types of knee replacements supplied at the same cost. The funders had no role in the design of the study, the data collection, the data analysis, interpretation of data, or writing of the manuscript.

Authors' contributions

IM and VP drafted this paper. All authors contributed to revisions of the manuscript, read and approved the final manuscript. All authors contributed to the development of the trial protocol.

- **Declaration of interest** *"All authors have completed the ICMJE uniform disclosure form at www.icmje.org/ coi_disclosure.pdf and declare: all authors had financial support from Smith and Nephew for the submitted work; no financial relationships with*

any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."

All authors must download and complete a copy of the ICMJE COI disclosure form and send a copy to the corresponding author.

DATA SHARING STATEMENT

Requests for access to individual participant data will be considered by the Chief Investigators. Requests can be made to dm.norwichctu@uea.ac.uk. The trial protocol and Statistical Analysis Plan (SAP) will also be made available as supplementary files.

Trial governance and quality assurance

The trial was managed by the Norwich Clinical Trials Unit (NCTU). Study data were collected and managed using REDCap electronic data capture tools. Quality assurance was undertaken by the NCTU according to their usual processes.

The trial was overseen by the Trial Management Group. This was chaired by the Chief Investigators and included expert advisors, members of the research team and Patient and Public Involvement (PPI) representatives. A safety committee (Prof Marcus Flather and Prof Simon Donell) periodically reviewed adverse events and relevant safety data by treatment group to monitor for potential harm.

Abbreviations

ADEs: Adverse Drug Events; AEs: Adverse Events; BCS: Bi-Cruciate Stabilised; Co-CI: Co-Chief Investigator; Consort: Consolidated Standards of Reporting Trials; CoP: Centre of Pressure; CRF: Case Report Form; CT: Computerised Tomography; DMC: Data Monitoring Committee; EMG: Electromyography; FJS: The Forgotten Joint Score; GCP: Good Clinical Practice; GDPR: General Data Protection Regulation; GISP3: General Information Security Policy 3; HADS: Hospital Anxiety and Depressions Score; HRA: Health Research Authority; ICH: International Council for Harmonisation; ISRCTN: International Standard Randomised Controlled Trials Number; MCL: Medial Collateral Ligament; MoveExLab: Movement Analysis Laboratory; mSEBT: Modified Star

Excursion Balance Test; NCTU: Norwich Clinical Trials Unit; NERP: Norwich Enhanced Recovery Programme; NICE: National Institute for Health and Care Excellence; NNUH: Norfolk and Norwich University Hospital NHS Foundation Trust; OKS: Oxford Knee Score; OKS-APQ: Oxford Knee Score Activity & Participation Questionnaire; PI: Principle investigator; PIN: Participant Identification Number; PIS: Patient information sheet; PROMs: Patient-reported outcome measures; QA: Quality Assurance; QC: Quality Control; QMMP: Quality Management and Monitoring Plan; REDCap Research Electronic Data Capture ROMs: Ranges of Movement; SAEs: Serious Adverse Events; SAP: Statistical Analysis Plan; TKR: Total knee replacement; TMG: Trial Management Group; TTB: time to boundary; UKCRC: UK Clinical Research Collaboration

Ethical approval: The CAPAbility trial was conducted in accordance with the ethical principles outlined in the latest version of the Declaration of Helsinki and the Guideline for Good Clinical Practice related to experiments on humans. Ethical approval was given by the East of England – Cambridge Central Research Ethics Committee (reference 16/EE/0230). All participants provided informed consent prior to enrolment.

The lead authors (the manuscript's guarantors) affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The results of the research will be disseminated to the participants and public through direct written communication, broadcasts, popular science articles, and newspapers.

Provenance and peer review: Not commissioned; externally peer reviewed.

REFERENCES

1. Price AJ, Alvand A, Troelsen A, Katz JN, Hooper G, Gray A, Beard D. Knee replacement. *Lancet*. 2018;392:1672–1682.
2. Judge A, Arden NK, Cooper C, Kassim javaid M, Carr AJ, Field RE, Dieppe PA. Predictors of outcomes of total knee replacement surgery. *Rheumatology*. 2012;51:1804–1813.
3. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. *BMJ Open.* 2012;2:e000435.
4. Heck DA, Robinson RL, Partridge CM, Lubitz RM, Freund DA. Patient outcomes after knee replacement. *Clin Orthop Relat Res.* 1998;356:93–110.
5. Kennedy L, Newman J, Ackroyd C, Dieppe P. When should we do knee replacements? *Knee.* 2003;10:161–6.
6. Jones C, Voaklander D, Suarez-Alma M. Determinants of function after total knee arthoplasty. *Phys Ther.* 2003;83:696–706.
7. Cisternas MG, Murphy L, Sacks JJ, Solomon DH, Pasta DJ, Helmick CG. Alternative methods for defining osteoarthritis and the impact on estimating prevalence in a US population-based survey. *Arthritis Care Res.* 2016;68:574–580.
8. Vos T, Flaxman M, Naghavi R, Lozano C, Michaud M, Ezzati M, Al E. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet.* 2012;380:2163–2196.
9. Collades-Maestre I, Lizaur-Utrilla A, Gonzalez-Navarro B, Miralles-Munoz F, Marco-Gomez L, Lopez-Prats F, Gil-Guillen V. Better functional outcome after single-radius TKA compared with multi-radius TKA. *Knee Surgery, Sport Traumatol Arthrosc.* 2017;25:3508–3514.
10. Cook L, Klika A, Szubski C, Rosneck J, Molloy R, Barsoum W. Functional outcomes used to compare single radius and multiradius of curvature designs in total knee arthoplasty. *J Knee Surg.* 2012;25:249–253.

11. Jacobs W, Christen B, Wymenga A, Schuster A, van der Schaaf D, ten Ham A, Wehr U. Functional performance of mobile versus fixed bearing total knee prostheses: a randomised controlled trial. *Knee surg Sport traumatol arthrosc.* 2012;20:1450–1455.
12. Hamilton D, Burnett R, Patton J. Implant design influences patient outcome after total knee arthroplasty: a prospective double-blind randomised controlled trial. *Bone Jt J.* 2015;97-B(1):64–70.
13. Pennington M, Grieve R, Black N, Van der Meulen JH. Cost-effectiveness of five commonly used prosthesis brands for total knee replacement in the UK: A study using the NJR Dataset. *PLoS One.* 2016;11:e0150074.
14. Dowsey M, Gould D, Spelman T, Pandy M, Choong P. A randomized controlled trial comparing a medial stabilized total knee prosthesis to a cruciate retaining and posterior stabilized design: a report of the clinical and functional outcomes following total knee replacement. *J Arthoplasty.* 2020;35:1582-1590.e2.
15. Hauer G, Hörlesberger N, Klim S, Bernhardt GA, Leitner L, Glehr M, Leithner A, Sadoghi P. Mid-term results show no significant difference in postoperative clinical outcome, pain and range of motion between a well-established total knee arthroplasty design and its successor: a prospective, randomized, controlled trial. *Knee Surgery, Sport Traumatol Arthrosc.* 2020:827–831.
16. Chua J, Goh G, Liow M, Tay D, Lo N, Yeo S. Modern TKA implants are equivalent to traditional TKA implants in functional and patellofemoral joint-related outcomes. *Knee Surgery, Sport Traumatol Arthrosc.* 2019;27:1116–1123.
17. Molloy I, Keeney B, Sparks M, Paddock N, Koeing K, Moschetti W, Jevsevar D. Short term patient outcomes after total knee arthroplasty: does the implant matter? *Knee.* 2019;26:687–699.
18. Ranawat C, White P, West S, Ranawat A. Clinical and radiographic results of attune and PFC sigma knee designs at 2-year follow-up: a prospective matched-pair analysis. *J Arthroplasty.* 2017;32:431–436.
19. Song S, Kang S, Park C, Bae D. Comparison of clinical results and risk of patellar injury between attune and PFC sigma knee systems. *Knee Surg Relat Res.* 2018;30:334–340.
20. Behrend BH, Zdravkovic V, Bosch M, Hochreiter B. No difference in joint awareness after TKA: a matched-pair analysis of a

classic implant and its evolutional design. *Knee Surgery, Sport Traumatol Arthrosc.* 2019;27:2124–2129.

21. Evans JT, Walker RW, Evans JP, Blom AW, Sayers, AdrianWhitehouse MR. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *Lancet.* 2019;393:655–663.
22. National Joint Registry for England, Wales N ireland and the I of M. National Joint Registry. 2019. Available from: https://reports.njrcentre.org.uk/portals/0/pdfdownloads/njr 16th annual report 2019.pdf
23. Moore C, Lenz N. The evolution of guided motional total knee arthroplasty – the Journey II Bi-Cruciate Stabilized Knee System. *Bone Jt Sci.* 2012;3:1–8.
24. Grieco T, Sharma A, Dessinger G, Cates H, Komistek R. In vivo kinematic comparison of a bicruciate stabilized total knee arthroplasty and the normal knee using fluoroscopy. *J Arthroplasty.* 2018;33:565–571.
25. Clarke C, Pomeroy V, Clark A, Creelman G, Hancock N, Horton S, Killett A, Mann C, Payerne E, Tomas A, et al. CAPAbility: Comparison of the JOURNEY II Bi-Cruciate Stabilised and GENESIS II total knee arthroplasty in performance and functional ability: Protocol of a randomised controlled trial. *Trials.* 2020;21:222.
26. Merle-Vincent F, Couris C, Schott A, Conrozier T, Piperno M, Mathieu P, Mignon E. Factors predicting patient satisfaction 2 years after total knee arthroplasty for osteoarthritis. *Jt Bone Spine.* 2011;78:383–386.
27. Singh J, O'Byrne M, Harmsen S, Lewallen D. Predictors of moderate-severe functional limitation after primary Total Knee Arthroplasty (TKA): 4701 TKAs at 2-years and 2935 TKAs at 5-years. *Osteoarthr Cartil.* 2010;18:515–521.
28. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) - a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inf.* 2009;42:377–381.
29. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, Al E. The REDCap consortium: building an international community of software platform partners. *J Biomed Inf.* 2019;95:103208.
30. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Jt*

Surg. 1998;80:63–69.

31. Bohm E, Loucks I, Tan Q, Turgeon T. Determining minimum clinically important difference and targeted clinical improvement values for the Oxford 12. In: *American Academy of Orthopaedic Surgeons 2012 Annual Conference.* ; 2012.
32. Beard D, Harris K, Dawson J, Doll H, Murray D, Carr A, Price A. Meaningful changes for the Oxford Hip and Knee Scores after joint replacement surgery. *J Clin Epidemiol.* 2015;68:73–79.
33. Williams D, O'Brien S, Doran E, Price A, Beard D, Murray D, Beverland D. Early postoperative predictors of satisfaction following total knee arthroplasty. *Knee.* 2013;20:442–446.
34. Dawson J, Beard D, Mckibbib H, Harris K, Jenkinson C, Price A. Development of a patient-reported outcome measure of activity and participation (the OKS-APQ) to supplement the Oxford knee score. *Bone Jt J.* 2014;96:331–338.
35. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* 2011;20:1727–1736.
36. Podsiadlo D, Richardson S. The timed "Up and Go": a test of basic functional mobilty for frail elderly persons. *JAGS.* 1991;39:142–148.
37. Yuksel E, Unver B, Kalkan S, Karatosun V. Reliability and minimal detectable change of the 2-minute walk test and Timed Up and Go test in patients with total hip arthroplasty. J *Arthroplasty.* 2017;32:426–430.
38. Kennedy DM, Stratford PW, Wessel J, Gollish JD, Penney D. Assessing stability and change of four performance measures: A longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord.* 2005;6:3.
39. Bennell K, Dobson F, Hinman R. Measures of physical performance assessments: Self-Paced Walk Test (SPWT), Stair Climb Test (SCT), Six-Minute Walk Test (6MWT), Chair Stand Test (CST), Timed Up & Go (TUG), Sock Test, Lift and Carry Test (LCT), and Car Task. *Arthritis Care Res.* 2011;63:S350–S370.
40. Naylor JM, Mills K, Buhagiar M, Fortunato R, Wright R. Minimal important improvement thresholds for the six-minute walk test in a knee arthroplasty cohort: triangulation of anchor- and distribution-based methods. *BMC Musculoskelet Disord.* 2016;17:390.

41. Kinzey SJ, Armstrong CW. The reliability of the Star-Excursion test in assessing dynamic balance. *J Orthop Sport Phys Ther.* 1998;27:356–360.

42. McChesney JW, Woollacott MH. The effect of age-related declines in proprioception and total knee replacement on postural control. Journals Gerontol - *Ser A Biol Sci Med Sci.* 2000;55:M658–M666.

43. Hertel J, Olmsted-Kramer LC, Challis J. Time-to-boundary measures of postural control during single-leg quiet standing. *J Appl Biomech.* 2006;22:67–73.

44. Naili JE, Wretenberg P, Lindgren V, Iversen MD, Hedström M, Broström EW. Improved knee biomechanics among patients reporting a good outcome in knee-related quality of life one year after total knee arthroplasty. *BMC Musculoskelet Disord.* 2017;18:122.

45. Rahman J, Tang Q, Monda M, Miles J, McCarthy I. Gait assessment as a functional outcome measure in total knee arthroplasty: A cross-sectional study. *BMC Musculoskelet Disord.* 2015;16:66.

46. Yoshida Y, Zeni J, Snyder-Mackler L. Do patients achieve normal gait patterns 3 years after total knee arthroplasty? *J Orthop Sports Phys Ther.* 2012;42:1039–1049.

47. Gauchard GC, Vançon G, Meyer P, Mainard D, Perrin PP. On the role of knee joint in balance control and postural strategies: Effects of total knee replacement in elderly subjects with knee osteoarthritis. *Gait Posture.* 2010;32:155–160.

48. Moutzouri M, Gleeson N, Billis E, Tsepis E, Panoutsopoulou I, Gliatis J. The effect of total knee arthroplasty on patients' balance and incidence of falls: a systematic review. *Knee Surgery, Sport Traumatol Arthrosc.* 2017;25:3439–3451.

49. Patterson KK, Nadkarni NK, Black SE, McIlroy WE. Temporal gait symmetry and velocity differ in their relationship to age. *Gait Posture* [Internet]. 2012;35:590–594. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624763/pdf/nihms412728.pdf

50. Richards JD, Pramanik A, Sykes L, Pomeroy VM. A comparison of knee kinematic characteristics of stroke patients and age-matched healthy volunteers. *Clin Rehabil.* 2003;17:565–571.

51. Nunley RM, Nam D, Berend K, Dennis D, Della Valle C, Barrack R. New total knee arthroplasty designs: do young patients

notice? *Clin Orthop relat Res.* 2015;473:101–108.

Figure legends

Figure 1. Consort diagram

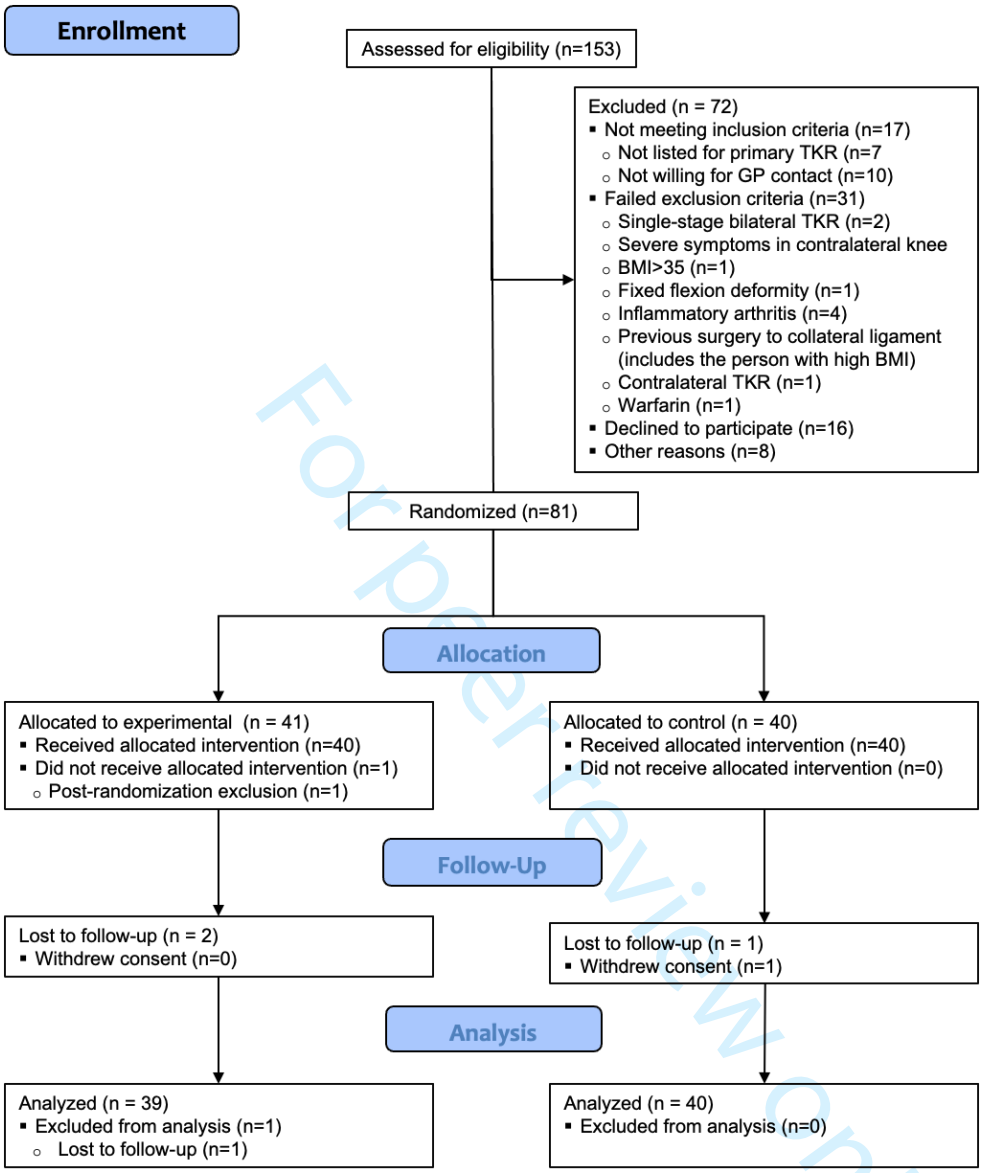
ACKNOWLEDGEMENTS

Thanks to all the participants and families who gave their time to be part of this study; Antony Colles, Martin Pond and the NCTU data management team; Estelle Payerne; Amanda Thacker; NNUH sponsorship team and the safety monitoring committee members, Prof Marcus Flather and Prof Simon Donell.

Also:

- Mr Charles Mann
- Mr Nish Chirodian
- Mr David Calder
- Dr Nicola Hancock
- Nursing and clinic staff at the Spire Hospital and NNUH
- Prof Andoni Toms and the Radiology department at Addenbrooke's hospital, Cambridge
- Dr Simon Horton
- Dr Anne Killett
- Mr Gareth Roberts

Figure 1. CONSORT Flow Diagram



Supplementary tables

Contents

Table S1. Non-operated leg cadence (steps/minute), step length and stride length from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	**Two months after surgery**	**Six months after surgery**
Cadence			
JII-BCS	107.37 (10.62) N=39	103.09 (13.21) N=37	113.09 (9.51) N=35
Genesis II	102.7(10.83) n=40	105.25(10.21) n=37	112.98(9.71) n=34
Step length			
JII-BCS	0.53(0.08) n=39	0.5(0.09) n=37	0.56(0.1) n=35
Genesis II	0.54(0.09) n=40	0.55(0.08) n=37	0.6(0.08) n=34
Stride length			
JII-BCS	1.06(0.17) n=39	1.04(0.18) n=37	1.15(0.21) n=35
Genesis II	1.08(0.17) n=40	1.11(0.15) n=37	1.2(0.16) n=34

Cadence (Steps/min), step length (m), and stride length (m)of non operative limb

Table S2. Post-operative clinical context: days of in-patient stay and consequences of surgery

	JII-BCS Number (%)	Genesis II Number (%)	Effect size (95% CI)	p-value
Length of in-patient stay				
Three days	14 (35%)	13 (33%)		
Four days	21 (53%)	21 (53%)		
Five days	4 (10%)	5 (13%)	NA	0.749[a]
Six days	1 (3%)	1 (3%)		
Median	4.00	4.00		
(IQR)	(3.00, 4.00)	(3.00, 4.00)		
Revision surgery for implant related problems*				
No	40 (100%)	40 (100%)	NA	NA
Yes	0	0		
Complications				
No	34 (85%)	35 (88%)	1.00	0.780
Yes	6 (15%)	5 (13%)	0.83 (0.23,3.01)	
Change pain medication				
No	1 (3%)	4 (10%)	-7.5% (-18.0,3.0)	0.359[a]
Yes	39 (98%)	36 (90%)		

NA = not appropriate; [a] Fisher exact test.

Length of stay, complications, revision for implant related problems and change in pain medication

*One patient in the JII-BCS had a revision of the polyethylene component for possible infection which was never diagnosed. As this is not implant related it is not included in the table.

Table S3. Composition of out-patient physiotherapy treatment received following TKR by JII-BCS and Genesis II groups.

	Number of sessions where exercises were performed: median (IQR)	
	JII-BCS (n=40)	**Genesis II (n=40)**
In-patient sessions (JII-BCS n=27, Genesis II n=26)		
Gait re-education	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Step exercise	1.0 (1.0, 1.0)	1.0 (1.0,2.0)
Knee ROM flexion exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Static quadriceps exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Inner range quadriceps exercise	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Straight leg raise exercise	0.0 (1.0, 1.0)	0.0 (1.0, 1.0)
Knee extension strengthening exercise in sitting	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Ice treatment	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)
Advice and education	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Other body region rehabilitation exercises	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Out-patient settings (JII-BCS n=33, Genesis II n=35)		
Other body region rehabilitation exercises	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Seat pedal exercises	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
Static bike exercises	1.0 (0.0, 3.0)	1.0 (0.0, 5.0)
Cross-trainer exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Calf stretch exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Gait re-education	1.0 (1.0, 2.0)	1.0 (1.0, 5.0)
Stair practice	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)
Step exercise	1.0 (0.0, 4.0)	1.0 (1.0, 5.0)
Sit to stand exercise (without arms of chair)	1.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Sit to stand exercise (with arms of chair)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Knee ROM flexion (sat in chair)	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Knee strengthening extension exercise with resistance band	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Static quadriceps exercise	1.0 (1.0, 1.0)	1.0 (1.0, 4.0)
Straight leg raise exercise	1.0 (1.0, 1.0)	1.0 (1.0, 3.0)
Inner range quadriceps exercise	1.0 (1.0, 3.0)	1.0 (1.0, 3.0)
Proprioceptive exercises in standing	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Proprioceptive exercises in standing (with support)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Proprioceptive exercises in standing (with eyes shut)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)
Advice and education	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)

Glutei strengthening exercise	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)

ROM – range of motion

Table S4. Seconds standing on non-operated leg with eyes open and Star-Excursion Test from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	**Two months after surgery**	**Six months after surgery**
Can stand on non-op for 10s with eyes open (number)			
JII-BCS	12 / 38	20/36	13/32
Genesis II	19/38	19/36	14/33
Seconds standing – eyes open			
JII-BCS	5.94(3.19) n=38	6.9(3.63) n=36	6.49(3.25) n=32
Genesis II	6.96(3.46) n=38	7.03(3.53) n=36	6.55(3.41) n=33
Star-Excursion Test (Non-op) (Anterior Reach)			
JII-BCS	40.54(6.12) n=36	41.87(6.18) n=34	42.16(9.37) n=32
Genesis II (Post lateral)	40.98(7.69) n=37	43.2(8.11) n=33	43.09(7.58) n=31
JII-BCS	59.86(11.45) n=32	62.16(11.73) n=32	62.81(16.63) n=30
Genesis II (Post medial)	60.1(11.77) n=34	62.03(15.15) n=31	63.21(14.49) n=29
JII-BCS	63.57(9.81) n=34	65.11(10.78) n=34	66.44(16.73) n=32
Genesis II	63.79(10.87) n=36	65.1(13.59) n=33	67.74(14.59) n=31
Star-Excursion Test (Op)			
Anterior (reach)			
JII-BCS	37.72(7.41) n=36	35.92(6.94) n=35	40(7.47) n=32
Genesis II (Post lateral)	41.83(6.85) n=34	36.84(7.45) n=32	44.98(21.54) n=30
JII-BCS	55.39(10.78) n=33	55.19(8.02) n=31	60.19(12.7) n=30

Genesis II (Post medial)	58.73(11.01) n=32	57.78(14.08) n=29	62.83(14.86) n=30
JII-BCS	59.32(10.23) n=36	59.57(8.87) n=34	65.59(11.43) n=32
Genesis II	64.18(11.69) n=34	62.44(12.74) n=32	66.1(14.1) n=31

Single stance on the non-operated lower limb for 10 seconds with eyes open (yes/no) and duration maintained.

Modified Star-Excursion Test (cm/leg length) where larger values indicate better balance.

Table S5. Centre of Pressure (COP) velocity (cm/s) in double stance from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	**Two months after surgery**	**Six months after surgery**
COP velocity cm/s			
JII-BCS	24.08(22.5) n=38	21.54(9.93) n=39	27.39(19.85) n=35
Genesis II	21.81(17.46) n=40	24.11(14.15) n=36	47.08(61.92) n=34

Resultant centre of pressure (COP) velocity (cm/s) in double stance with eyes closed: lower velocity indicates better balance ability

Table S6. Non-operated leg lower limb kinetics from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	Two months after surgery	Six months after surgery
Peak extension moment during walking (Nm/Kg)			
JII-BCS	-0.16(0.11) n=38	-0.19(0.12) n=38	-0.23(0.13) n=34
Genesis II	-0.2(0.11) n=40	-0.22(0.11) n=36	-0.21(0.1) n=34
Peak flexion moment during walking (Nm/Kg)			
JII-BCS	0.58(0.25) n=38	0.44(0.22) n=38	0.55(0.31) n=34
Genesis II	0.5(0.26) n=40	0.48(0.24) n=36	0.58(0.27) n=34

Peak extension and flexion moments of non-operated knee during the gait cycle (Nm/kg). A higher value indicates better function.

Table S7. Non-operated leg lower limb kinematics from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	Two months after surgery	Six months after surgery
Knee range-of-movement – walk (degrees)			
JII-BCS	40.01(6.37) n=39	40.65(7.02) n=38	42.24(6.2) n=35
Genesis II	40.92(6.51) n=40	42.46(6.03) n=37	42.7(6.34) n=34
Hip range-of-movement – walk (degrees)			
JII-BCS	46.91(7.08) n=39	47.67(6.66) n=38	51.17(5.2) n=35
Genesis II	48.46(7.18) n=40	50.93(6.8) n=37	52.71(6.18) n=34
Ankle range-of-movement – walk (degrees)			
JII-BCS	23.97(5.63) n=39	23.55(5.89) n=38	24.78(7.37) n=35
Genesis II	24.77(4.71) n=40	24.96(3.78) n=37	24.74(4) n=34
Peak knee angular velocity (op)– walk (degrees/s)			
JII-BCS	283.1(53.83) n=39	269.65(36.75) n=38	307.69(38.96) n=35
Genesis II	300.36(55.56) n=40	293.06(62.1) n=36	337.85(46.15) n=34
Peak knee angular velocity (non-op)– walk (degrees/s)			
JII-BCS	309.68(44.93) n=39	321.65(43.31) n=38	330.38(41.4) n=35
Genesis II	313.77(57.12) n=40	329.25(45.72) n=37	338.69(46.06) n=34

Hip, knee, and ankle range-of-motion during walking of non-operative limb. Higher values indicate better function

Peak knee angular velocity during walking of non-operative limb. Higher value indicates better function.

Table S8. Non-operated leg lower limb muscle activity during walking from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	Two months after surgery	Six months after surgery
Peak activation Vastus Medialis (% of gait cycle)			
JII-BCS	26.64(25.63) n=39	22.9(23.59) n=39	18.23(20.25) n=39
Genesis II	19.83(17.66) n=40	19.73(17.36) n=40	22.65(26.98) n=40
Peak activation Vastus Lateralis (% of gait cycle)			
JII-BCS	33.85(32.77) n=39	25.9(18.3) n=38	17.29(20.6) n=38
Genesis II	34.05(32.89) n=40	28.4(18.61) n=40	30.18(29.19) n=38
Peak activation Tibialis Anterior (% of gait cycle)			
JII-BCS	17.71(19.08) n=38	25.61(26.2) n=38	21.76(23.85) n=38
Genesis II	18(15.31) n=38	18.71(23.46) n=38	30.53(32) n=38
Peak activation Biceps Femoris (% of gait cycle)			
JII-BCS	23.71(18.59) n=38	25.41(23.86) n=34	19(20.8) n=34
Genesis II	24.32(16.2) n=38	25.63(22.6) n=32	15.5(8.35) n=32
Peak activation Lateral head of Gastricnemius (% of gait cycle)			
JII-BCS	19.68(19.83) n=34	35.09(35.58) n=34	23.53(15.2) n=34
Genesis II	19.94(20.77) n=32	22.44(27.39) n=32	28.22(18.19) n=32

Percentage of gait cycle for peak activation of Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Biceps Femoris and Lateral head of Gastrocnemius (% of gait cycle).

Table S9. Complications and adverse events

Complication type	Numbers of participants	
	JII-BCS	Genesis II
Post operative reaction to analgesia requiring admission		1
Pulmonary embolus	1	1
Wound haematoma / swelling	2	4
Postoperative bleeding requiring blood transfusion		1
Iliotibial tract discomfort		1
Chest infection	1	1
Urinary tract infection		1
Debridement and implant retention (DAIR)	1	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	13,14
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10,11,12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
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	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
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	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	14, 15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
	14b	Why the trial ended or was stopped	13
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
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)	19, 22,25 29,31
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	As above
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	33, Supplementary table 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	33
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	33
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	34,35
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	provided
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	35

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility, blinded, randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061648.R1
Article Type:	Original research
Date Submitted by the Author:	18-Oct-2022
Complete List of Authors:	McNamara, Iain; Norfolk and Norwich University Hospital; University of East Anglia Pomeroy, Valerie; University of East Anglia Clark, Allan; University of East Anglia, Norwich Medical School Creelman, Graham; Mental Health Act Review Panels, Whitehouse, Celia; Norfolk and Norwich University Hospital Wells, J.; University of East Anglia Harry, B; University of Cambridge, Department of clinical neurosciences Smith, Toby; University of East Anglia, Faculty of Medicine and Health Sciences High, Juliet; norwich clinical trials unit Swart, Ann Marie; University of East Anglia; University of East Anglia, Health Sciences Clarke, Celia; University of East Anglia
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	HEALTH ECONOMICS, Clinical trials < THERAPEUTICS, ORTHOPAEDIC & TRAUMA SURGERY, Knee < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

TITLE PAGE

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility, blinded, randomised controlled trial

Authors with affiliations, ORCID IDs and twitter handles

McNamara, I. Consultant Orthopaedic Surgeon Norfolk and Norwich University Hospital NHS foundation trust and Honorary Professor, University of East Anglia. ORCID ID: https://orcid.org/0000-0002-2051-8451

Pomeroy, V M. Professor of Neurorehabilitation, School of Health Sciences, University of East Anglia. ORCID ID: https://orcid.org/0000-0003-4487-823X

Clark, A. B. Associate Professor in Medical Statistics, Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia ORCID ID: https://orcid.org/0000-0003-2965-8941

Creelman, G. Chair, Mental Health Act Review Panels, Norfolk and Suffolk, NHS Foundation Trust; Visiting Professor of Media, Norwich University of the Arts.

Whitehouse, C.E., Orthopaedic Clinical Trials Research Nurse, Norfolk and Norwich University Hospital NHS Foundation trust

Wells, J. Researcher, School of Health Sciences, University of East Anglia. ORCID ID: 0000-0002-6752-762X.

Harry, B. Clinical Trials Project Coordinator, Department of Clinical Neurosciences, University of Cambridge. ORCID ID: https://orcid.org/0000-0002-6938-567X

Smith, T,O. Associate Professor in Physiotherapy, School of Health Sciences, University of East Anglia. ORCID ID: 0000-0003-1673-2954

High, J. Senior Trials Manager, Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia. ORCID ID: https://orcid.org/0000-0003-2555-2349

Swart, A M. Norwich Clinical Trials Unit, Norwich Medical School, University of East Anglia

Clarke, C. Lecturer in School of Health Sciences, University of East Anglia. ORCID ID: https://orcid.org/0000-0001-6584-9601

Corresponding author: Iain McNamara

Department of Trauma and Orthopaedics

Norfolk and Norwich University Hospital NHS Foundation Trust

Norwich

NR4 7UY

Iain.mcnamara@nnuh.nhs.uk

Word count: 4,229

ABSTRACT (300 words)

Objectives: To determine if a newer design of TKR (Journey II BCS) produces superior patient reported outcomes scores and biomechanical outcomes than the older, more established design (Genesis II).

Setting: Patients were recruited from an NHS University Hospital between July 2018 and October 2019 with surgery at two sites. Biomechanical and functional capacity measurements were at a University Movement and Exercise Laboratory.

Participants: 80 participants undergoing single-stage TKR.

Interventions: Patients were randomised to receive either the Journey II BCS or Genesis II TKR

Primary and secondary outcome measures: Primary outcome was the Oxford Knee Score (OKS), at six months. Secondary outcomes were: OKS Activity and Participation Questionnaire (OKS-APQ), EQ-5D-5L and UCLA Activity scores, Timed Up and Go Test (TUG), six-minute walk test (6MWT), lower limb kinematics and lower limb muscle activity during walking and balance.

Results: This study found no difference in the OKS between groups. The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20) respectively, adjusted effect size 0.35 (-2.01,2.71) p=0.771

In secondary outcome measures, the Genesis II group demonstrated a significantly greater walking range-of-movement (50.62 (7.33) versus 46.07 (7.71) degrees, adjusted effect size, 3.14 (0.61,5.68) p=0.02) and higher peak knee flexion angular velocity during walking (mean (SD) 307.69 (38.96) versus 330.38 (41.40) degrees/second, adjusted effect size was 21.75 (4.54,38.96), p=0.01) and better postural control

(smaller resultant centre of path length) during quiet standing than the JII-BCS group (mean (SD) 158.14 (65.40) versus 235.48 (176.94) mm, adjusted effect size, 59.91 (-105.98,-13.85) p=0.01.).

Conclusions: In this study population, the findings do not support the hypothesis that the Journey II BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at six months after surgery.

Trial registration: ISRCTN32315753, 12 December 2017.

Key words: Total knee replacement**,** Genesis II, Journey II BCS, PROMS, biomechanical analysis

Strengths and limitations

Strengths:

- This is a two arm, superiority, observer-blind, participant-blind and clinical staff-blind, randomised control trial
- It uses a wide variety of patient reported outcomes measures and biomechanical measurements to determine if one implant is superior to the other
- the required sample size was achieved with only one person lost to follow-up.

Weaknesses

- A potential limitation is the relatively large number of secondary outcomes.
- The surgeons all had a much greater familiarity with the implantations of Genesis II implants.

ORIGINAL PROTOCOL FOR THE STUDY UPLOADED AS A SUPPLEMENTAL FILE

INTRODUCTION

Despite total knee replacement (TKR) being an recommended surgical treatment for end-stage knee osteoarthritis[1], up to 34% of all patients following TKR have poor functional outcomes [2–6]. With estimates of osteoarthritis of the knee affecting one in eight people in the USA [7] and 250 million individuals worldwide [8] the number of patients with intrusive symptoms after surgery is significant.

Multiple changes in implant design have been introduced to try to improve patient outcomes and whilst some implant design alterations have led to improvements in patient-reported outcome measures (PROMS) [9–11] and kinematics [12,13] not all have led to differences [14–20].

The Genesis II (Smith & Nephew, Memphis, TN) TKR has been reported to have good survivorship and patient satisfaction [13,21] and commonly used in the UK [22] An evolutionary design, the Journey II BCS (JII-BCS; Smith & Nephew, Memphis, TN), also manufactured by Smith and Nephew, has been developed with the aim of improving kinematic outcome compared to the Genesis II by using a bicruciate design [23] This design change has been supported by encouraging fluoroscopic studies. However, to date, no randomised controlled trials have been conducted to assess if there is a difference in the outcome compared to its predicate design. [24].

The aim of this trial was to assess whether the JII-BCS would produce better patient reported and movement outcomes than the Genesis II.

The published protocol included the aims for investigating: the rotational profile around the native knee and following TKR; and patients' experiences and surgeons' experiences [25]. These findings will be reported in subsequent manuscripts.

METHODS

Trial design, randomisation, blinding to intervention allocation, ethics and registration

A two-arm, superiority randomised controlled trial (RCT) comparing the JII-BCS knee implant (experimental intervention) to the Genesis II knee implant (control intervention) was performed. The trial was observer-blind, participant-blind and clinical staff-blind. Only the operating surgeon and theatre team knew which implant was used for an individual participant.

Trial participants were assigned to either the JII-BCS or Genesis II group using a computer-generated, 1:1 randomisation schedule stratified by site and age (<60 years = younger; ≥60 years = older) [26,27]. Group allocation was revealed using REDCap [28,29], the interactive web-randomisation system, to a member of the research team who was not involved in either the clinical care or assessments of any participant. Allocation was concealed from the surgical team until after the pre-operation baseline measures were completed.

Ethical approval

Ethical approval was given by the East of England – Cambridge Central Research Ethics Committee (reference 16/EE/0230). All participants provided informed consent prior to enrolment.

Sample size

The sample size was calculated from the Oxford Knee Score (OKS, primary outcome measure) [30]. The RCT was powered at 80% with a 5% significance level to detect a minimally important clinical difference of five points [31,32] with a standard deviation of 7.4 points [33]. Accounting for an estimated attrition rate of 10% at six months post-surgery the estimated sample size was 80 participants (40 per group).

Participants, setting and recruitment

Full eligibility criteria are provided in the published protocol [25]. In brief, participants were aged at least 18 years and met the clinical and radiological criteria for a single-stage TKR. People were excluded if they: had a fixed-flexion deformity of at least 15° or non-correctable varus/valgus deformity of at least 15°; had inflammatory arthritis or previous septic arthritis; had previous surgery to the collateral ligaments of the affected knee; had a contralateral TKR implanted less than one year earlier; had severe co-morbidity that could present an unacceptable safety risk or were pregnant; were a private patient; were likely to be living outside the clinical centre catchment area at six months post-surgery; or were enrolled on another clinical trial.

Patients were recruited at a university teaching hospital with surgery conducted at two sites. Outpatient physiotherapy was conducted in a single hospital. The Movement and Exercise Laboratory at the associated University (MoveExLab) was the setting for measures of functional capacity and biomechanics.

Interventions

All participants received routine NHS care for people with TKR irrespective of the implant received. This included following a standard post-operative rehabilitation of out-patient physiotherapy centred on knee strength and range of motion exercises within the first six weeks after surgery. Patients received the same physiotherapy protocols and classes.

Experimental intervention

Participants in the experimental group received the JII-BCS. The JII-BCS is a dual-cam post designed to substitute for both the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) to In addition the femoral component is asymmetric and the polyethylene insert is a medially concave and laterally convex shape. The device is designed to provide guided motion, and thus improve knee kinematics, and increase anteroposterior (AP) stability throughout knee flexion.

Control intervention

- Participants in the control group received the Genesis II (Smith and Nephew, Memphis TN), posterior stabilised (PS) TKR. The design features specific to the implant and a lateralized trochlear groove to improve patellar contact and tracking, an externally rotated femoral implant design and an anatomically-shaped tibial baseplates.

Surgical techniques

All four surgeons had extensive experience, at least five years, of the Genesis II implant. All undertook cadaveric training on the JII-BCS and declared that they were competent in the surgical technique having completed their operative learning curve before starting the trial. Both implants are uncoated, cemented implants. The surgical procedure followed the standard manual surgical approach and technique through a medial parapatellar approach in all cases with intramedullary femoral and tibial rods to provide the alignment of the components. Patella resurfacing was used in both groups.

Data collection schedule

Data collection timepoints for the primary outcome measure were: at least one day before surgery (baseline), 7±1 days after surgery (one-week post-operatively), 6-8±2 weeks after surgery (two months), six months ±4 weeks after surgery (outcome, primary time point). Secondary outcomes were collected at baseline, two months and six months. Any differences from these timepoints are provided in the outcome measures section.

Outcome measures

Primary outcome measure

The Oxford Knee Score (OKS) was the primary outcome measure. This is a 12-question patient self-assessment of knee function and pain [30] with values ranging from 0 (worst outcome) to 48 (best outcome.

Secondary outcome measures

1. Patient reported outcome questionnaires
   a. The OKS Activity and Participation Questionnaire (OKS-APQ) which complements the OKS by assessing everyday activity and social participation [34]. The overall score is from 12 to 60 with 12 being the best outcome.
   b. The EQ-5D-5L is a self-report questionnaire consisting of five questions and a visual analogue scale (VAS). Higher values indicate better quality of life [35].
   c. The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10 (participation in impact sport).
2. Walking and balance functional ability
   a. Timed Up and Go Test (TUG) – seconds to rise from chair, walk 3m and return to sitting; mean of three trials [36]. The reported minimal detectable change after TKR is 2.27 seconds [37]. A lower value indicates better function.
   b. Six-minute walk test - metres walked in six minutes around a 20-metre circuit [38,39]. The reported minimal detectable change from baseline after TKR is 26 metres [40]. A higher value indicates greater function.
   c. Modified Star-Excursion Test [41] (cm/leg length) where larger values indicate better balance.
3. Movement performance during walking and balance

   For these simultaneous measures, participants wore shorts and were bare-footed. Reflective sensors were placed in accordance with the Plug-In Gait model (Vicon) for the lower limb and 3D motion data were collected, at 100 HZ, with eight wall-mounted infrared cameras (Vicon Motion System, Oxford UK). Three embedded force plates (BERTEC, Ohio, USA) were used to collect kinetic

data at 2000Hz for walking tasks and 100hz for balance tasks. Surface electromyographic sensors (EMG, Delsys) were placed bilaterally on the Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Bicep Femoris and lateral head of the Gastrocnemius following SENIAM guidance. EMG data was collected at 2000 Hz.

For walking tasks, participants were asked to walk in a straight line along a 10-metre walkway at their self-selected speed. For double stance balance activities, participants were instructed to stand with their feet shoulder-width apart. For single stance balance activities, participants were instructed to stand on one leg with hands-on-hips. Three trials of 10 seconds were recorded for each activity.

For the stair ambulation task, participants were asked to complete six ascents and six descents all unaided, leading with the operated limb for three trials and the non-operated limb for the remainder. The stairs had four steps. The first step was 16.5 cm, and the others were 15 cm high. Handrails were available if participants needed support.

Movement data were processed in accordance with the Vicon Plug-in Gait Model (Oxford Metrics, Oxford, UK). Raw EMG was filtered with pass bands at 10 and 500 Hz, rectified and low pass filtered using a 4th order Butterworth with a 10 Hz cut off. Walking data were normalised to 101 data points for the gait cycle. Three trials of tasks were used to create a mean for each measure per participant. Values were extracted using a purpose-built MATLAB script. Data were processed by motion analysis experts in the research team.

a. Primary movement performance measures

The JII-BCS is expected to provide more normal kinematics during knee movement than Genesis II due to the design changes discussed earlier. Other authors have indicated that the femo-tibial relationship may be more normal during deep knee bend [42]and more stable during walking [43] Accordingly, people with the Journey prosthesis may [44,45] or may [43] have

greater knee ROM, may walk faster [46,47], and may have a longer stride length[46,47] than people receiving a comparison knee replacement . In addition, greater stability of the femur on the tibia could produce greater knee flexion angular velocity as dynamic knee loading could be more normal. However, there is only one non randomised study of 18 patients comparing the JII-BCS directly with the Genesis II [45] . On the basis of the available literature, the hypothesis driving the kinematic investigation was that people receiving the Journey compared with those receiving the Genesis would have greater walking velocity, step-length symmetry (resulting from longer stride length), knee range of motion (ROM), and peak knee flexion angular velocity.

i. Walking speed (meters/second). A higher value indicates better performance
ii. Step length symmetry during walking. Step length ratio was calculated as ((2xOp/Op+NOp))-1); where Op is the step length of the operated leg and NOp is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.
iii. Knee ROM during walking (degrees). Higher values indicate better performance.
iv. Peak knee flexion angular velocity during walking (degrees per second). This was inadvertently omitted from the statistical analysis plan. Higher value indicates better performance.

b. Secondary movement performance measures.

i. Double stance support (% of gait cycle). It was planned to measure cadence, (steps/min), step length (m), and stride length (m). However, there is redundancy with the temporal-spatial gait parameters of walking speed and step length symmetry which are included in the primary movement performance measures.
ii. Peak extension and flexion moments of operated knee during the gait cycle (Nm/kg).

iii. Hip and ankle ROM during walking.
iv. Peak knee flexion angular velocity during stepping up onto a stair.
v. Percentage of gait cycle for peak activation of Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Biceps Femoris and Lateral head of Gastrocnemius (% of gait cycle).
vi. Balance measures were derived from kinetic data (from force plates) during standing still: single stance on the operated lower limb for 10 seconds with eyes open (yes/no) and duration maintained; resultant centre of pressure path length (COP cm) in double stance with eyes closed; and resultant COP velocity (cm/s) in double stance with eyes closed.

Clinical context and adverse events

Data on length of hospital stay and complications related to the surgery (e.g. anaesthesia-related problems, bleeding, morbidities) was collected from a notes review. At each visit, participants were asked about their pain medication and if they had received additional treatment since their surgery/previous visit and what this entailed. Any need for revision surgery was recorded. All adverse events identified were tracked until resolution.

Analysis

The statistical analysis plan (SAP) was finalised and agreed prior to database lock and analysis was completed blinded to group allocation (Supplementary file). For all outcomes the hypothesis tests and 95% confidence intervals (CI) were two-sided; and a p-value of <0.05 was considered significant. An intention-to-treat analysis was conducted i.e., all randomised participants regardless of their eligibility or

adherence were analysed according to the treatment they were randomised to receive. The analysis was undertaken by the Trial Statistician using Stata version 16.

For the primary outcome, the mean OKS at six months was compared between the control and experimental groups using a general linear model adjusting for site and age (<60years/≥60years). An adjusted analysis was conducted using the same model but adjusting for the OKS at baseline. The model assumptions were checked graphically, and sensitivity analysis done using a non-parametric bootstrap using 5,000 repetitions.

All the other outcomes were analysed separately at two months and six months using the same general linear model specified above and a corresponding adjusted analysis. The exception was ability to balance for 10 seconds. This was analysed using a logistic regression model adjusting for site and age.

Patient and public involvement

A patient representative, who had previously undergone knee replacement surgery, was involved in the protocol development, assessment of the burden of the intervention and time taken to participate in the research and oversight of the trial as a member the trial management group. The representative also contributed to the planning and writing of research dissemination materials.

RESULTS

Participants were recruited between July 2018 and October 2019. Last follow-up visits were in October 2020 with some impact and delayed visits due to COVID-19.

In the published protocol [25] the analysis plan included a per-protocol and safety analysis. This was not undertaken as the implants were used as intended so these populations would be the same as the intention-to-treat population.

Flow of participants through the trial

In total, 105 of 153 people screened were eligible to take part, 16 declined participation and eight were excluded for other reasons. Therefore, 81 of 153 people (53%) were recruited. All participants in the Genesis II group (n=40) received their allocated intervention. In the JII-BCS group (n=41) one participant withdrew prior to surgery (post-randomisation exclusion). Full details are in the CONSORT Flowchart (Figure I).

Participant characteristics

There were no discernible baseline differences between the groups. (Table 1) .

Table 1. The baseline characteristics of participants

	JII-BCS (n=40)	Genesis II (n=40)
Age, mean (SD)	69.28 (7.50)	67.95 (6.28)
Sex, female, number (%)	24 (60.0%)	20 (50.0%)
Body Mass Index, mean (SD)	28.77 (4.25)	29.86 (4.29)
Operated knee, right, number (%)	23 (57.0%)	14 (35.0%)
Intraoperative Am Soc Anaesthesiologists		
Score 1, number (%)	4 (10%)	2 (5%)
Score 2, number (%)	35 (88%)	36 (90%)
Score 3, number (%)	1 (3%)	2 (5%)
Previous contralateral knee implant		
yes, number (%)	7 (17.5%)	6 (15.0%)

no, number (%)	26 (65.0%)	22 (55.0%)
Missing, number (%)	7 (17.5%)	12 (30.0%)
Previous hip surgery, yes, number (%)	5 (13.0%)	5 (13.0%)
Employment, retired, number (%)	25 (63.0%)	24 (60.0%)
Pain Self-Efficacy-2 Questionnaire, median (IQR)	8.0 (6.0,10.0)	6.0 (3.0,9.5)
Hospital Anxiety & Depression Scale		
Anxiety total, mean (SD)	6.32 (3.54)	7.43 (3.05)
Depression total, mean (SD)	6.03 (2.37)	8.05 (3.55)
Oxford Knee Score, mean (SD)	20.25 (5.69)	19.05 (5.28)
EQ-5D utility score, mean (SD)	0.52 (0.16)	0.47 (0.20)
EQ-5D visual analogue score, mean (SD)	59.78 (17.70)	51.30 (17.71)
Timed Up and Go time (seconds), mean (SD)	11.34 (3.40)	11.04 (3.33)
Six-minute walk distance (metres), mean (SD)	304.03 (79.75)	299.09 (85.69)
Walking speed, mean (SD)	0.95 (0.21)[a]	0.93 (0.20)
Step length ratio, mean (SD)	-0.00 (0.04)[a]	-0.00 (0.04)
Operated knee range-movement (degrees), mean (SD)	42.11 (9.90)[a]	44.35 (8.56)
Operated leg single stance eyes open (secs), mean (SD)	5.60 (3.44)[b]	5.58 (3.28)[b]

[a] = 39 participants; [b] = 38 participants.

EQ-5D is a measure of health-related quality of life, in the range of -0.109 (worst possible state) and 1.0 (perfect health), anchored at 0 (death).

EQ-VAS is a health state assessment ranging between 0 and 100, in which zero is worst imaginable health state and 100 is best imaginable health state.

OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).

Timed Up and Go Test (TUG) – seconds to rise from chair, walk 3m and return to sitting; mean of three trials. A lower value indicates better function.

Six-minute walk test - metres walked in six minutes around a 20-metre circuit A higher value indicates greater function.

The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10

Primary outcome comparison – six months post-operatively (Table 2)

The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20) respectively. There was no significant difference between the groups: adjusted effect size 0.35 (-2.01,2.71) p=0.771 (Table 2).

Table 2. Oxford Knee Scores (OKS, primary outcome), OKS-APQ, EQ5D-5L and UCLA from baseline to six months after surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	Unadjusted p-value	Adjusted[a] effect size (95% CI)	Adjusted[a] p-value	Unadjusted effect size (95% CI)	Unadjusted p-value	Adjusted[a] effect size (95% CI)	Adjusted[a] p-value
OKS											
JII-BCS	20.25 (5.69) (n=40)	34.10 (7.10) (n=39)	42.97 (5.21) (n=39)	1.97 (-1.37,5.32)	0.24	2.5 (-0.71,5.71)	0.12	0.24 (-2.10,2.58)	0.84	0.35 (-2.01,2.71)	0.77
Genesis II	19.05 (5.28) (n=40)	36.00 (7.61) (n=40)	43.13 (5.20) (n=40)								

[a] adjusted for strata used in randomisation and for baseline scores, [b] median (IQR)

OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).

The OKS Activity and Participation Questionnaire (OKS-APQ) which complements the OKS by assessing everyday activity and social participation. The overall score is from 12 to 60 with 12 being the best outcome.

EQ-5D is a measure of health-related quality of life, in the range of -0.109 (worst possible state) and 1.0 (perfect health), anchored at 0 (death).

EQ-VAS is a health state assessment ranging between 0 and 100, in which zero is worst imaginable health state and 100 is best imaginable health state.

The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10 (participation in impact sport)

Secondary outcome comparisons – six months post-operatively

Patient-reported outcome questionnaires

There were no differences between the two groups for any of the secondary patient reported outcomes (online supplement Tables S1).

Walking and balance functional ability

There was no difference between the JII-BCS and Genesis II groups in the time to complete the TUG Test or the distance covered in the six-minute walk test (Online supplement Table S2). The Star-Excursion Test was attempted by all participants but 59% of participants at baseline, 59% at follow up and 63% at outcome were unable to complete it. (Online supplement Table S3). Therefore, statistical analysis was not undertaken.

Movement performance during walking and balance

The primary movement performance measures are reported in Table 3. In summary at six months post-surgery the Genesis II group had a significant advantage for knee ROM and peak knee flexion angular velocity during walking. There were no differences between the groups for walking speed or peak flexion angular knee velocity on stair climbing.

Table 3. Movement performance primary measures during walking from baseline to six months post-surgery (primary timepoint): walk speed, step length symmetry, knee range of motion (ROM) and peak knee flexion angular velocity.

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Walking speed (ms/sec)											
JII-BCS	0.95 (0.21)	0.90 (0.23)	1.09 (0.22)	0.08	0.11	0.09	**0.03**	0.05	0.34	0.03	0.40

	(n=39)	(n=37)	(n=35)	(-0.02,0.17)		(0.01,0.17)		(-0.05,0.07)		(-0.04,0.09)	
Genesis II	0.93 (0.20) (n=40)	0.97 (0.17) (n=37)	1.13 (0.18) (n=34)								
Step length symmetry (ratio)											
JII-BCS	-0.00 (0.04) (n=40)	0.03 (0.04) (n=37)	0.02 (0.04) (n=35)	-0.02 (-0.04,0.00)	**0.02**	-0.02 (-0.04,0.00)	**0.02**	-0.01 (-0.03,0.00)	0.10	-0.01 (-0.03,0.00)	**0.05**
Genesis II	-0.00 (0.04) (n=40)	0.01 (0.04) (n=37)	0.00 (0.04) (n=34)								
Knee ROM (degrees)											
JII-BCS	42.11 (9.90 (n=39)	37.87 (7.73) (n=38)	46.07 (7.71) (n=35)	4.51 0.39,8.64)	**0.03**	3.42 (-0.41,7.24)	0.08	4.77 (1.11,8.43)	**0.01**	3.14 (0.61,5.68)	**0.02**
Genesis II	40.31 (5.93) (n=40)	42.25 (9.75 (n=38)	50.62 (7.33) (n=34)								
Peak knee flexion angular velocity – walking (degrees/second											
JII-BCS	283.10 (53.83) (n=39)	269.65 (36.75) (n=38)	307.69 (38.96) (n=35)	23.15 (-0.84,47.14)	0.06	16.47 (-6.21,39.14)	0.15	31.00 (10.34,51.66)	**0.01**	21.75 (4.54,38.96)	**0.01**
Genesis II	300.36 (55.56) (n=40)	321.65 (43.31) (n=38)	330.38 (41.40) (n=35)								
Peak knee flexion angular velocity – stairs (degrees/second)											
JII-BCS	283.10 (53.83) (n=39)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31 (16.67,91.96)	**0.01**	51.63 (15.36,87.89)	**0.01**	50.01 (5.97,94.04)	**0.03**	35.15 (-3.09,73.39)	0.07
Genesis II	300.36 (55.56) (n=40)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)								

[a] adjusted for strata used in randomisation and for baseline scores

Step length symmetry – step length ratio calculated as ((2xOp)/Op+NOP))-1); where Op is the step length of the operated leg and NOP is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.

Data for all secondary movement performance measures are provided in the online supplement (Tables S4 – S8). The only difference between groups that reached statistical significance was for COP path length in double stance with eyes closed (On line supplement table S7). The mean (SD) values for the Genesis II and JII-BCS groups were 158.14 (65.40) mm and 235.48 (176.94) mm, respectively. Adjusted effect size was -59.91 (-105.98,-13.85) p=0.01 in favour of the Genesis II group.

Post-operative clinical context

There were no between-group significant differences for: length of stay, change in pain medication from randomisation or physiotherapy received (online supplement Tables S9 and S10).

Adverse events

One patient with a JII-BCS developed acute swelling and pain in the knee and was systemically unwell at 4 months post operatively. The joint aspiration demonstrated turbid fluid and an exchange of the polyethylene spacer and retention of the femoral and tibial components (Debridement And Implant Retention, (DAIR)) was performed with post operative antibiotic treatment. Subsequent microbiology was negative so infection was never conclusively demonstrated. The numbers and type of complications are reported in Table S11.

DISCUSSION

The findings do not support the hypothesis that the JII-BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at six months after surgery. No differences between groups were also found for: other patient reported outcomes; measures

of balance and walking function; hip and ankle range-of-motion; knee moments during walking; double support time during walking and percentage of gait cycle for peak muscle activation. However, significant advantages for the control group (Genesis II) were found for: operated knee range-of-movement and peak knee flexion angular velocity during walking, and postural control (COP path length).

Whilst some investigators have demonstrated differences between generations of knee designs [12] not all modern generation TKR designs have demonstrated an improvement in outcomes when compared to their predecessors. [15–20,48]. One possible reason for this is that the predecessor is already producing good results and therefore is difficult to improve upon. Regarding the JII-BCS, at the time of writing, only Bialy et al [45] have directly compared the Genesis II and the JII-BCS. Their study was non randomised and consisted of 18 patients between the two groups. They reported a greater supine range of movement of the JII-BCS compared to the Genesis II when measured with a long arm goniometer. They also reported an improvement in functional knee scores and stability when balancing. Their conclusions were that the JII-BCS restores more normal anatomy and kinematics which is correlates into the improvements that they found. None of the other papers reporting outcomes of the JII-BCS compared the JII-BCS to the Genesis II, all none used a randomised design and none used methodology or outcomes that could be compared to the methodology used in this trial [42-46]. However, on the basis of the available literature this we measured outcomes that would be expected to be difference on the basis of the available literature, walking velocity, step-length symmetry (resulting from longer stride length), knee range of motion (ROM) and peak knee angular velocity.

Within our trial we found differences in some biomechanical measures of motor impairment but not for others; patient-reported outcomes; and, walking and balance function. It is possible that knee range-of-movement during walking, walking symmetry, peak knee flexion angular velocity during walking, and postural control (COP path length) are detecting motor impairment improvement for the Genesis II group and/or because statistical significance was a result of testing multiple outcomes. The latter explanation is clearly possible but knee range-of-movement is greater for people reporting good outcome after knee replacement than

for those reporting poor outcome [49]. Moreover, knee range-of-movement has been found to be the main biomechanical effect of TKR [50] and to improve over time whilst other biomechanical measures do not [50,51]. Likewise, postural control improves over time [52,53] and approaches healthy control values [52]. Importantly, gait symmetry is an indicator of walking control [54] and, whilst of borderline statistical significance (p=0.05) can possibly detect differences following insertion of different prostheses. Peak knee angular velocity during walking is also an indicator of walking control [55] and has been found to change beneficially after insertion of the Genesis II prosthesis [50]. These findings indicate that secondary, in-depth, analysis of the biomechanical data should be undertaken.

A potential limitation is the relatively large number of secondary outcomes. However, this is also a strength as it ensured comprehensive examination of the potential impact of TKR on functional ability, motor impairment and health-related quality of life. Another potential limitation is that the surgeons all had a much greater familiarity with the Genesis II implant. However, all surgeons were very experienced with the Genesis implant with at least 10 years of experience implanting the device. All surgeons received thorough training with the JII-BCS and the surgical technique and instrumentation are similar for both devices with only one additional femoral cut being necessary for the JII-BCS compared to the Genesis II. A key strength of this trial is that the required sample size was achieved with only one person lost to follow-up. Other strengths include minimisation of selection bias through a robust randomisation procedure and use of double blinding to minimise interpretation bias.

The lack of difference between implant designs is important for patients, surgeons, healthcare providers and implant companies. For the patient and surgeons, reassurance can be gained that older designs, with proven track record of function and survivorship, can provide the same patient reported and functional outcome as more modern designs. For the healthcare providers, older implants are often less expensive and, in the absence of clinical benefit with and demonstrable longevity, if the additional expenditure on more modern designs is avoided for the hundreds of thousands of patients undergoing surgery worldwide the cost savings are potentially significant. Finally, for the implant companies, it is more likely than not than implant design has reached a point when non-implant

related factors play a more important role in patient outcome. The future of design and innovation may come in the form of more modern surgical techniques such as robotic assisted implantation to assist in placing the knee in a more kinematically sympathetic position which in turn may allow the newer design philosophies to positively influence outcome. It is possible, only then in combination with modern surgical techniques, that improvements in patient outcomes can be realised but well-constructed surgical trials will need to answer such questions.

Conclusion

This study demonstrated no difference between the Genesis II and its successor the JII-BCS for patient reported outcome measures, walking function, temporal-spatial gait parameters, balance ability and lower limb kinematic results at 6 months follow up. However, significant advantages were seen in for the Genesis II in the operated knee range-of-movement, peak knee flexion angular velocity during walking, and postural control.

FUNDING STATEMENT

This work was supported by an investigator initiated grant from Smith and Nephew, with both types of knee replacements supplied at the same cost. The funders had no role in the design of the study, the data collection, the data analysis, interpretation of data, or writing of the manuscript.

COMPETING INTERESTS

The trial was funded by Smith and Nephew via an unrestricted grant, administered by the Sponsor NNUH. Funding was used within NNUH for running the trial. Funds were provided via NNUH to UEA for the members of the trial team based in the movement and

Exercise Laboratory (MoveExLab) at UEA and the clinical trials unit (CTU) based at UEA for statistics, and trial and data management.

Authors' contributions

IM and VP drafted this paper. All authors (IM, VP, AC, GC, CW, CW, JW, BH, TO, JH and AMS) contributed to revisions of the manuscript, read and approved the final manuscript. All authors (IM, VP, AC, GC, CW, CW, JW, BH, TO, JH and AMS) contributed to the development of the trial protocol as well as conception or design of the work; the acquisition, analysis, or interpretation of data for the work.

- **Declaration of interest** *"All authors have completed the ICMJE uniform disclosure form at www.icmje.org/ coi_disclosure.pdf and declare: all authors had financial support from Smith and Nephew for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."*

  All authors must download and complete a copy of the ICMJE COI disclosure form and send a copy to the corresponding author.

DATA SHARING STATEMENT

Requests for access to individual participant data will be considered by the Chief Investigators. Requests can be made to dm.norwichctu@uea.ac.uk. The trial protocol and Statistical Analysis Plan (SAP) will also be made available as supplementary files.

Trial governance and quality assurance

The trial was managed by the Norwich Clinical Trials Unit (NCTU). Study data were collected and managed using REDCap electronic data capture tools. Quality assurance was undertaken by the NCTU according to their usual processes.

The trial was overseen by the Trial Management Group. This was chaired by the Chief Investigators and included expert advisors, members of the research team and Patient and Public Involvement (PPI) representatives. A safety committee (Prof Marcus Flather and Prof Simon Donell) periodically reviewed adverse events and relevant safety data by treatment group to monitor for potential harm.

Abbreviations

ADEs: Adverse Drug Events; AEs: Adverse Events; BCS: Bi-Cruciate Stabilised; Co-CI: Co-Chief Investigator; Consort: Consolidated Standards of Reporting Trials; CoP: Centre of Pressure; CRF: Case Report Form; CT: Computerised Tomography; DMC: Data Monitoring Committee; EMG: Electromyography; FJS: The Forgotten Joint Score; GCP: Good Clinical Practice; GDPR: General Data Protection Regulation; GISP3: General Information Security Policy 3; HADS: Hospital Anxiety and Depressions Score; HRA: Health Research Authority; ICH: International Council for Harmonisation; ISRCTN: International Standard Randomised Controlled Trials Number; MCL: Medial Collateral Ligament; MoveExLab: Movement Analysis Laboratory; mSEBT: Modified Star Excursion Balance Test; NCTU: Norwich Clinical Trials Unit; NERP: Norwich Enhanced Recovery Programme; NICE: National Institute for Health and Care Excellence; NNUH: Norfolk and Norwich University Hospital NHS Foundation Trust; OKS: Oxford Knee Score; OKS-APQ: Oxford Knee Score Activity & Participation Questionnaire; PI: Principle investigator; PIN: Participant Identification Number; PIS: Patient information sheet; PROMs: Patient-reported outcome measures; QA: Quality Assurance; QC: Quality Control; QMMP: Quality Management and Monitoring Plan; REDCap Research Electronic Data Capture ROMs: Ranges of Movement; SAEs: Serious Adverse Events; SAP: Statistical Analysis Plan; TKR: Total knee replacement; TMG: Trial Management Group; TTB: time to boundary; UKCRC: UK Clinical Research Collaboration

Ethical approval: The CAPAbility trial was conducted in accordance with the ethical principles outlined in the latest version of the Declaration of Helsinki and the Guideline for Good Clinical Practice related to experiments on humans. Ethical approval was given by the East of England – Cambridge Central Research Ethics Committee (reference 16/EE/0230). All participants provided informed consent prior to enrolment.

The lead authors (the manuscript's guarantors) affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The results of the research will be disseminated to the participants and public through direct written communication, broadcasts, popular science articles, and newspapers.

Provenance and peer review: Not commissioned; externally peer reviewed.

REFERENCES

1. Price AJ, Alvand A, Troelsen A, Katz JN, Hooper G, Gray A, Beard D. Knee replacement. *Lancet*. 2018;392:1672–1682.
2. Judge A, Arden NK, Cooper C, Kassim javaid M, Carr AJ, Field RE, Dieppe PA. Predictors of outcomes of total knee replacement surgery. *Rheumatology*. 2012;51:1804–1813.
3. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. *BMJ Open.* 2012;2:e000435.
4. Heck DA, Robinson RL, Partridge CM, Lubitz RM, Freund DA. Patient outcomes after knee replacement. *Clin Orthop Relat Res.* 1998;356:93–110.
5. Kennedy L, Newman J, Ackroyd C, Dieppe P. When should we do knee replacements? *Knee.* 2003;10:161–6.
6. Jones C, Voaklander D, Suarez-Alma M. Determinants of function after total knee arthoplasty. *Phys Ther.* 2003;83:696–706.
7. Cisternas MG, Murphy L, Sacks JJ, Solomon DH, Pasta DJ, Helmick CG. Alternative methods for defining osteoarthritis and the impact on estimating prevalence in a US population-based survey. *Arthritis Care Res.* 2016;68:574–580.
8. Vos T, Flaxman M, Naghavi R, Lozano C, Michaud M, Ezzati M, Al E. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet.* 2012;380:2163–2196.
9. Collades-Maestre I, Lizaur-Utrilla A, Gonzalez-Navarro B, Miralles-Munoz F, Marco-Gomez L, Lopez-Prats F, Gil-Guillen V. Better functional outcome after single-radius TKA compared with multi-radius TKA. *Knee Surgery, Sport Traumatol Arthrosc.* 2017;25:3508–3514.
10. Cook L, Klika A, Szubski C, Rosneck J, Molloy R, Barsoum W. Functional outcomes used to compare single radius and multiradius of curvature designs in total knee arthoplasty. *J Knee Surg.* 2012;25:249–253.

11. Jacobs W, Christen B, Wymenga A, Schuster A, van der Schaaf D, ten Ham A, Wehr U. Functional performance of mobile versus fixed bearing total knee prostheses: a randomised controlled trial. *Knee surg Sport traumatol arthrosc.* 2012;20:1450–1455.
12. Hamilton D, Burnett R, Patton J. Implant design influences patient outcome after total knee arthroplasty: a prospective double-blind randomised controlled trial. *Bone Jt J.* 2015;97-B(1):64–70.
13. Pennington M, Grieve R, Black N, Van der Meulen JH. Cost-effectiveness of five commonly used prosthesis brands for total knee replacement in the UK: A study using the NJR Dataset. *PLoS One.* 2016;11:e0150074.
14. Dowsey M, Gould D, Spelman T, Pandy M, Choong P. A randomized controlled trial comparing a medial stabilized total knee prosthesis to a cruciate retaining and posterior stabilized design: a report of the clinical and functional outcomes following total knee replacement. *J Arthoplasty.* 2020;35:1582-1590.e2.
15. Hauer G, Hörlesberger N, Klim S, Bernhardt GA, Leitner L, Glehr M, Leithner A, Sadoghi P. Mid-term results show no significant difference in postoperative clinical outcome, pain and range of motion between a well-established total knee arthroplasty design and its successor: a prospective, randomized, controlled trial. *Knee Surgery, Sport Traumatol Arthrosc.* 2020:827–831.
16. Chua J, Goh G, Liow M, Tay D, Lo N, Yeo S. Modern TKA implants are equivalent to traditional TKA implants in functional and patellofemoral joint-related outcomes. *Knee Surgery, Sport Traumatol Arthrosc.* 2019;27:1116–1123.
17. Molloy I, Keeney B, Sparks M, Paddock N, Koeing K, Moschetti W, Jevsevar D. Short term patient outcomes after total knee arthroplasty: does the implant matter? *Knee.* 2019;26:687–699.
18. Ranawat C, White P, West S, Ranawat A. Clinical and radiographic results of attune and PFC sigma knee designs at 2-year follow-up: a prospective matched-pair analysis. *J Arthroplasty.* 2017;32:431–436.
19. Song S, Kang S, Park C, Bae D. Comparison of clinical results and risk of patellar injury between attune and PFC sigma knee systems. *Knee Surg Relat Res.* 2018;30:334–340.
20. Behrend BH, Zdravkovic V, Bosch M, Hochreiter B. No difference in joint awareness after TKA: a matched-pair analysis of a

classic implant and its evolutional design. *Knee Surgery, Sport Traumatol Arthrosc.* 2019;27:2124–2129.

21. Evans JT, Walker RW, Evans JP, Blom AW, Sayers, AdrianWhitehouse MR. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *Lancet.* 2019;393:655–663.
22. National Joint Registry for England, Wales N ireland and the I of M. National Joint Registry. 2019. Available from: https://reports.njrcentre.org.uk/portals/0/pdfdownloads/njr 16th annual report 2019.pdf
23. Moore C, Lenz N. The evolution of guided motional total knee arthroplasty – the Journey II Bi-Cruciate Stabilized Knee System. *Bone Jt Sci.* 2012;3:1–8.
24. Grieco T, Sharma A, Dessinger G, Cates H, Komistek R. In vivo kinematic comparison of a bicruciate stabilized total knee arthroplasty and the normal knee using fluoroscopy. *J Arthroplasty.* 2018;33:565–571.
25. Clarke C, Pomeroy V, Clark A, Creelman G, Hancock N, Horton S, Killett A, Mann C, Payerne E, Tomas A, et al. CAPAbility: Comparison of the JOURNEY II Bi-Cruciate Stabilised and GENESIS II total knee arthroplasty in performance and functional ability: Protocol of a randomised controlled trial. *Trials.* 2020;21:222.
26. Merle-Vincent F, Couris C, Schott A, Conrozier T, Piperno M, Mathieu P, Mignon E. Factors predicting patient satisfaction 2 years after total knee arthroplasty for osteoarthritis. *Jt Bone Spine.* 2011;78:383–386.
27. Singh J, O'Byrne M, Harmsen S, Lewallen D. Predictors of moderate-severe functional limitation after primary Total Knee Arthroplasty (TKA): 4701 TKAs at 2-years and 2935 TKAs at 5-years. *Osteoarthr Cartil.* 2010;18:515–521.
28. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) - a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inf.* 2009;42:377–381.
29. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, Al E. The REDCap consortium: building an international community of software platform partners. *J Biomed Inf.* 2019;95:103208.
30. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Jt*

Surg. 1998;80:63–69.

31. Bohm E, Loucks I, Tan Q, Turgeon T. Determining minimum clinically important difference and targeted clinical improvement values for the Oxford 12. In: *American Academy of Orthopaedic Surgeons 2012 Annual Conference.* ; 2012.
32. Beard D, Harris K, Dawson J, Doll H, Murray D, Carr A, Price A. Meaningful changes for the Oxford Hip and Knee Scores after joint replacement surgery. *J Clin Epidemiol.* 2015;68:73–79.
33. Williams D, O'Brien S, Doran E, Price A, Beard D, Murray D, Beverland D. Early postoperative predictors of satisfaction following total knee arthroplasty. *Knee.* 2013;20:442–446.
34. Dawson J, Beard D, Mckibbib H, Harris K, Jenkinson C, Price A. Development of a patient-reported outcome measure of activity and participation (the OKS-APQ) to supplement the Oxford knee score. *Bone Jt J.* 2014;96:331–338.
35. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* 2011;20:1727–1736.
36. Podsiadlo D, Richardson S. The timed "Up and Go": a test of basic functional mobilty for frail elderly persons. *JAGS.* 1991;39:142–148.
37. Yuksel E, Unver B, Kalkan S, Karatosun V. Reliability and minimal detectable change of the 2-minute walk test and Timed Up and Go test in patients with total hip arthroplasty. J *Arthroplasty.* 2017;32:426–430.
38. Kennedy DM, Stratford PW, Wessel J, Gollish JD, Penney D. Assessing stability and change of four performance measures: A longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord.* 2005;6:3.
39. Bennell K, Dobson F, Hinman R. Measures of physical performance assessments: Self-Paced Walk Test (SPWT), Stair Climb Test (SCT), Six-Minute Walk Test (6MWT), Chair Stand Test (CST), Timed Up & Go (TUG), Sock Test, Lift and Carry Test (LCT), and Car Task. *Arthritis Care Res.* 2011;63:S350–S370.
40. Naylor JM, Mills K, Buhagiar M, Fortunato R, Wright R. Minimal important improvement thresholds for the six-minute walk test in a knee arthroplasty cohort: triangulation of anchor- and distribution-based methods. *BMC Musculoskelet Disord.* 2016;17:390.

41. Kinzey SJ, Armstrong CW. The reliability of the Star-Excursion test in assessing dynamic balance. *J orthop Sport Phys Ther.* 1998;27:356–360.

42. Smith LA, Nachtrab J, LaCour M, Cates H, Freeman MG, Komistek RD. In Vivo Knee Kinematics: How Important Are the Roles of Femoral Geometry and the Cruciate Ligaments? *J Arthroplasty*. 2021;36(4):1445-1454.

43. Tomite T, Saito H, Aizawa T, Kijima H, Miyakoshi N, Shimada Y. Gait Analysis of Conventional Total Knee Arthroplasty and Bicruciate Stabilized Total Knee Arthroplasty Using a Triaxial Accelerometer. *Case Rep Orthop*. 2016;2016:6875821.

44. Di Benedetto P, Vidi D, Colombo A, Buttironi MM, Cainero V, Causero A. Pre-operative and post-operative kinematic analysis in total knee arthroplasty. A pilot study. *Acta Biomed*. 2019;90(12-S):91-97.

45. Biały M, Corte R, Dec J, Pierzchała A, Gnat R. Evaluation of Functional Status in Patients after Total Knee Arthroplasty: A Comparison of the Journey II Bi-Cruciate Stabilized Total Knee System and Genesis II Cruciate-Retaining Implant. *Physiotherapy Review*. 2021;25(3):24-34.

46. Hyodo K, Kanamori A, Kadone H, Takahashi T, Kajiwara M, Yamazaki M. Gait Analysis Comparing Kinematic, Kinetic, and Muscle Activation Data of Modern and Conventional Total Knee Arthroplasty. *Arthroplast Today*. 2020;6(3):338-342.

47. Amemiya K, Kaneko T, Omata M, Igarashi T, Takada K, Ikegami H, Musha Y. Anatomical bi-cruciate retaining TKA improves gait ability earlier than bi-cruciate stabilized TKA based on triaxial accelerometery data: A prospective cohort study. *Asia Pac J Sports Med Arthrosc Rehabil Technol.* 2021;25:35-41.

48. Nunley RM, Nam D, Berend K, Dennis D, Della Valle C, Barrack R. New total knee arthroplasty designs: do young patients notice? *Clin Orthop relat Res.* 2015;473:101–108.

49. Naili JE, Wretenberg P, Lindgren V, Iversen MD, Hedström M, Broström EW. Improved knee biomechanics among patients reporting a good outcome in knee-related quality of life one year after total knee arthroplasty. *BMC Musculoskelet Disord.* 2017;18:122.

50. Rahman J, Tang Q, Monda M, Miles J, McCarthy I. Gait assessment as a functional outcome measure in total knee arthroplasty: A cross-sectional study. *BMC Musculoskelet Disord.* 2015;16:66.

51. Yoshida Y, Zeni J, Snyder-Mackler L. Do patients achieve normal gait patterns 3 years after total knee arthroplasty? *J Orthop Sports Phys Ther.* 2012;42:1039–1049.

52. Gauchard GC, Vançon G, Meyer P, Mainard D, Perrin PP. On the role of knee joint in balance control and postural strategies: Effects of total knee replacement in elderly subjects with knee osteoarthritis. *Gait Posture.* 2010;32:155–160.

53. Moutzouri M, Gleeson N, Billis E, Tsepis E, Panoutsopoulou I, Gliatis J. The effect of total knee arthroplasty on patients' balance and incidence of falls: a systematic review. *Knee Surgery, Sport Traumatol Arthrosc.* 2017;25:3439–3451.

54. Patterson KK, Nadkarni NK, Black SE, McIlroy WE. Temporal gait symmetry and velocity differ in their relationship to age. *Gait Posture* [Internet]. 2012;35:590–594. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624763/pdf/nihms412728.pdf

55. Richards JD, Pramanik A, Sykes L, Pomeroy VM. A comparison of knee kinematic characteristics of stroke patients and age-matched healthy volunteers. *Clin Rehabil.* 2003;17:565–571.

Figure legends

Figure 1. Consort diagram

ACKNOWLEDGEMENTS

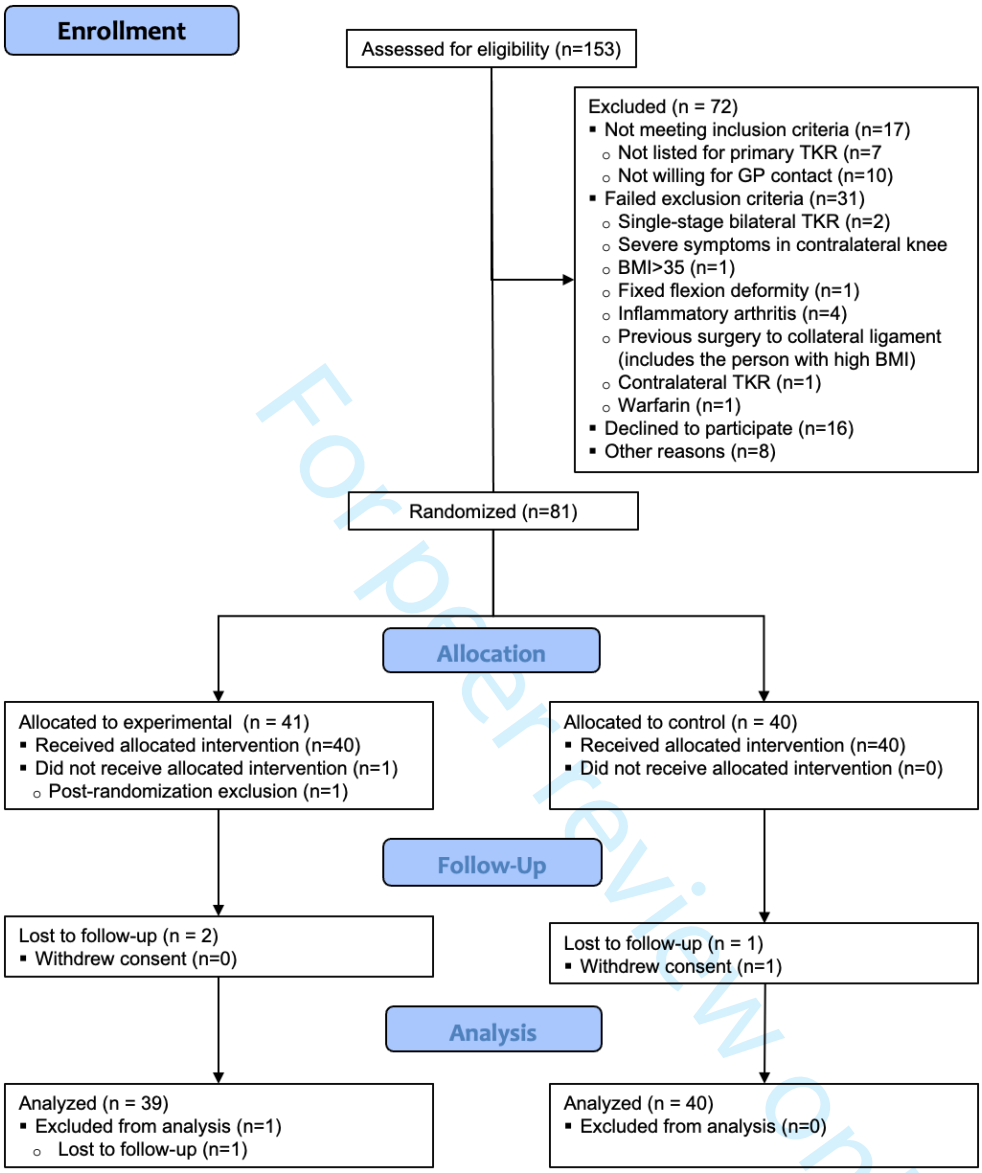
Thanks to all the participants and families who gave their time to be part of this study; Antony Colles, Martin Pond and the NCTU data management team; Estelle Payerne; Amanda Thacker; NNUH sponsorship team and the safety monitoring committee members, Prof Marcus Flather and Prof Simon Donell.

Also:

- Mr Charles Mann
- Mr Nish Chirodian

Mr David Calder
Dr Nicola Hancock
Nursing and clinic staff at the Spire Hospital and NNUH
Prof Andoni Toms and the Radiology department at Addenbrooke's hospital, Cambridge
Dr Simon Horton
Dr Anne Killett
Mr Gareth Roberts

Figure 1. CONSORT Flow Diagram



Supplement to

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility randomised controlled trial

Contents

Table S1. OKS-APQ, EQ5D-5L and UCLA from baseline to six months after surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
OKS-APQ											
JII-BCS	2.81 (6.63) (n=40)	36.09 (27.05) (n=40)	70.83 (23.81) (n=39)	11.63 (-1.87,25.14)	0.09	12.09 (-1.63,25.8)	0.08	3.66 (-7.53,14.84)	0.52	3.31 (-8.05,14.67)	0.56
Genesis II	1.41 (3.39) (n=40)	47.34 (32.50) (n=40)	74.14 (25.46) (n=40)								
EQ5D Utility											
JII-BCS	0.52 (0.16) (n=40)	0.74 (0.10) (n=40)	0.90 (0.12) (n=39)	0.05 (-0.01,0.1)	0.11	0.05 (0.00,0.11)	**0.05**	0.00 (-0.06,0.05)	0.89	0.00 (-0.06, 0.05)	0.95
Genesis II	0.47 (0.20) (n=40)	0.78 (0.14) (n=40)	0.89 (0.13) (n=40)								
EQ5D VAS											
JII-BCS	59.78 (17.70) (n=40)	77.85 (14.12) (n=40)	89.03 (9.44) (n=39)	0.65 (-6.18,7.48)	0.85	2.89 (-3.92,9.70)	0.40	-1.71 (-6.77,3.35)	0.50	-1.04 (-6.32,4.23)	0.70
Genesis II	51.30 (17.71) (n=40)	78.25 (16.11) (n=40	87.55 (12.75) (n=40)								
UCLA											
JII-BCS	1.10 (0.78) (n=40)	4.82 (1.62)[b] (n=40)	6.87 (1.38) N=38)	0.23 (-0.5,0.95)	0.53	0.25 (-0.48,0.98)	0.49	-0.13 (-0.74,0.48)	0.67	0.08 (-0.69,0.53)	0.79
Genesis II	3.00 (0.85) (n=40)	5.05 (1.60)[b] (n=40)	6.68 (1.44) (n=40)								

[a] adjusted for strata used in randomisation and for baseline scores, [b] median (IQR)

Table S2. Walking functional ability from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Walking function											
Timed Up & Go Test (secs)											
JII-BCS	11.34 (3.40) (n=40)	11.89 (3.92) (n=37)	10.30 (2.90) (n=35)	1.61 (-3.11,-0.1)	**0.04**	-1.32 (-2.48,-0.16)	**0.03**	-0.62 (-1.91,0.66)	0.34	-0.37 (-1.25,0.50)	0.40
Genesis II	11.04 (3.33) (n=40)	10.42 (2.45) (n=37)	9.76 (2.36) (n=34)								
6-minute walk test (metres)											
JII-BCS	304.03 (79.95) (n=40)	272.20 (71.51) (n=39)	343.41 (73.44) (n=35)	30.12 (-1.16,61.39	0.06	32.2 (5.74,58.65)	**0.02**	22.24 (-9.72,54.2)	0.17	20.19 (-1.60,41.98)	0.07
Genesis II	299.09 (85.69) (n=40)	298.87 (65.23) (n=37)	363.39 (58.85) (n=34)								

[a] adjusted for strata used in randomisation and for baseline scores.

Timed Up and Go Test – seconds to rise from chair, walk 3m and return to sitting; mean of three trials. A lower value indicates better function.

Six-minute walk test - metres walked in six minutes around a 20-metre circuit. A higher value indicates greater function.

Table S3. Balance functional ability, Star Excursion Test, from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	**Two months after surgery**	**Six months after surgery**
Anterior reach (cm)– non-operated leg			
JII-BCS	40.98 (7.69) (n=37)	43.20 (8.11) (n-33)	43.09 (7.58) (n=31)
Genesis II	40.54 (6.12) (n=36)	41.87 (6.18) (n=34)	42.16 (9.37) (n=32)
Anterior reach (cm) – operated leg			
JII-BCS	41.83 (6.85) (n=34)	36.84 (7.45) (n=32)	44.98 (21.54) (n=30)
Genesis II	37.72 (7.41) (n=36)	35.92 (6.94) (n=35)	40.00 (7.47) (n=32)
Postero-medial reach (cm) – non-operated leg			
JII-BCS	63.79 (10.87) (n=36)	65.10 (13.59) (n=33)	67.74 (14.59) (n=31)
Genesis II	63.57 (9.81) (n=34)	65.11 (10.78) (n=34)	66.44 (16.73) (n=32)
Postero-medial reach (cm) – operated leg			
JII-BCS	64.18 (11.69) (n=34)	62.44 (12.74) (n-32)	66.10 (14.10) (n=31)
Genesis II	59.32 (10.23) (n=36)	59.57 (8.87) (n=34)	65.59 (11.43) (n=32)
Postero-lateral reach (cm) – non-operated leg			
JII-BCS	60.10 (11.77) (n=34)	62.03 (15.15) (n=31)	63.21 (14.49) (n=29)
Genesis II	59.86 (11.45) (n=32)	62.16 (11.73) (n=32)	62.81 (16.63) (n=30)
Postero-lateral reach (cm) – operated leg			
JII-BCS	58.73 (11.01) (n=32)	57.78 (14.08) (n=29)	62.83 (14.86) (n=30)
Genesis II	55.39 (10.78) (n=33)	55.19 (8.02) (n=31)	60.19 (12.70) (n=30)

[a] adjusted for strata used in randomisation and for baseline scores.
No statistical analysis as insufficient number of participants could undertake the Star Excursion Test.

Table S4. Double stance support (percentage of the gait cycle) from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Double stance support (% gait cycle)											
JII-BCS	0.30 (0.07) (n=39)	0.32 (0.11) (n=37)	0.25 (0.08) (n=35)	-0.02 (-0.06,0.02)	0.33	-0.03 (-0.07,0.00)	0.07	-0.01 (-0.04,0.02)	0.60	0.00 (-0.02,0.02)	0.69
Genesis II	0.32 (0.09) (n=40)	0.30 (0.07) (n=37)	0.25 (0.05) (n=34)								

[a] adjusted for strata used in randomisation and for baseline scores.

Double stance support (% of gait cycle). A lower value indicates better performance

Table S5. Joint parameters from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
During walking											
Hip ROM (degrees)											
JII-BCS	40.00 (6.04) (n=39)	38.90 (5.44) (n=38)	41.56 (6.01) (n=35)	2.24 (-0.48,4.95)	0.11	1.93 (-0.20,4.06)	0.07	3.01 (0.20,5.82)	**0.04**	1.64 (-0.11,3.39)	0.07
Genesis II	40.31 (5.93) (n=40)	41.03 (6.15) (n=37)	44.44 (5.48) (n=34)								
Ankle ROM (degrees)											
JII-BCS	24.84 (6.57) (n=39)	21.69 (4.54) (n=38)	24.54 (6.63) (n=35)	0.75 (-1.21,2.71)	0.45	1.36 (0.22,2.94)	0.09	-1.37 (-4.01,1.28)	0.31	0.08 (-1.89,2.04)	0.94
Genesis II	23.10 (5.52) (n=40)	22.43 (3.76) (n=37)	23.22 (3.77) (n=34)								
Knee peak extension moment (Nm/Kg)											
JII-BCS	-0.34 (0.09) (n=37)	-0.30 (0.10) (n=38)	-0.41 (0.08) (n=34)	-0.03 (-0.08,0.01)	0.16	-0.03 (-0.07,0.02)	0.22	-0.02 (-0.05,0.02)	0.45	-0.02 (-0.05,0.02)	0.35
Genesis II	-0.32 (0.08) (n=40)	-0.33 (0.10) (n= 37)	-0.42 (0.08) (n=34)								
Knee peak flexion moment (Nm/Kg)											
JII-BCS	0.52 (0.25) (n=37)	0.38 (0.22 (n=38)	0.55 (0.27) (n=34)	-0.06 (-0.16,0.04)	0.22	-0.06 (-0.15,0.04)	0.26	0.11 (-0.23,0.42)	0.10	-0.07 (-0.19,0.05)	0.22
Genesis II	0.44 (0.21) (n=40)	0.34 (0.21) (n=37)	0.45 (0.25) (n=34)								
During stepping onto a stair											
Peak knee angular velocity (degrees/sec)											
JII-BCS	221.70 (88.35) (n=37)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31 (16.67,91.96)	**0.01**	51.63 (15.36,87.89)	**0.01**	50.01 (5.97,94.04)	**0.03**	35.15 (-3.09,73.39)	0.07
Genesis II	243.74 (84.05) (n=38)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)								

[a] adjusted for strata used in randomisation and for baseline scores. Higher values for measures indicate better movement.

Table S6. Muscle activity during walking from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Peak activation Vastus Medialis (% gait cycle)											
JII-BCS	28.62 (27.23) n=39	25.42 (24.93 n=38	23.20 (22.72) n=35	-1.22 (-12.1,9.65)	0.82	-1.13 (-11.98,9.72)	0.84	1.86 (-9.45,13.16)	0.74	1.4 (-9.43,12.22)	0.80
Genesis II	30.10 (27.73) n=40	23.18 (22.66) n=38	24.64 (24.94) n=33								
Peak activation Vastus Lateralis (% gait cycle)											
JII-BCS	18.44 (12.15) n=39	17.29 (11.51) n=38	13.03 (5.61) n=35	1.20 (-5.67,8.07)	0.73	1.11 (-5.78,8.01)	0.75	5.59 (-1.52,12.71)	0.12	5.63 (-1.65,12.9)	0.13
Genesis II	20.23 (20.35) n=40	18.47 (17.46) n=38	18.79 (19.89) n=33								
Peak activation Tibialis Anterior (% gait cycle)											
JII-BCS	23.46 (24.74) n=39	18.97 (20.91) n=38	15.20 (14.27) n=35	0.47 (-9.18,10.13)	0.92	0.54 (-9.21,10.28)	0.91	4.68 (-3.92,13.28)	0.28	6.06 (-2.14,14.26)	0.14
Genesis II	28.88 (27.88) n=40	19.82 (20.76) n=38	19.61 (20.32) n=33								
Peak activation Biceps Femoris (% gait cycle)											
JII-BCS	25.03 (25.32) n=39	21.87 (21.34) n=38	35.77 (34.01) n=35	6.76 (-5.49,19.01)	0.28	5.71 (-6.42,17.84)	0.35	-9.78 (-25.33,5.76)	0.21	-10.97 (-26.69,4.74)	0.17
Genesis II	29.98 (28.00) n=40	29.16 (31.55) n=38	25.30 (28.86) n=33								
Peak activation Lateral head of Gastrocnemius (% gait cycle)											
JII-BCS	24.67 (17.24) n=39	23.87 (19.34) n=38	20.66 (15.99) n=35	-1.18 (-8.9,6.53)	0.76	-1.01 (-8.55,6.52)	0.79	-1.84 (-8.61,4.93)	0.59	-1.89 (-8.79,5.01)	0.59
Genesis II	25.23 (22.36) n=40	23.39 (14.60) n=38	20.00 (13.80) n=33								

[a] adjusted for strata used in randomisation and for baseline scores

Table S7. Balance parameters from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
				Two months				Six months			
	Baseline	Two months after surgery	Six months after surgery	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value	Unadjusted effect size (95% CI)	p-value	Adjusted[a] effect size (95% CI)	p-value
Can stand for 10 secs only on operated leg, eyes open (number)											
JII-BCS	13/40 (32.5%)	13/39 (33.3%)	15/35 (42.9%)	0.92 (0.34,2.49)	0.88	1.17 (0.34,4.07)	0.80	0.36 (0.20,2.51)	0.249	0.62 (0.17,2.28)	0.47
Genesis II	10/40 (25.0%)	11/37 (29.7%)	10/34 (29.4%)								
Seconds standing only on operated leg, eyes open (secs)											
JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	235.48 (176.94) (n=35)	7.00 (-48.53,62.53)	0.80	23.72 (-10.93,58.37)	0.18	82.42 (-147.17,-17.67)	**0.01**	-59.91 (-105.98,-13.85)	**0.01**
Genesis II	188.25 (125.93) (n=40)	226.09 (137.15) (n= 36)	158.14 (65.40) (n=34)								
COP path length standing on both legs, eyes closed (mm)											
JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	235.48 (176.94) (n=35)	7.00 (-48.53,62.53)	0.80	23.72 (-10.93,58.37)	0.18	82.42 (-147.17,-17.67)	**0.01**	-59.91 (-105.98,-13.85)	**0.01**
Genesis II	188.25 (125.93) (n=40)	226.09 (137.15) (n= 36)	158.14 (65.40) (n=34)								

[a] adjusted for strata used in randomisation and for baseline scores

Resultant centre of pressure path length (COP cm) in double stance with eyes closed: lower path length indicates better balance ability.

Table S8. Non-operated leg cadence (steps/minute), step length and stride length from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	**Two months after surgery**	**Six months after surgery**
Cadence			
JII-BCS	107.37 (10.62) N=39	103.09 (13.21) N=37	113.09 (9.51) N=35
Genesis II	102.7(10.83) n=40	105.25(10.21) n=37	112.98(9.71) n=34
Step length			
JII-BCS	0.53(0.08) n=39	0.5(0.09) n=37	0.56(0.1) n=35
Genesis II	0.54(0.09) n=40	0.55(0.08) n=37	0.6(0.08) n=34
Stride length			
JII-BCS	1.06(0.17) n=39	1.04(0.18) n=37	1.15(0.21) n=35
Genesis II	1.08(0.17) n=40	1.11(0.15) n=37	1.2(0.16) n=34

Cadence (Steps/min), step length (m), and stride length (m)of non operative limb

Table S9. Post-operative clinical context: days of in-patient stay and consequences of surgery

	JII-BCS Number (%)	Genesis II Number (%)	Effect size (95% CI)	p-value
Length of in-patient stay				
Three days	14 (35%)	13 (33%)		
Four days	21 (53%)	21 (53%)		
Five days	4 (10%)	5 (13%)	NA	0.749[a]
Six days	1 (3%)	1 (3%)		
Median	4.00	4.00		
(IQR)	(3.00, 4.00)	(3.00, 4.00)		
Revision surgery for implant related problems*				
No	40 (100%)	40 (100%)	NA	NA
Yes	0	0		
Complications				
No	34 (85%)	35 (88%)	1.00	0.780
Yes	6 (15%)	5 (13%)	0.83 (0.23,3.01)	
Change pain medication				
No	1 (3%)	4 (10%)	-7.5% (-18.0,3.0)	0.359[a]
Yes	39 (98%)	36 (90%)		

NA = not appropriate; [a] Fisher exact test.

Length of stay, complications, revision for implant related problems and change in pain medication

*One patient in the JII-BCS had a revision of the polyethylene component for possible infection which was never diagnosed. As this is not implant related it is not included in the table.

Table S10. Composition of out-patient physiotherapy treatment received following TKR by JII-BCS and Genesis II groups.

	Number of sessions where exercises were performed: median (IQR)	
	JII-BCS (n=40)	**Genesis II (n=40)**
In-patient sessions (JII-BCS n=27, Genesis II n=26)		
Gait re-education	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Step exercise	1.0 (1.0, 1.0)	1.0 (1.0,2.0)
Knee ROM flexion exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Static quadriceps exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Inner range quadriceps exercise	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Straight leg raise exercise	0.0 (1.0, 1.0)	0.0 (1.0, 1.0)
Knee extension strengthening exercise in sitting	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Ice treatment	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)
Advice and education	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Other body region rehabilitation exercises	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Out-patient settings (JII-BCS n=33, Genesis II n=35)		
Other body region rehabilitation exercises	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Seat pedal exercises	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
Static bike exercises	1.0 (0.0, 3.0)	1.0 (0.0, 5.0)
Cross-trainer exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Calf stretch exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Gait re-education	1.0 (1.0, 2.0)	1.0 (1.0, 5.0)
Stair practice	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)
Step exercise	1.0 (0.0, 4.0)	1.0 (1.0, 5.0)
Sit to stand exercise (without arms of chair)	1.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Sit to stand exercise (with arms of chair)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Knee ROM flexion (sat in chair)	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Knee strengthening extension exercise with resistance band	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Static quadriceps exercise	1.0 (1.0, 1.0)	1.0 (1.0, 4.0)
Straight leg raise exercise	1.0 (1.0, 1.0)	1.0 (1.0, 3.0)
Inner range quadriceps exercise	1.0 (1.0, 3.0)	1.0 (1.0, 3.0)
Proprioceptive exercises in standing	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Proprioceptive exercises in standing (with support)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Proprioceptive exercises in standing (with eyes shut)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)
Advice and education	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
Glutei strengthening exercise	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)

Table S11. Complications and adverse events

Complication type	Numbers of participants	
	JII-BCS	Genesis II
Post operative reaction to analgesia requiring admission		1
Pulmonary embolus	1	1
Wound haematoma / swelling	2	4
Postoperative bleeding requiring blood transfusion		1
Iliotibial tract discomfort		1
Chest infection	1	1
Urinary tract infection		1
Debridement and implant retention (DAIR)	1	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	13,14
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10,11,12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
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	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
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	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	14, 15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
	14b	Why the trial ended or was stopped	13
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
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)	19, 22,25 29,31
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	As above
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	33, Supplementary table 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	33
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	33
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	34,35
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	provided
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	35

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.