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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

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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

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136/bmjopen-2022-061648 on **ABSTRACT (300 words)** Objectives: To determine if a newer design of TKR (Journey II BCS) produces superior patient reported outcomes scores and ary 2023. 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 sugery 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, Timer 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 Genetiss 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 by gue 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 opyright.

 BMJ Open path length) during quiet standing than the JII-BCS group (mean (SD) 158.14 (65.40) versus 235.48 (176.94) mgn, adjusted effect size, 59.91 (-105.98,-13.85) p=0.01.). 1648 on

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. Downloaded from http://bmjopen

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 • April 17, 2024 by guest. Protected by copyright. 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.

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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. Bewer 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 wheth at the risks and costs of erien newer devices implant will translate to patient benefits. //bmjopen.bmj.com

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 2024 by 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 seakeholders 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 by copyright. undertaken before supporting widespread adoption of newer implants into use.

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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 osteoarthrity [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, Methonis, 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, $\vec{t_{0}}$ 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.

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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 rand misation schedule stratified by site and age (<60 years = younger; \geq 60 years = older) [26,27]. Group allocation was revealed using REDC [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 6/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 perticipants (40 per group).

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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 bould present an unacceptable safety risk or were pregnant; were a private patient; were likely to be living outside the clinical center 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.

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Control intervention

Participants in the control group received the Genesis II (Smith and Nephew, Memphis TN), posterior stabilise $\mathbf{\hat{E}}(PS)$ TKR.

Surgical techniques

All four surgeons had extensive experience, at least five years, of the Genesis II implant. All undertook cadaveries training on the JII-BCS and declared that they were competent in the surgical technique having completed their operative learning curves 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 (oneweek post-operatively), $6-8\pm 2$ 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. guest. Protected by copyright.

Secondary outcome measures

1. Patient reported outcome questionnaires

- BMJ Open 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)23. Dowr 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. Protected by copyright.

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For walking tasks, participants were asked to walk in a straight line along a 10-metre walkway at their solution of the speed. For double stance activities, participants were instructed to stand with their feet shoulder-width apart. For solutions, 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 perfect symmetry.
- 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 da to 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 vague indicates better function.
- f. Hip, knee, and ankle range-of-motion during walking. Higher values indicate better function

136/bmjopen-202 Peak knee angular velocity during walking (inadvertently omitted from the statistical analysis play) and stepping up onto a g. 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). Single stance on the operated lower limb for 10 seconds with eyes open (yes/no) and duration mathematication. i. 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 alance 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. guest. Protec **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

ight.

BMJ Open 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. 1648 on 4 Ja

Analysis

The statistical analysis plan (SAP) was finalised and agreed prior to database lock and analysis was completed banded 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 ($\frac{2}{60}$) 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 24 by gues 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. copyright.

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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 as 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	Genesis II	
	(n=40)	(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,	8.0 (6.0,10.0)	6.0 (3.0,9.5)	
median (IQR)			
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	59.78 (17.70)	51.30 (17.71)	
(SD)			
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)	

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age 17 d	of 58		BMJ	Open		136/bmj
0 1 2 3 4 5 6 7	Walking speed, mean (SD) Step length ratio, mean (SD) Operated knee range-movement (degrees), mean (SD) Operated leg single stance eyes open (secs), mean (SD) a = 39 participants; $b = 38$ participants. EQ-5D is a measure of health-related qua EQ-VAS is a health state assessment rang OKS is a 12-item knee function assessment Timed Up and Go Test (TUG) – seconds Six-minute walk test - metres walked in	ging between 0 an ent, ranging from 0 to rise from chair six minutes aroun	d 100, in which ze) (worst score) to 4 , walk 3m and retu d a 20-metre circu	ro is worst imaginable healt 48 (best score). rn to sitting; mean of three it A higher value indicates	th state and 100 is trials. A lower va greater function.	best imaginable health state.
8 9	The UCLA Activity score to assess physical structure of the term of term o	ical activity self-ra	iting scale ranged	from 0 (complete inactivity)) to 10	om http
0 1	Primary outcome comparison – six	months post-op	eratively (Table	2)		o://bn
2 3	The OKS scores for the JII-BCS and	Genesis II group	s were mean (SD) 42.97 (5.21) and 43.13	(5.20) respectiv	gy. There was no significant
4 5 6	difference between the groups: adjust	ed effect size 0.3	95 (-2.01,2.71) p=	=0.771.		n.bmj.com
	Post-operative clinical context and	adverse events				
)	There were no between-group signific	cant differences f	for: length of stay	, change in pain medicati	ion from randor	f masation or physiotherapy
) <u>2</u> }	received (online supplement Tables S	2 and S3).				17, 2024 b
-	Secondary outcome comparisons –	six months post	-operatively (Ta	ible 2)		y guest
, ,	Patient-reported outcome questionna	uires		,		אל. פ
	There was no difference between the	two groups for C	KS-APQ. The r	nean (SD) values for the .	JII-BCS and Ge	g Besis II groups were 70.83
	(23.81) and 74.14 (25.46) respectively		-			ted by copyright
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136/bmjopen-2022-06 No difference between the groups was found for EQ-5D-5L. Utility score mean (SD) values for the JII-BCS an \vec{E} 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 (-9.32,4.23) 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)				Betwe	een grou	ps comparison	т р		
	(nu	mber of particip	ants)		Two n	nonths			Six n	onths	
		Two months	Six months	Unadjust	ted	Adjuste	da	Unadjus	ted	Adjuste	da
	Baseline	after surgery	after surgery	effect size (95% CI)	p- value	effect size (95% CI)	p- value	effect size (95% CI)	g p- Svalue	effect size (95% CI)	p- valu
OKS									<u> </u>		
JII-BCS	20.25 (5.69) (n=40)	34.10 (7.10) (n=39)	42.97 (5.21) (n=39)	1.97	0.24	2.5	0.12	0.24	on on	0.35	0.7
Genesis II	19.05 (5.28) (n=40)	36.00 (7.61) (n=40)	43.13 (5.20) (n=40)	(-1.37,5.32)	0.24	(-0.71,5.71)	0.12	(-2.10,2.58)	n 0.84 April 1	(-2.01,2.71)	0.7
OKS-APQ									7, 2		
JII-BCS	2.81 (6.63) (n=40)	36.09 (27.05) (n=40)	70.83 (23.81) (n=39)	11.63	0.00	12.09	0.00	3.66	17, 2024 by	3.31	0.5
Genesis II	1.41 (3.39) (n=40)	47.34 (32.50) (n=40)	74.14 (25.46) (n=40)	(-1.87,25.14)	0.09	(-1.63,25.8)	0.08	(-7.53,14.84)	9 0.52 guest	(-8.05,14.67)	0.50
EQ5D Utility									P		
JII-BCS	0.52 (0.16) (n=40)	0.74 (0.10) (n=40)	0.90 (0.12) (n=39)	0.05 (-	0.11	0.05	0.05	0.00	7 guest. Protected b	0.00	0.95
Genesis II	0.47 (0.20) (n=40)	0.78 (0.14) (n=40)	0.89 (0.13) (n=40)	0.01,0.1)	0.11	(0.00,0.11)	0.05	(-0.06,0.05)	Š.	(-0.06, 0.05)	0.9.
		-	eer review only -	L., //L ·		/ · · / · · · /			copyright.		

Page 19 o	f 58				BMJ	Open				136/bmjope		
1 2 3 4 5 6 7 8	EQ5D VAS JII-BCS Genesis II	59.78 (17.70) (n=40) 51.30 (17.71) (n=40)	77.85 (14.12) (n=40) 78.25 (16.11) (n=40	89.03 (9.44) (n=39) 87.55 (12.75) (n=40)	0.65 (-6.18,7.48)	0.85	2.89 (-3.92,9.70)	0.40	-1.71 (-6.77,3.35)	n-2022-061648	-1.04 (-6.32,4.23)	0.70
9	UCLA									anu		
10 11 12 13	JII-BCS Genesis II	1.10 (0.78) (n=40) 3.00 (0.85) (n=40)	4.82 (1.62) ^b (n=40) 5.05 (1.60) ^b (n=40)	6.87 (1.38) N=38) 6.68 (1.44) (n=40)	0.23 (-0.5,0.95)	0.53	0.25 (-0.48,0.98)	0.49	-0.13 (- 0.74,0.48)	iary 2023. D	0.08 (- 0.69,0.53)	0.79
14	^a adjusted for str	rata used in randor	· · ·		median (IOR)					Wr		

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

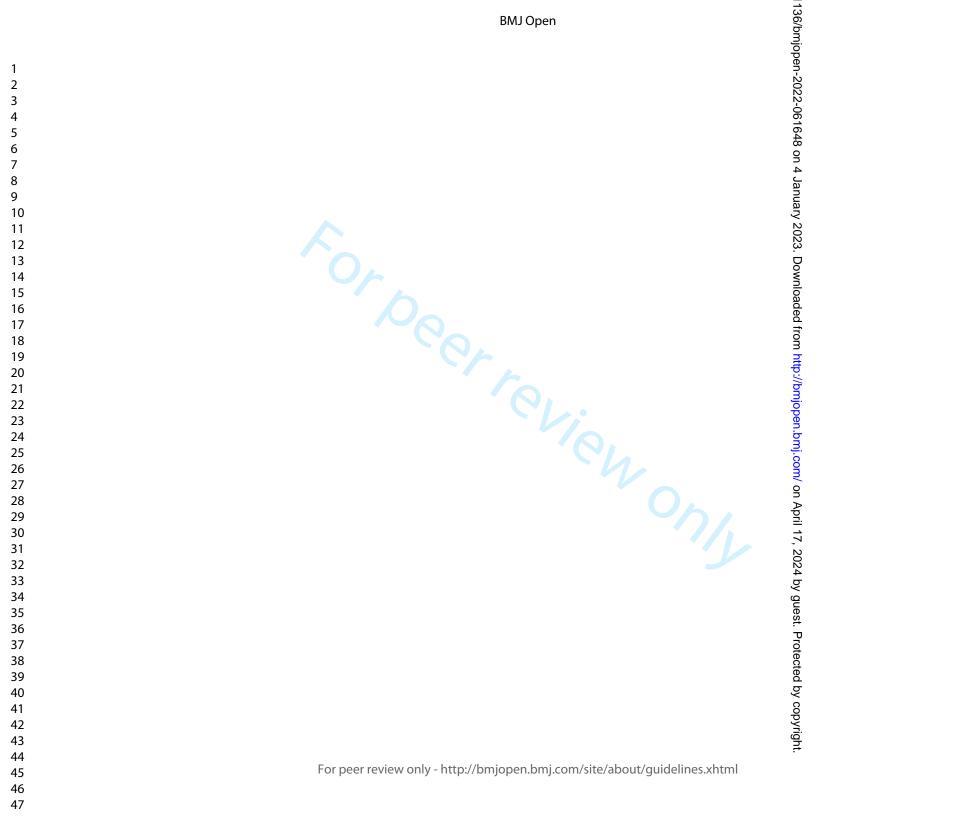
 a adjusted for strata used in randomisation and for baseline scores, b median (IQR)
 Image: Constraint of the second score is a second score in the score is a second score in the score is a second score in the score is a second score is a second score is a second score in the score in the score is a second score in the score is a second score in the score in the score is a second score in the score in the score in the score is a second score in the score in 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 of 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 impaces port).

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				BMJ Open	۱			136/bmjopen-2022			
	<i>nction (Table 3)</i> no difference betw	veen the JII-BC	S and Genesis	II groups in 1	the time	to complete	the TUC	6	n (SD) fo	or the JII-BCS	5
group was 1	0.30 (2.90) secon	nds and for the	Genesis II grou	ıp was 9.76 (2	2.36) se	conds. The a	djusted	effect size	was -0.3	7 (-1.25,-	
0.50), p=0.4	10.							4 Janua			
No statistica	ally significant di	fference was fc	ound between g	roups for six	-minute	walk distanc	e (p=0.0	7). Meage	SD) dista	ance for JII-	
BCS was 34	43.41 (73.44) met	res and for Ger	nesis II was 363	3.39 (58.85) r	metres: a	adjusted effec	et size w	vas 20.19🖫	1.60,41.9	98), p=0.07.	
								wnlo			
Table 3. W	alking function	and temporal	-spatial gait pa	arameters fr	om base	eline to six m	onths r	post-surer	y (prima	ary timepoint	;)
		Means (SDs)				Betw		ips compare	n	•	/
	(nui	mber of participa	ants)	TT. 1*	Two m		19			nonths	Ja
	Baseline	Two months after surgery	Six months after surgery	Unadjust effect size (95% CI)	ted p- value	Adjuste effect size (95% CI)	p- value	Una đ ju effect size (95% Q)	sted p- value	Adjuste effect size (95% CI)	p-valı
Walking fun	nction			(9370 CI)	value	(9370 CI)	value	en en	value	(9370 CI)	
-	c Go Test (secs)							.bmj			
JII-BCS	11.34 (3.40) (n=40)	11.89 (3.92) (n=37)	10.30 (2.90) (n=35)	1.61	0.04	-1.32	0.03	-0.62m	0.34	-0.37	0.40
	11.04 (3.33)	10.42 (2.45)	9.76 (2.36)	(-3.11,-0.1)		(-2.48,-0.16)		(-1.91,0.66)		(-1.25,0.50)	
Genesis II	(n=40)	(n=37)	(n=34)								
	(n=40)										
	(n=40)	(n=37) 272.20 (71.51) (n=39)	(n=34) 343.41 (73.44) (n=35)	30.12	0.06	32.2	0.02	April 17, 202 22.24	0.17	20.19	0.07
6-minute wa JII-BCS Genesis II	(n=40) alk test (metres) 304.03 (79.95) (n=40) 299.09 (85.69) (n=40)	272.20 (71.51) (n=39) 298.87 (65.23) (n=37)	343.41 (73.44)	30.12 (-1.16,61.39	0.06	32.2 (5.74,58.65)	0.02	April 17, 22.2422 (-9.72,542)	0.17	20.19 (-1.60,41.98)	0.07
6-minute wa JII-BCS Genesis II Temporal-sp	(n=40) alk test (metres) 304.03 (79.95) (n=40) 299.09 (85.69) (n=40) patial gait parameter	272.20 (71.51) (n=39) 298.87 (65.23) (n=37)	343.41 (73.44) (n=35) 363.39 (58.85)		0.06		0.02	April 17, 22.2422 (-9.72,542)	0.17		0.07
6-minute wa JII-BCS Genesis II Temporal-sp	(n=40) alk test (metres) 304.03 (79.95) (n=40) 299.09 (85.69) (n=40) patial gait paramete (metres per sec) 0.95 (0.21)	272.20 (71.51) (n=39) 298.87 (65.23) (n=37) ers 0.90 (0.23)	343.41 (73.44) (n=35) 363.39 (58.85) (n=34) 1.09 (0.22)	(-1.16,61.39		(5.74,58.65)		April 17, 22.2422 (-9.72,542)		(-1.60,41.98)	
6-minute wa JII-BCS Genesis II Temporal-sp Walk speed	(n=40) alk test (metres) 304.03 (79.95) (n=40) 299.09 (85.69) (n=40) patial gait paramete (metres per sec)	272.20 (71.51) (n=39) 298.87 (65.23) (n=37)	343.41 (73.44) (n=35) 363.39 (58.85) (n=34)		0.06		0.02	April 17,	0.17 0.34		0.07 0.40

				BMJ Open	I			136/bmjopen-2022-061648 -0.01			Page 22 c
Step length ra								2-06			
JII-BCS	-0.00 (0.04) (n=40)	0.03 (0.04) (n=37)	0.02 (0.04) (n=35)	-0.02	0.02	-0.02	0.02	-0.01 6 48	0.10	-0.01	0.05
Genesis II	-0.00 (0.04) (n=40)	0.01 (0.04) (n=37)	0.00 (0.04) (n=34)	(-0.04,0.00)	*	(-0.04,0.00)	*	(-0.03,0. Q 0) 4	÷.	(-0.03,0.00)	••• -
Double stance	e (% gait cycle)	((Janua			
JII-BCS	0.30 (0.07) (n=39)	0.32 (0.11) (n=37)	0.25 (0.08) (n=35)	-0.02	0.33	-0.03	0.07	-0.01 ^V	0.60	0.00	0.69
Genesis II	0.32 (0.09) (n=40)	0.30 (0.07) (n=37)	0.25 (0.05) (n=34)	(-0.06,0.02)	0.22	(-0.07,0.00)		(-0.04,0.殿)		(-0.02,0.02)	0.02
				and return to sitti							
Walking speed (Walking symme operated leg. Zo	k test - metres walk (meters/second). A etry – step length ra ero indicates perfec support (% of gait cy	higher value indication to the second s	cates better funct (2xOp)/Op+NOP est performance.	tion. P))-1); where Op				leg and NOt on	the step l	ength of the non-	
Walking speed (Walking symme operated leg. Ze Double stance se	(meters/second). A etry – step length ra ero indicates perfec	higher value indication calculated as ((at symmetry and be ycle). A lower val	cates better funct (2xOp)/Op+NOP est performance.	tion. P))-1); where Op				leg and NOom/ on April 17, 2024 by	the step l	ength of the non-	- ·
Walking speed (Walking symme operated leg. Zo Double stance so <i>Balance func</i>	(meters/second). A etry – step length ra ero indicates perfec support (% of gait cy	higher value indic tio calculated as ((et symmetry and be ycle). A lower val cs (Table 4)	cates better funct (2xOp)/Op+NOP est performance. lue indicates bette	re circuit A high tion. P))-1); where Op ter performance	is the ste	ep length of the o		leg and NOom/ on April 17, 2024 by gue		-	
Walking speed (Walking symme operated leg. Zo Double stance so <i>Balance func</i> There was no	(meters/second). A etry – step length ra ero indicates perfec support (% of gait c <u>y</u> c <i>tion and kinetic</i>	higher value indic tio calculated as ((et symmetry and be ycle). A lower val cs (Table 4) difference for s	cates better funct (2xOp)/Op+NOP est performance. lue indicates bette standing on op	re circuit A high tion. P))-1); where Op ter performance	is the ste ly for 10	ep length of the o	operated by the eyes of the ey	leg and NO ^{bo} m/ on April 17, 2024 by gue no popen. The p	umber ((%) for the JII-	-
Walking speed (Walking symme operated leg. Zo Double stance so <i>Balance func</i> There was no BCS and Gen	(meters/second). A etry – step length ra ero indicates perfec support (% of gait c <u>y</u> c <i>tion and kinetic</i> b between-group	higher value indication calculated as (for the symmetry and between value). A lower value of the symmetry and between values (<i>Table 4</i>) difference for state of the symmetry of the symmetry and state of the symmetry and symmet	cates better funct (2xOp)/Op+NOP est performance. lue indicates bette standing on op %) and 10/34 (re circuit A high tion. P))-1); where Op ter performance perated leg onl (29.4%) respe	is the ste ly for 10 ectively.	ep length of the o 0 seconds wit . The adjusted	operated to the eyes of the ey	leg and NOT is on April 17, 2024 by gue open. The Prop. 62	umber (2 (0.17,	(%) for the JII- ,2.28) p=0.471	-

				BMJ	Open			136/bmjopen-2			
	Genesis II 6.03 (3.23 completeness in the c			was -0.41 (0.4	8) p=0.4	48. Data for th	ne non-op	02	provided f	ĵor	
	The Star-Excursion 7	Test was attempted	ed with participation	ants but 59% o	of partic	ipants at basel	line, 59%	ع بط at follow u	and 63% a	at outcome	
	were unable to comp	lete it. Therefore	e, collected data	is provided in	n Table S	S4 of the onlir	ne supple	ment. ¹ 2023			
	The Genesis II group	had a smaller C	OP path length	than the JII-B	CS grou	p (p=0.001).	The mean	n (SD) values	for the G	enesis II and	
	JII-BCS groups were				_	·		<u>n</u>			
		150.11 (05.10)	and 255.10	(170.94) IIIII,	respect	rvery. Trajušk	eu enteet		1 (105.)	0, 15.05)	
	p=0.01.							from			
								http://www.com			
	online supplement.										
		oility and opera	ted lower limb	knee kinetics	from b	aseline to six	months	mjopen.bmj post-surgegy	(primary	timepoint)	
	Table 4. Balance ab		ted lower limb	knee kinetics	from b				(primary	timepoint)	
	Table 4. Balance ab	Means (SDs)		knee kinetics		Bet		mjopen.bmj.gy post-surgedy ops comparisop			
	Table 4. Balance ab	Means (SDs) mber of participar	its)	knee kinetics Unadjust	Two m	Bet	ween grou		Six mo] a
	Table 4. Balance ab	Means (SDs)			Two m	Bet	ween grou	ips comparison	Six mo	onths] ^a p- value
	Table 4. Balance ab (nu Baseline nd for 10 secs only on ope	Means (SDs) mber of participar Two months after surgery erated leg, eyes ope	nts) Six months after surgery en (number)	Unadjust effect size (95% CI)	Two m ed p-	Bet ionths Adjusted effect size (95% CI)	tween grou d ^a p-	Unadjus effect size (95% CI)	Six mo ted p-	onths Adjusted effect size (95% CI)	p-
JII-BCS	Table 4. Balance at (nu Baseline nd for 10 secs only on ope 13/40 (32.5%)	Means (SDs) mber of participar Two months after surgery erated leg, eyes ope 13/39 (33.3%)	nts) Six months after surgery en (number) 15/35 (42.9%)	Unadjust effect size (95% CI) 0.92	Two n ed p- value	Bet nonths Adjusted effect size (95% CI) 1.17	d ^a p- value	Unadjus effect size (95% CI)	Six mo ted p- value	onths Adjusted effect size (95% CI) 0.62	p- value
JII-BCS Genesis	Table 4. Balance at (nu Baseline nd for 10 secs only on op 13/40 (32.5%) II 10/40 (25.0%)	Means (SDs) mber of participar Two months after surgery erated leg, eyes ope 13/39 (33.3%) 11/37 (29.7%)	nts) Six months after surgery en (number)	Unadjust effect size (95% CI)	Two m ed p-	Bet ionths Adjusted effect size (95% CI)	tween grou d ^a p-	Unadjus effect size (95% CI) ⁴ 0.56 (0.20,1.51) ⁵	Six mo ted p-	onths Adjusted effect size (95% CI)	p-
JII-BCS Genesis	Table 4. Balance at (nu Baseline nd for 10 secs only on operation (10/10/10/10/10/10/10/10/10/10/10/10/10/1	Means (SDs) mber of participar Two months after surgery erated leg, eyes ope 13/39 (33.3%) 11/37 (29.7%) ed leg, eyes open	Six months after surgery en (number) 15/35 (42.9%) 10/34 (29.4%)	Unadjust effect size (95% CI) 0.92	Two n ed p- value	Bet nonths Adjusted effect size (95% CI) 1.17	d ^a p- value	Unadjus effect size (95% CI) ⁴ 0.56 (0.20,1.51) ⁵	Six mo ted p- value	onths Adjusted effect size (95% CI) 0.62	p- value
JII-BCS Genesis	Table 4. Balance at (nu Baseline nd for 10 secs only on operation 13/40 (32.5%) II 10/40 (25.0%) standing only on operation 5.60 (3.44)	Means (SDs) mber of participar Two months after surgery erated leg, eyes oper 13/39 (33.3%) 11/37 (29.7%) ed leg, eyes open 5.95 (3.56)	Six months after surgery en (number) 15/35 (42.9%) 10/34 (29.4%) 6.67 (3.36)	Unadjust effect size (95% CI) 0.92 (0.34,2.49) -0.09	Two n ed p- value 0.88	Bet nonths Adjusted effect size (95% CI) 1.17 (0.34,4.07) 0.26	d ^a p- value 0.80	ups comparison Unadjus effect size (95% CI) 0.56 (0.20,1.51) Protected	Six mo ted p- value 0.249	Onths Adjusted effect size (95% CI) 0.62 (0.17,2.28) -0.41	p- value 0.47
JII-BCS Genesis Seconds JII-BCS	Table 4. Balance at (nu Baseline nd for 10 secs only on operator 13/40 (32.5%) II 10/40 (25.0%) standing only on operator 5.60 (3.44) (n=38)	Means (SDs) mber of participar Two months after surgery erated leg, eyes open 13/39 (33.3%) 11/37 (29.7%) ed leg, eyes open 5.95 (3.56) (n=35)	Six months after surgery en (number) 15/35 (42.9%) 10/34 (29.4%) 6.67 (3.36) (n=33)	Unadjust effect size (95% CI) 0.92 (0.34,2.49)	Two n ed p- value	Bet nonths Adjusted effect size (95% CI) 1.17 (0.34,4.07)	d ^a p- value	Unadjus effect size (95% CI) 0.56 (0.20,1.51) -0.65 (-2.29,1.002	Six mo ted p- value	onths Adjusted effect size (95% CI) 0.62 (0.17,2.28)	p- value
JII-BCS Genesis Seconds	Table 4. Balance at (nu Baseline nd for 10 secs only on operator 13/40 (32.5%) II 10/40 (25.0%) standing only on operator 5.60 (3.44) (n=38)	Means (SDs) mber of participar Two months after surgery erated leg, eyes oper 13/39 (33.3%) 11/37 (29.7%) ed leg, eyes open 5.95 (3.56)	Six months after surgery en (number) 15/35 (42.9%) 10/34 (29.4%) 6.67 (3.36)	Unadjust effect size (95% CI) 0.92 (0.34,2.49) -0.09	Two n ed p- value 0.88	Bet nonths Adjusted effect size (95% CI) 1.17 (0.34,4.07) 0.26	d ^a p- value 0.80	Unadjus effect size (95% CI) 0.56 (0.20,1.51) -0.65 (-2.29,1.002	Six mo ted p- value 0.249	Onths Adjusted effect size (95% CI) 0.62 (0.17,2.28) -0.41	p- value 0.47
JII-BCS Genesis Seconds JII-BCS	Table 4. Balance at (nu Baseline nd for 10 secs only on operator 13/40 (32.5%) II 10/40 (25.0%) standing only on operator 5.60 (3.44) (n=38)	Means (SDs) mber of participar Two months after surgery erated leg, eyes open 13/39 (33.3%) 11/37 (29.7%) ed leg, eyes open 5.95 (3.56) (n=35)	Six months after surgery en (number) 15/35 (42.9%) 10/34 (29.4%) 6.67 (3.36) (n=33)	Unadjust effect size (95% CI) 0.92 (0.34,2.49) -0.09	Two n ed p- value 0.88	Bet nonths Adjusted effect size (95% CI) 1.17 (0.34,4.07) 0.26	d ^a p- value 0.80	ups comparison Unadjus effect size (95% CI) 0.56 (0.20,1.51) Protected	Six mo ted p- value 0.249	Onths Adjusted effect size (95% CI) 0.62 (0.17,2.28) -0.41	p- value 0.47

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1									136/bmjopen-2022-061648			
2 3		((-26)	(2022			
4	COP noth len	(n=38) gth (mm) standing o	(n=36) on both legs	(n=33)					06			
5	COI patilitei		-	235.48					1648			
6 7 8	JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	(176.94) (n=35)	7.00	0.80	23.72	0.18	82.42 ⁹	0.01	-59.91	0.01
9 10	Genesis II	188.25 (125.93) (n=40)	226.09 (137.15) (n= 36)	158.14 (65.40) (n=34)	(-48.53,62.53)		(-10.93,58.37)		(-147.17,-17. م رً7) nuary		(-105.98,-13.85)	
11	Peak extensio	n moment operated	knee during walk	ing (Nm/Kg)					2023.			
12 13	JII-BCS	-0.34 (0.09) (n=37)	-0.30 (0.10) (n=38)	-0.41 (0.08) (n=34)	-0.03	0.16	-0.03	0.22	-0.02 D	0.45	-0.02	0.25
14 15	Genesis II	-0.32 (0.08) (n=40)	-0.33 (0.10) (n= 37)	-0.42 (0.08) (n=34)	(-0.08,0.01)	0.16	(-0.07,0.02)	0.22	-0.02 0 (-0.05,0.025)	0.45	(-0.05,0.02)	0.35
16	Peak flexion r	noment operated kn	· · · ·						loaded			
17 18	JII-BCS	0.52 (0.25) (n=37)	0.38 (0.22 (n=38)	0.55 (0.27) (n=34)	-0.06		-0.06		0.11 h		-0.07	
19 20	Genesis II	0.44 (0.21)	0.34 (0.21)	0.45 (0.25)	(-0.16,0.04)	0.22	(-0.15,0.04)	0.26	(-0.23,0.029	0.10	(-0.19,0.05)	0.22
21		(n=40)	(n=37)	(n=34)					bmji			
22 23	^a adju	isted for strata used in	n randomisation and	d for baseline scor	es				jopen			
24 25	Singl	e stance on the opera	ted lower limb for	10 seconds with e	yes open (yes/no)	and dura	tion maintained.		n.bmj.co			
26 27 28	Resu	ltant centre of pressu	re path length (COI	P cm) in double sta	ance with eyes clo	sed: low	er path length indi	icates be	Ĕ			
29	Peak	extension and flexion	n moments of opera	ated knee during th	ne gait cycle (Nm	'kg). A h	igher value indicat	tes bette	April 17, 2024 by			
30 31			1	6	8 9 (27	0		17, 20			
32 33									124 by			
34									y guest			
35 36 37	<i>Tem</i> Mea	poral-spatial gai n (SD) walking sj	t parameters (Ta beed was greate	<i>able 3)</i> r for the Genesi	s II group, 1.1	3 (0.18)) metres/second	l. than t	<u> </u>	up. 1.09	(0.22)	
38										·····	()	
39 40	meti	res/second. Howe	, the auguster		s not statistica	iry 51511	111 -u iit. 0.05 (-(5.04,0.0	ע, איז איז, איז			
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136/bmjopen-202 Walking symmetry as assessed by step length ratio was not significantly different between groups. Mean (SIX) for JII-BCS 0.03 1648 on (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. ary 2023. Dov **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, 5.6) 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 2024 by 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 ted by copyright. (4.54,38.96), p=0.01.

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

	non-operated lov	-					point)	136/bmjopen-2022-061648 on 4 Janua		Page	26 of 58
		Means (SDs)				Bet	ween gro	ups comparison			
	(nu	mber of participa	ants)		Two n		in con gro		Six m	onths	
	× ×			Unadjust	ed	Adjuste	da	.∽ ⊈Unadjust	ed	Adjusted	a
	Baseline	Two months	Six months	effect size	p-	effect size	p-	effect size	р-	effect size	р-
		after surgery	after surgery	(95% CI)	value	(95% CI)	value	(9\$) CI)	value	(95% CI)	value
Knee range-o	of-movement – wal	k (degrees)						ded			
JII-BCS	42.11 (9.90)	37.87 (7.73)	46.07 (7.71)					ded from 77			
JII Deb	(n=39)	(n=38)	(n=35)	4.51	0.03	3.42	0.08		0.01	3.14	0.02
Genesis II	40.31 (5.93)	42.25 (9.75)	50.62)7.33)	(0.39,8.64)	0.00	(-0.41,7.24)	0.00	(1. 4.8.43)	0101	(0.61,5.68)	0102
	(n=40)	(n=38)	(n=34)					/bm			
Hip range-of	-movement – walk		41.56(6.01)					jope			
JII-BCS	40.00 (6.04) (n=39)	38.90 (5.44) (n=38)	41.56 (6.01) (n=35)	2.24		1.93		//bmjopen.bm		1.64	
	40.31 (5.93)	41.03 (6.15)	(11-33) 44.44 (5.48)	(-0.48,4.95)	0.11	(-0.20,4.06)	0.07	(0.20, 5.82)	0.04	(-0.11,3.39)	0.07
Genesis II	(n=40)	(n=37)	(n=34)	(-0.40,4.95)		(-0.20,4.00)		(0.20,5.62)		(-0.11,5.59)	
Ankle range-	of-movement – wa	· /	(on Aprii-1.37			
0	24.84 (6.57)	21.69 (4.54)	24.54 (6.63)					Ap			
JII-BCS	(n=39)	(n=38)	(n=35)	0.75	0.45	1.36	0.00	- I .37	0.21	0.08	0.04
Genesis II	23.10 (5.52)	22.43 (3.76)	23.22 (3.77)	(-1.21,2.71)	0.45	(0.22,2.94)	0.09	(-4.21,1.28)	0.31	(-1.89,2.04)	0.94
Genesis II	(n=40)	(n=37)	(n=34)					-1.37 (-4.201,1.28)			
Peak knee an	ıgular velocity – wa							by			
JII-BCS	283.10 (53.83)	269.65 (36.75)	307.69 (38.96)					ୁ ପ୍ରାର୍ଥ୍ୟ .00			
	(n=39)	(n=38)	(n=35)	23.15	0.06	16.47	0.15	<u>3</u> 21.00	0.01	21.75	0.01
Genesis II	300.36 (55.56)	321.65 (43.31)	330.38 (41.40)	(-0.84,47.14)		(-6.21,39.14)		(10.3찤,51.66) 호		(4.54,38.96)	
	(n=40)	(n=38)	(n=35)					:ect			
геак кпее ап	igular velocity – st 221.70 (88.35)	airs (degrees/seco 198.09 (62.56)	271.84 (95.48)	54.31		51.63		(10.34,51.66) of ected \$0.01		35.15	
JII-BCS	(n=37)	(n=34)	(n=32)	34.31 (16.67,91.96)	0.01	(15.36,87.89)	0.01	(5.9 8 ,94.04)	0.03	(-3.09,73.39)	0.07
	(II 37)	(1 57)	(11 52)	(10.07,71.70)		(10.00,07.07)		(3.5 <u>0</u> ,54.04) P		(3.09,13.39)	
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Genesis II	243.74 (84.05) (n=38)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)					22-0616		
^a adjusted for str	rata used in random	nisation and for ba	seline scores					;48 on 4		
Hip, knee, and a	inkle range-of-mot	ion during walkin	g. Higher values i	ndicate better fu	nction			January		
Peak knee angul	lar velocity during	walking and stair	climbing. Higher	value indicates b	etter funct	ion.		2023.		
Muscle activi	ity, operated lov	var limb duriv	ng walking (Ta	(a, 6)				Downloade		
	es were found b	· · · · ·	0	/	gait cycl	e for peak act	vity of v	astus ⁸ nediali	s, vastus l	ateralis,
tibialis anterio	or, biceps femor	ris or lateral he	ad of gastrocne	mius. Adjust	ed effect	sizes ranged	from -10.	97(-25 .69,4.7	74) p=0.17	' for
peak activation	on of biceps fem	noris to 6.06 (-2	2.14,14.26) p=0	.14 for tibialis	s anterio	r.		://bmjop		
	on onerstad la	uar limb ara pr						ven.b		
Data for the n	ion-operated iov	wer mind are pr	ovided in Table	e S8 of the onl	ine supp	olement.		mj.cc		
	scle activity du	-					s post-sı	urger¥ (prim	ary time	ooint)
	-	uring walking,				e to six month		April 1		ooint)
	scle activity du	-	operated lowe			e to six month Bet		irger (prim		-
	scle activity du	Iring walking, Means (SDs)	operated lowe	r limb, from Unadjust effect size	baseline Two n	e to six month Bet nonths Adjusted effect size	ween grou	ps comparison	Six m	onths A effect
Table 6. Mu	scle activity du	Means (SDs) Means (SDs) mber of participa Two months after surgery s (% of gait cycle	operated lowe nts) Six months after surgery	r limb, from Unadjust	baselino Two n ced P-	e to six month Bet 10nths Adjuster	ween grou l ^a p-	ps comparison Ps comparison Dinadjus effect size (95% CI)	Six m sted p-	onths A effect
Table 6. Mu	number of the section	Means (SDs) Means (SDs) mber of participa Two months after surgery s (% of gait cycle 25.42 (24.93 n=38	operated lowe ants) Six months after surgery) 23.20 (22.72) n=35	r limb, from Unadjust effect size (95% CI) -1.22	baseline Two n red p- value	e to six month Bet nonths Adjusted effect size (95% CI) -1.13	ween grou j ^a p- value	ps comparison PJ nadjus effect size (95% CI) Poteog.86	Six m sted p- value	onths A effect (95%
Table 6. Mu Peak activatio	(num Baseline On Vastus Mediali 28.62 (27.23)	Means (SDs) Means (SDs) mber of participa Two months after surgery s (% of gait cycle 25.42 (24.93	operated lowe ants) Six months after surgery) 23.20 (22.72)	r limb, from Unadjust effect size (95% CI)	baselino Two n ced P-	e to six month Bet nonths Adjusted effect size (95% CI)	ween grou l ^a p-	ps comparison Ps comparison Dinadjus effect size (95% CI)	Six m sted p- value	onths A effect (95%

Adjusted^a

p-

value

0.80

effect size

(95% CI)

(-9.43,12.22)

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Peak activatio	n Vastus Laterali	s (% of gait cycle	e))22-(
JII-BCS	18.44 (12.15) n=39	17.29 (11.51) n=38	13.03 (5.61) n=35	1.20	0.73	1.11	0.75	06164859	0.12	5.63	0.13
Genesis II	20.23 (20.35) n=40	18.47 (17.46) n=38	18.79 (19.89) n=33	(-5.67,8.07)	0.75	(-5.78,8.01)	0.75	(-1. 9 ,12.71) 4	0.12	(-1.65,12.9)	0.1.
Peak activation	n Tibialis Anterio	or (% of gait cycl	e)					lanu			
JII-BCS	23.46 (24.74) n=39	18.97 (20.91) n=38	15.20 (14.27) n=35	0.47	0.92	0.54	0.91	Lanuary 2868 (-3.92,13.28)	0.28	6.06	0.14
Genesis II	28.88 (27.88) n=40	19.82 (20.76) n=38	19.61 (20.32) n=33	(-9.18,10.13)	0.92	(-9.21,10.28)	0.91	(-3.92,13.28) ट्र	0.28	(-2.14,14.26)	0.14
Peak activatio	n Biceps Femoris	(% of gait cycle)						wnla			
JII-BCS	25.03 (25.32) n=39	21.87 (21.34) n=38	35.77 (34.01) n=35	6.76	0.20	5.71	0.25	Downloaded.78	0.21	-10.97	0.17
Genesis II	29.98 (28.00) n=40	29.16 (31.55) n=38	25.30 (28.86) n=33	(-5.49,19.01)	0.28	(-6.42,17.84)	0.35	(-25 อีรี 3,5.76)	0.21	(-26.69,4.74)	0.17
Peak activation cycle)	n Lateral head of	Gastrocnemius	(% of gait					http://bmjopen.84			
JII-BCS	24.67 (17.24) n=39	23.87 (19.34) n=38	20.66 (15.99) n=35	-1.18	0.76	-1.01	0.79	jopen	0.59	-1.89	0.59
	25.23 (22.36)	23.39 (14.60)	20.00 (13.80) n=33	(-8.9,6.53)	0.70	(-8.55,6.52)	0.79	(-8. <u>§</u> 1,4.93)	0.39	(-8.79,5.01)	0.55
Genesis II	n=40	n=38	1:								
adjusted for stra	ata used in random	nisation and for ba		s Lateralis, Tibiali	is Anteric	or, Biceps Femori	s and Late	eral head of Gastro	cnemius (% of gait	
adjusted for stra Percentage of ga cycle). Adverse even	ata used in random it cycle for peak ad	isation and for ba	s Medialis, Vastus								
adjusted for stra Percentage of ga cycle). Adverse even One patient w	ata used in random it cycle for peak ad ts ith a JII-BCS d	isation and for ba ctivation of Vastu eveloped acute	s Medialis, Vastus e swelling and p	pain in the knee	e and wa	as systemically	y unwell	Age of Gastro Age of Gastro 17, 2024 by gue	st operat	tively.	
adjusted for stra Percentage of ga cycle). Adverse even One patient w Гhe joint aspin	ata used in random it cycle for peak ac its ith a JII-BCS d ration demonstr	nisation and for ba ctivation of Vastu eveloped acute rated turbid flu	s Medialis, Vastus swelling and p id and an excha	pain in the knee ange of the pol	e and way	as systemically ne spacer and 1	y unwell retentior	eral head of Gastro	st operat and tibi	tively. al	
adjusted for stra Percentage of ga cycle). Adverse even One patient w Гhe joint aspin	ata used in random it cycle for peak ac its ith a JII-BCS d ration demonstr	nisation and for ba ctivation of Vastu eveloped acute rated turbid flu	s Medialis, Vastus swelling and p id and an excha	pain in the knee ange of the pol	e and way	as systemically ne spacer and 1	y unwell retentior	at 4 months po	st operat and tibi	tively. al	

 BMJ Open microbiology was negative so infection was never conclusively demonstrated. The numbers and type of complications are reported in Table S9. 1648 on 4 January 2023

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 implans. 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-ofmovement during walking, walking symmetry, peak knee angular velocity during walking, and postural contol (COP path length) are detecting motor impairment improvement for the Genesis II group and/or because statistical significance was result of testing

right.

136/bmjopen-202 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-mover needed 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, ig-depth, analysis of the biomechanical data should be undertaken. loaded

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. jopen

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 agd 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. copyright.

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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 Downloaded from change from an older to a newer implant design.

FUNDING STATEMENT

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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. 2024 by gues

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

BMJ Open 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 uary 2023. Do 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 by the Norwich Clinical Trials Unit (NCTU). 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 monk for potential harm.

Abbreviations

 ADDreviations 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: ComputeFised Tomography; DMC: Data Monitoring Committee; EMG: Electromyography; FJS: The Forgotten Joint Score; GCP: Good @inical Practice; GDPR: General Data Protection Regulation; GISP3: General Information Security Policy 3; HADS: Hospital Anxiet 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 Sebre Modified Star

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136/bmjopen-202 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; OA: Quality Assurance; OC: 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; THEG: 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 participarts provided informed consent prior to enrolment.

The lead authors (the manuscript's guarantors) affirm that this manuscript is an honest, accurate, and transpatient 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.

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Figure legends

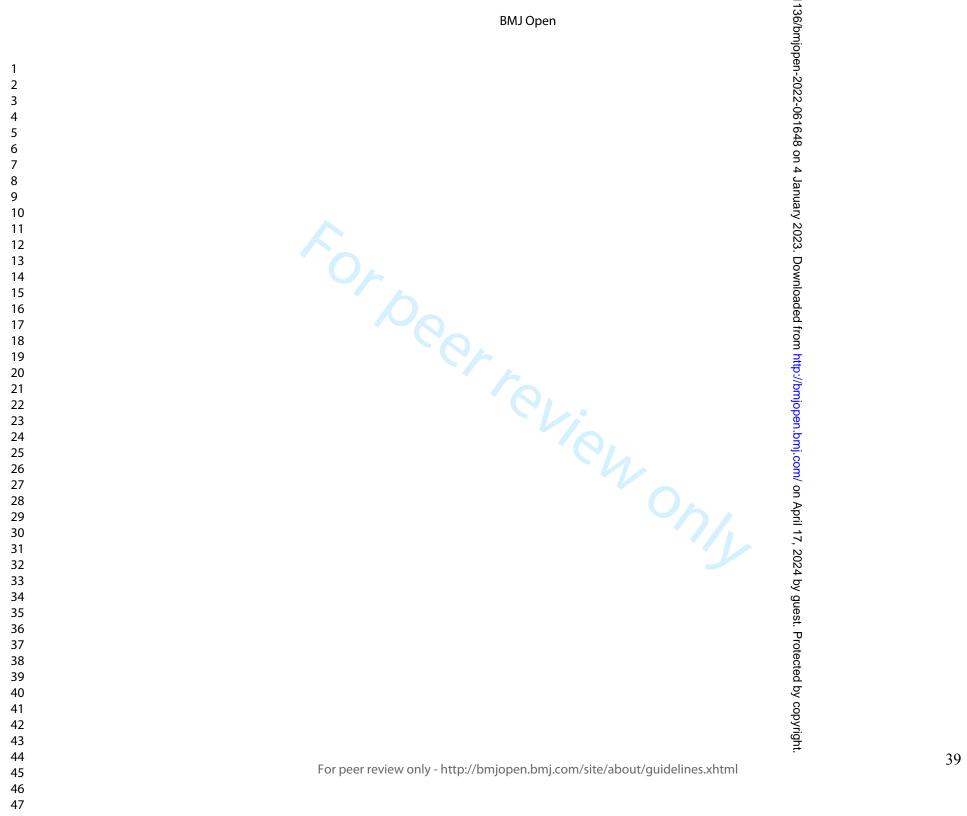
Figure 1. Consort diagram

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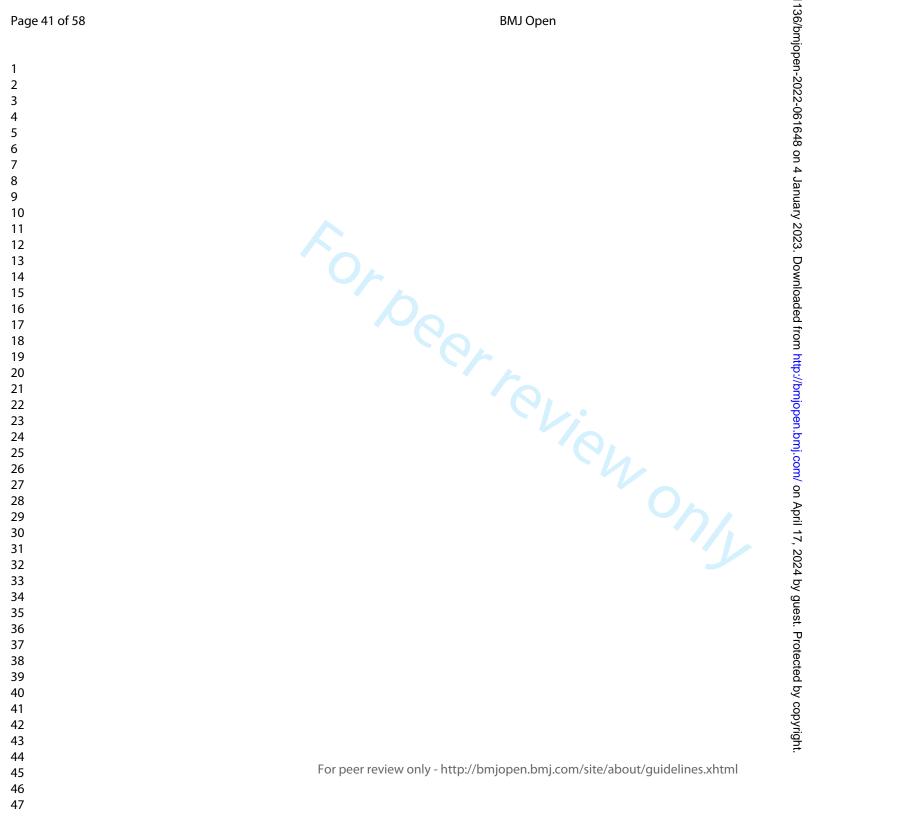
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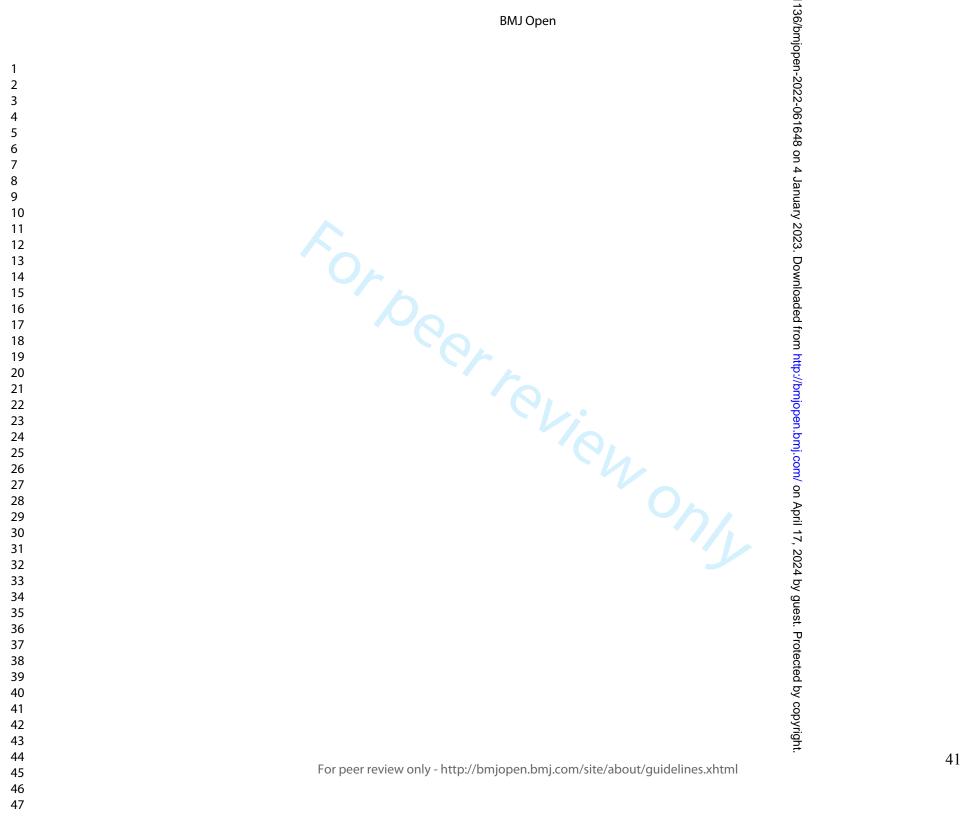
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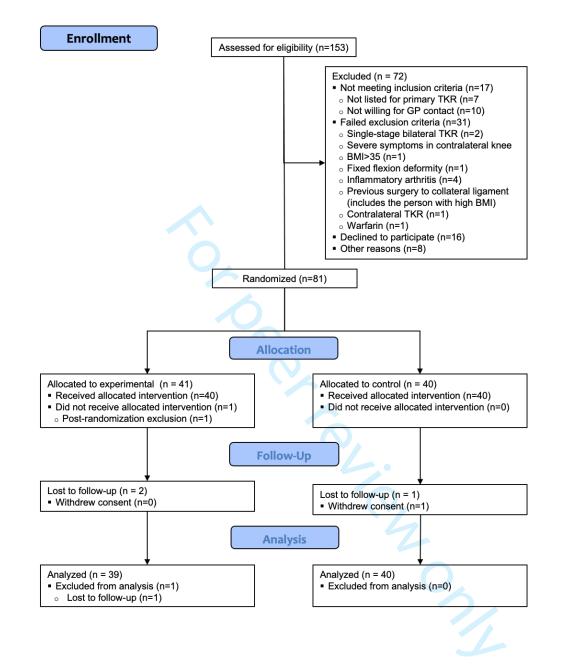


Figure 1. CONSORT Flow Diagram

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	Means (SDs)			
	(number of participants)			
	Baseline	Two months	Six months after	
		after surgery	surgery	
Cadence				
	107.37	103.09 (13.21)	113.09 (9.51)	
JII-BCS	(10.62)	N=37	N=35	
	N=39			
Constant	102.7(10.8	4 105.25(10.21)		
Genesis II	3) n=40	n=37	112.98(9.71) n=34	
Step length				
JII-BCS	0.53(0.08)			
JII-BC2	n=39	0.5(0.09) n=37	0.56(0.1) n=35	
Comosia II	0.54(0.09)			
Genesis II	n=40	0.55(0.08) n=37	0.6(0.08) n=34	
Stride length				
U	1.06(0.17)			
JII-BCS	n=39	1.04(0.18) n=37	1.15(0.21) n=35	
Comosia II	1.08(0.17)			
Genesis II	n=40	1.11(0.15) n=37	1.2(0.16) n=34	

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

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

	JII-BCS	Genesis II	Effect size	p-value
	Number (%)	Number (%)	(95% CI)	-
Length of in-				
patient stay				
Three days	14 (35%)	13 (33%)		
Four days	21 (53%)	21 (53%)		
Five days	4 (10%)	5 (13%)		0 7409
Six days	1 (3%)	1 (3%)	NA	0.749ª
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	NA	INA
Complications				
No	34 (85%)	35 (88%)	1.00	0.780
Yes	6 (15%)	5 (13%)	0.83 (0.23,3.01)	0.780
Change pain				
medication				
No	1 (3%)	4 (10%)	7.5% (18.0.2.0)	0.359ª
Yes	39 (98%)	36 (90%)	-7.5% (-18.0,3.0)	

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.

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

	exercises were per	rformed: median
	(IQR)	
	JII-BCS	Genesis II
	(n=40)	(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	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
resistance band		
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)

1			
3 Glu	itei strengthening exercise	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
2 3 4 5 ROM – rang 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53	e of motion		0.0 (0.0, 1.0)
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Table S4. Seconds standing on non-ope	erated leg with eyes open and Star-Excursion Te
from baseline to six months post-surger	ry (primary timepoint)
	Means (SDs)
	(number of nonticipants)

	Means (SDs) (number of participants)		
	Baseline	Two months	Six months
		after surgery	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)	7.03(3.53)	
	n=38	n=36	6.55(3.41) n=33
Star-Excursion Test (Non-op)			
(Anterior Reach)			
JII-BCS	40.54(6.12)	41.87(6.18)	42.16(9.37)
\sim	n=36	n=34	n=32
Genesis II	40.98(7.69)	43.2(8.11)	43.09(7.58)
(Post lateral)	n=37	n=33	n=31
JII-BCS	59.86(11.4	62.16(11.73)	62.81(16.63)
	5) n=32	n=32	n=30
Genesis II	60.1(11.77)	62.03(15.15)	63.21(14.49)
(Post medial)	n=34	n=31	n=29
JII-BCS	63.57(9.81)	65.11(10.78)	66.44(16.73)
	n=34	n=34	n=32
Genesis II	63.79(10.8	65.1(13.59)	67.74(14.59)
	7) n=36	n=33	n=31
Star-Excursion Test (Op)			
Anterior (reach)			
JII-BCS	37.72(7.41)	35.92(6.94)	
	n=36	n=35	40(7.47) n=32
Genesis II	41.83(6.85)	36.84(7.45)	44.98(21.54)
(Post lateral)	n=34	n=32	n=30
JII-BCS	55.39(10.7	55.19(8.02)	60.19(12.7)
	8) n=33	n=31	n=30

Genesis II	58.73(11.0	57.78(14.08)	62.83(14.86)
(Post medial)	1) n=32	n=29	n=30
JII-BCS	59.32(10.2	59.57(8.87)	65.59(11.43)
	3) n=36	n=34	n=32
Genesis II	64.18(11.6	62.44(12.74)	66.1(14.1) n=31
	9) n=34	n=32	

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

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

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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)	21.54(9.93)	27.39(19.85)	
JII-DCS	n=38	n=39	n=35	
Genesis II	21.81(17.4	24.11(14.15)	47.08(61.92)	
	6) n=40	n=36	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)			
	(nu	(number of participants)			
	Baseline	Two months	Six months		
	Dasenne	after surgery	after surgery		
Peak extension moment during walking (N	m/Kg)				
JII-BCS		-0.19(0.12)			
JII-DC3	-0.16(0.11) n=38	n=38	-0.23(0.13) n=34		
Genesis II		-0.22(0.11)			
Genesis II	-0.2(0.11) n=40	n=36	-0.21(0.1) n=34		
Peak flexion moment during walking (Nm/l	Kg)				
JII-BCS		0.44(0.22)			
JII-BCS	0.58(0.25) n=38	n=38	0.55(0.31) n=34		
Genesis II		0.48(0.24)			
Genesis II	0.5(0.26) n=40	n=36	0.58(0.27) n=34		
	4				

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

		Means (SDs)	
	(number of participants)		
		Two months	Six months
	Baseline	after surgery	after surgery
Knee range-of-movement – walk (degrees)			
JII-BCS	40.01(6.37)		
JII-DC5	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)		
JII-DC5	n=39	47.67(6.66) n=38	51.17(5.2) n=35
Genesis II	48.46(7.18)		52.71(6.18)
	n=40	50.93(6.8) n=37	n=34
Ankle range-of-movement – walk (degrees)			
JII-BCS	23.97(5.63)		24.78(7.37)
JII-DC5	n=39	23.55(5.89) n=38	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 (deg	rees/s)		
	283.1(53.8	269.65(36.75) n=38	307.69(38.96)
JII-BCS	3) n=39		n=35
Genesis II	300.36(55. 56) n=40	293.06(62.1) n=36	337.85(46.15) n=34
Genesis II	56) N=40		11=34
Peak knee angular velocity (non-op)– walk	(degrees/s)		
reak knee angular verbeity (non-op)- walk	309.68(44.	321.65(43.31) n=38	330.38(41.4)
JII-BCS	93) n=39	e_1.00(10.01) // 00	n=35
	,		
	313.77(57.	329.25(45.72) n=37	338.69(46.06)
Genesis II	12) n=40		n=34

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

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.

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		Means (SDs)	
	(number of participants)		
	Baseline	Two months	Six months
	Dasenne	after surgery	after surgery
Peak activation Vastus Medialis (% of gait cycle)		
JII-BCS	26.64(25.6	22.9(23.59)	18.23(20.25)
JII-BCS	3) n=39	n=39	n=39
Genesis II	19.83(17.6	19.73(17.36)	22.65(26.98)
	6) n=40	n=40	n=40
Peak activation Vastus Lateralis (% of gait cycle	2)		
JII-BCS	33.85(32.7		17.29(20.6)
JII-BCS	7) n=39	25.9(18.3) n=38	n=38
Genesis II	34.05(32.8	28.4(18.61)	30.18(29.19)
	9) n=40	n=40	n=38
Peak activation Tibialis Anterior (% of gait cycle	e)		
JII-BCS	17.71(19.0	25.61(26.2)	21.76(23.85)
	8) n=38	n=38	n=38
Genesis II	18(15.31)	18.71(23.46)	
	n=38	n=38	30.53(32) n=3
Peak activation Biceps Femoris (% of gait cycle)			
JII-BCS	23.71(18.5	25.41(23.86)	
	9) n=38	n=34	19(20.8) n=34
Genesis II	24.32(16.2)	25.63(22.6)	
	n=38	n=32	15.5(8.35) n=3
Peak activation Lateral head of Gastricnemius (% of gait 🔹		
cycle)	10 00/40 0		
JII-BCS	19.68(19.8	35.09(35.58)	23.53(15.2)
	3) n=34	n=34	n=34
Genesis II	19.94(20.7	22.44(27.39)	28.22(18.19)

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

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Table S9. Complications and adverse events

Complication type	Numbers of participants		
	JII-BCS	Genesis II	
Post operative reaction to analgesia		1	
requiring admission			
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		
	elien en		

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	ONSC	DRT 2010 checklist of information to include when reporting a randomised	trial*
Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract		4 ح	
	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		023	
Background and	2a	Scientific background and explanation of rationale	6
objectives	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 \vec{P}	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:		when applicable, explanation of any interim analyses and stopping guidelines	-
Sequence	8a		7
generation	8b	Method used to generate the random allocation sequence 양 Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially dumbered containers),	7
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned ਰੋੱ ਕਰੋ	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who as signed participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

			BMJ Open	Page 58 of 58
_			$\overline{1}$	
1 2		11b	assessing outcomes) and how Not the similarity of interventions	6
2	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
5 6	Results			
7	Participant flow (a	13a	تے For each group, the numbers of participants who were randomly assigned, received in≌nded treatment, and	14
8	diagram is strongly	100	were analysed for the primary outcome	
9 10	recommended)	13b		14, 15
10	Recruitment	14a	For each group, losses and exclusions after randomisation, together with reasons	13
12		14b	Why the trial ended or was stopped	13
13	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16
14 15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and weether the analysis was	16
16	,		by original assigned groups	
17	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	19, 22,25
18 19	estimation		precision (such as 95% confidence interval)	29,31
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
21 22	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	As above
23 24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for marms)	33,
25				Supplementar
26				y table 9
27 28	Discussion			
20	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	33
30	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	33
31 32	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	34,35
33	Other information			
34	Registration	23	Registration number and name of trial registry	4
35 36	Protocol	24	Where the full trial protocol can be accessed, if available	provided
37	Funding	25	Where the full trial protocol can be accessed, if available Sources of funding and other support (such as supply of drugs), role of funders	35
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43 44	CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Page 2

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*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. 61648 on 4 January 2023. Downloaded from http://bmjopen.bmj.com/ on April 17, 2024 by guest. Protected by copyright

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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

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136/bmjopen-2022-061648 on **ABSTRACT (300 words)** Objectives: To determine if a newer design of TKR (Journey II BCS) produces superior patient reported outcomes scores and ary 2023. 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 sugery 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, Time 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 Genetiss 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 by gue 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 velocit 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 opyright.

136/bmjopen-202 (smaller resultant centre of path length) during quiet standing than the JII-BCS group (mean (SD) 158.14 (65.4) versus 235.48 (176.94) 1648 on 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. ry 2023. Downloaded from http://bm

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 n/ on April 17, 2024 by guest. Protected by copyright. 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.

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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 osteoarthrity [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 to the Genesis II by using 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.

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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 infervention) 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 rand misation schedule stratified by site and age (<60 years = younger; \geq 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 6/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 perticipants (40 per group).

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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 bould present an unacceptable safety risk or were pregnant; were a private patient; were likely to be living outside the clinical center 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 kine matics, and increase anteroposterior (AP) stability throughout knee flexion.

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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 $\mathbf{\hat{E}}$ acking, an externally rotated femoral implant design and an anatomically-shaped tibial baseplates. 2023. Downloaded

Surgical techniques

All four surgeons had extensive experience, at least five years, of the Genesis II implant. All undertook cadaverie 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), $7\pm \overline{2}$ days after surgery (oneweek post-operatively), $6-8\pm 2$ weeks after surgery (two months), six months ± 4 weeks after surgery (outcome, paimary time point). Secondary outcomes were collected at baseline, two months and six months. Any differences from these timepoints are provided in the juest. Protected by copyright. outcome measures section.

Outcome measures

Primary outcome measure

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136/bmjopen-202 The Oxford Knee Score (OKS) was the primary outcome measure. This is a 12-question patient self-assessment \bigotimes^{∞} f knee function and pain 1648 on 4 January [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 $\overline{\mathbf{g}}$ 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 ril 17, 2024 by gue 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 copyright. For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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ight.

data at 2000Hz for walking tasks and 100hz for balance tasks. Surface electromyographic sensors (EMC 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 selected speed. For double stance balance activities, participants were instructed to stand with their feet shoulder-width apair. For single stance balance activities, participants were instructed to stand on one leg with hands-on-hips. Three trials of 10 second 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 steps 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 [\$4,45] or may [43] have

BMJ Open 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 Downloaded from ht angular velocity.

- Walking speed (meters/second). A higher value indicates better performance i.
- 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.
- Knee ROM during walking (degrees). Higher values indicate better performance. iii.
- Peak knee flexion angular velocity during walking (degrees per second). This waginadvertently omitted from iv. April 17, 2024 by gue 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), $\frac{\mu}{\tau}$ step length (m), and stride length (m). However, there is redundancy with the temporal-spatial gait parameters of waking speed and step length ed by copyright. 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).

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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 gouble stance with eyes closed. oaded from http://bmjoper

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 oril 17, 2024 by identified were tracked until resolution.

Analysis

The statistical analysis plan (SAP) was finalised and agreed prior to database lock and analysis was completed by inded 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

BMJ Open adherence were analysed according to the treatment they were randomised to receive. The analysis was undertaken by the Trial Statistician using Stata version 16. 1648 or

For the primary outcome, the mean OKS at six months was compared between the control and experimental $\operatorname{grow}_{H}^{*}$ by using a general linear model adjusting for site and age (<60years/≥60years). An adjusted analysis was conducted using the same mode but adjusting for the OKS at baseline. The model assumptions were checked graphically, and sensitivity analysis done using a non-parameteric 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 \vec{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. on April 17, 2024 by gue

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

 53 BMJ Open for 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. 1648 on 4 Ja

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	Genesis II
	(n=40)	(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%)

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				open-
no, number (%)	26 (65.0%)	22 (55.0%)		2022-
Missing, number (%)	7 (17.5%)	12 (30.0%)		061
Previous hip surgery, yes, number (%)	5 (13.0%)	5 (13.0%)		648
Employment, retired, number (%)	25 (63.0%)	24 (60.0%)		9
Pain Self-Efficacy-2 Questionnaire,	8.0 (6.0,10.0)	6.0 (3.0,9.5)		4 J
median (IQR)	0.0 (0.0,10.0)	0.0 (0.0,0.0)		anua
Hospital Anxiety & Depression Scale				ary
Anxiety total, mean (SD)	6.32 (3.54)	7.43 (3.05)		2022
Depression total, mean (SD)	6.03 (2.37)	8.05 (3.55)		3. D
Oxford Knee Score, mean (SD)	20.25 (5.69)	19.05 (5.28)		O WY
EQ-5D utility score, mean (SD)	0.52 (0.16)	0.47 (0.20)		lloa
EQ-5D visual analogue score, mean	59.78 (17.70)	51.30 (17.71)		de
(SD)				fror
Timed Up and Go time (seconds),	11.34 (3.40)	11.04 (3.33)		5 5
mean (SD)				- tp ://
Six-minute walk distance (metres),	304.03 (79.75)	299.09 (85.69)		
mean (SD)				ope
Walking speed, mean (SD)	0.95 (0.21) ^a	0.93 (0.20)		n. br
Step length ratio, mean (SD)	-0.00 (0.04)ª	-0.00 (0.04)		
Operated knee range-movement	42.11 (9.90) ^a	44.35 (8.56)		о л
(degrees), mean (SD)				9
Operated leg single stance eyes open	5.60 (3.44) ^b	5.58 (3.28) ^b		Apri
(secs), mean (SD)				II 17
a = 39 participants; $b = 38$ participants.				, 20
EQ-5D is a measure of health-related qua	lity of life, in the	range of -0.109 (v	worst possible state) and 1.0 (perfect health),	, $a\mathbf{\hat{k}}$ chored at 0 (death).
			ero is worst imaginable health state and 100	is best imaginable health state.
OKS is a 12-item knee function assessme	ent, ranging from () (worst score) to	48 (best score).	jues
Timed Up and Go Test (TUG) – seconds	to rise from chair,	, walk 3m and ret	urn to sitting; mean of three trials. A lower v	/aftie indicates better function.
Six-minute walk test - metres walked in	six minutes aroun	d a 20-metre circu	uit A higher value indicates greater function	
The UCLA Activity score to assess physi	cal activity self-ra	ting scale ranged	from 0 (complete inactivity) to 10	ctec
				d by
				cop
				ſŶſĬġ
			urn to sitting; mean of three thats. A lower v uit A higher value indicates greater function from 0 (complete inactivity) to 10	ht.
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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) re	spectivery.	There was no significant
difference between the groups: adjusted effect size 0.35 (-2.01,2.71) p=0.771 (Table 2).	on 2	

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

Means (SDs)			Between groups comparison 들									
	(nu	mber of particip	ants)		Two r	nonths			Six m	👸 Six months		
		Two months	Six months	Unadjus	ted	Adjusted ^a		Unadjusted		Adjusted ^a		
	Baseline	after surgery	after surgery	effect size	p-	effect size	p-	effect size	Gp-	effect size	p-	
		alter surgery	alter surgery	(95% CI)	value	(95% CI)	value	(95% CI)	zvalue	(95% CI)	value	
OKS				h					p://			
JII-BCS	20.25 (5.69)	34.10 (7.10)	42.97 (5.21)						bm			
JII-DCS	(n=40)	(n=39)	(n=39)	1.97	0.24	2.5	0.12	0.24	0.84	0.35	0.77	
Comosia II	19.05 (5.28)	36.00 (7.61)	43.13 (5.20)	(-1.37,5.32)	0.24	(-0.71,5.71)	0.12	(-2.10,2.58)	90.84	(-2.01,2.71)	0.77	
Genesis II	(n=40)	(n=40)	(n=40)						<u>, mi</u>			
adjusted for st	rata used in rando	misation and for	baseline scores, b	median (IQR)					ğ			
OKS is a 12-ite	m knee function a	ssessment, rangir	g from 0 (worst s	core) to 48 (bes	t score).				2			
The OKS Activ	ity and Participati	ion Questionnaire	(OKS-APQ) whi	ch complements	s the OKS	by assessing e	veryday a	ctivity and soci	atpartici	oation. The over	all score	
rom 12 to 60 w	vith 12 being the b	best outcome.							, pri			

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 Otdeath).

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

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

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136/bmjopen-2022-061648 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). January 2023 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, om http://bm 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. on Apri

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.

								4				
		Means (SDs)			Between groups comparison							
	(nu	mber of participation	ants)		Two m	onths		Jues	Six months			
	T d c		Sir months	Unadjus	ted	Adjuste	ısted ^a Unad		sted	Adjust	ted ^a	
	Baseline	after surgery	Two monthsSix monthsafter surgeryafter surgery	effect size (95% CI)	p- value	effect size (95% CI)	p- value	effect size (95% C	p- value	effect size (95% CI)	p-value	
Walking spee	d (ms/sec)							d p				
JII-BCS	0.95 (0.21)	0.90 (0.23)	1.09 (0.22)	0.08	0.11	0.09	0.03	0.05 copyright.	0.34	0.03	0.40	

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		(n=39)	(n=37)	(n=35)	(-0.02,0.17)		(0.01,0.17)		(-0.05,0.50)		(-0.04,0.09))	
	Genesis II	0.93 (0.20) (n=40)	0.97 (0.17) (n=37)	1.13 (0.18) (n=34)	(, , ,				061648 on			,	
	Sten length sv	mmetry (ratio)							n 4				
	JII-BCS	-0.00 (0.04) (n=40)	0.03 (0.04) (n=37)	0.02 (0.04) (n=35)	-0.02	<u> </u>	-0.02	<u> </u>	-0.01anuar (-0.03,0.00)	<u> </u>	-0.01		
) 1 2	Genesis II	-0.00 (0.04) (n=40)	0.01 (0.04) (n=37)	0.00 (0.04) (n=34)	(-0.04,0.00)	0.02	(-0.04,0.00)	0.02	(-0.03,0.00)	0.10	(-0.03,0.00)) 0.05	
<u>′</u> }	Knee ROM (d	egrees)											
		42.11 (9.90	37.87 (7.73)	46.07 (7.71)					Dow				
	JII-BCS	(n=39)	(n=38)	(n=35)	4.51	0.03	3.42	0.08	4.77 g	0.01	3.14	0.02	
	Genesis II	40.31 (5.93)	42.25 (9.75	50.62 (7.33)	0.39,8.64)	0.03	(-0.41,7.24)	0.08	4.77 load (1.11,8.4gg)	0.01	(0.61,5.68	5) 0.02	
	Genesis II	(n=40)	(n=38)	(n=34)					d fro				
	Peak knee flex	tion angular veloc	ty – walking (de	grees/second					from				
	JII-BCS	283.10 (53.83)	269.65 (36.75)	307.69 (38.96)					 				
	JII-DC5	(n=39)	(n=38)	(n=35)	23.15	0.06	16.47	0.1			0.01	21.75	0.01
	Genesis II	300.36 (55.56)	321.65 (43.31)	330.38 (41.40)	(-0.84,47.14)	0.00	(-6.21,39.14)) 0.1.	(10. ع لم)	1.66)	0.01 (4	.54,38.96)	0.01
		(n=40)	(n=38)	(n=35)									
	Peak knee flex	tion angular veloc	rity – stairs (degr	ees/second)					pen.bmj.com/				
									nj. co				
	JII-BCS	283.10 (53.83)	198.09 (62.56)	271.84 (95.48)					, j				
		(n=39)	(n=34)	(n=32)	54.31	0.01	51.63	0.01	50.01g	0.03	35.15	0.07	
	Genesis II	300.36 (55.56) (n=40)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)	(16.67,91.96)		(15.36,87.89)		(5.97,94.04)		(-3.09,73.3	9)	
-		(1 10)	(1 5 1)	(11 50)					, ,				_
1	^a adjusted for stra	ata used in random	nisation and for ba	seline scores					202				
c				500105					2024 by				
	Stan langth sum	metry – step length	ratio coloulated a	$((2x \cap n) / \cap n \perp N)$	\mathbf{D} \mathbf{D} \mathbf{D} \mathbf{D} \mathbf{D}	n is the	stan langth of the	oporata		is the st	on longth of t	•••	
						p is the	step length of the	operate		is the st	ep lengui ol u	le	
1	non-operated leg	g. Zero indicates p	erfect symmetry a	ind best performan	nce.				24 T				
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BMJ Open Data for all secondary movement performance measures are provided in the online supplement (Tables S4 – §8). The only difference between groups that reached statistical significance was for COP path length in double stance with aver closed (On line supplement 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.

respectively. Adjusted effect size was -59.91 (-105.98,-13.85) p=0.01 in favour of the Genesis II group. physiotherapy received (online supplement Tables S9 and S10). from http://bmjope

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. 2024 by guest. Pro

DISCUSSION

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

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136/bmjopen-202 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). lanuary

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]. Gene 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 not and mised and consisted of 18 patients between the two groups. They reported a greater supine range of movement of the JIL-BCS compared to the Genesis II when measured with a long arm goniometer. They also reported an improvement in functional knew 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), include the stride strike strike length is the strike str 17, 2024 by (ROM) and peak knee angular velocity.

Within our trial we found differences in some biomechanical measures of motor impairment but not for others; patientreported 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 aft $\hat{\mathbf{x}}$ knee replacement than

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136/bmjopen-202 for those reporting poor outcome [49]. Moreover, knee range-of-movement has been found to be the main bigmechanical effect of TKR [50] and to improve over time whilst other biomechanical measures do not [50,51]. Likewise, postural point 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 bimechanical data should Download 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 implants. However, all surgeons were very experienced with the Genesis implant with at least 10 years of experience implanting the device. Add 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

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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 kinen stically 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. ry 2023. Dov

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 . evir during walking, and postural control.

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This work was supported by an investigator initiated grant from Smith and Nephew, with both types of knee eplacements 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 ril 17, 2024 by gue 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

136/bmjopen-202 Exercise Laboratory (MoveExLab) at UEA and the clinical trials unit (CTU) based at UEA for statistics, and rial and data 1648 on 4 January 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, JU and AMS) contributed to the development of the trial protocol as well as conception or design of the work; the acquisition, analysis, st interpretation of data for the work. aded from

Declaration of interest "All authors have completed the ICMJE uniform disclosure form at www.icme.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 April 17, 2024 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

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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 Ginical 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.

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 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. on 4 January

Dissemination to participants and related patient and public communities: The results of the research we 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.

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Figure legends

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45 46 47 Figure 1. Consort diagram

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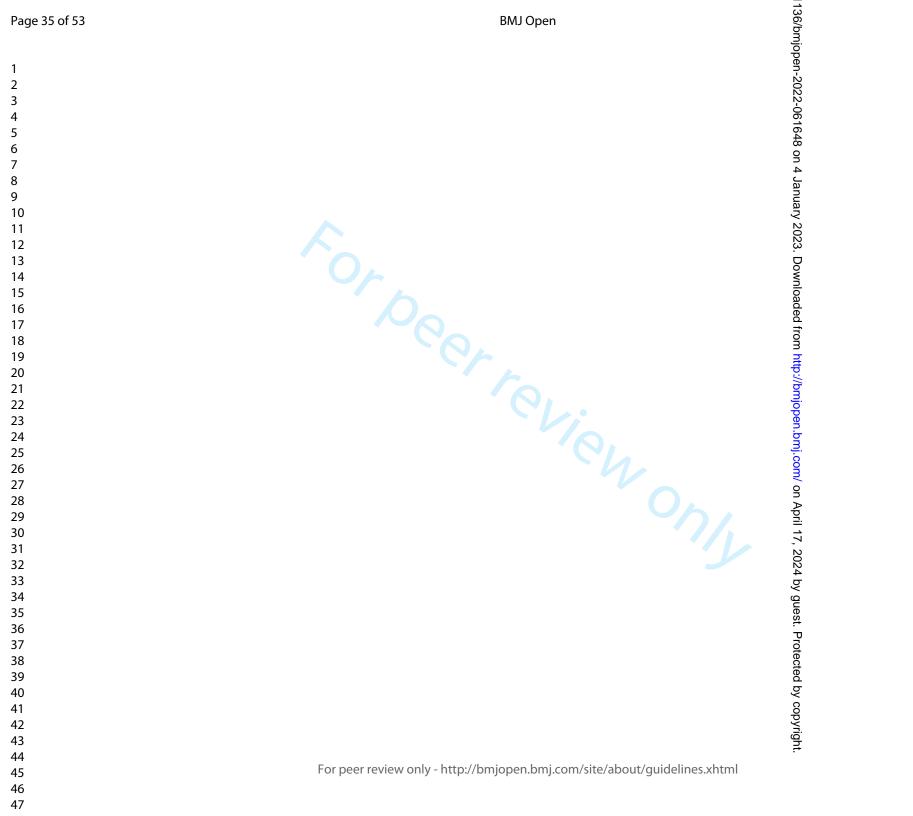
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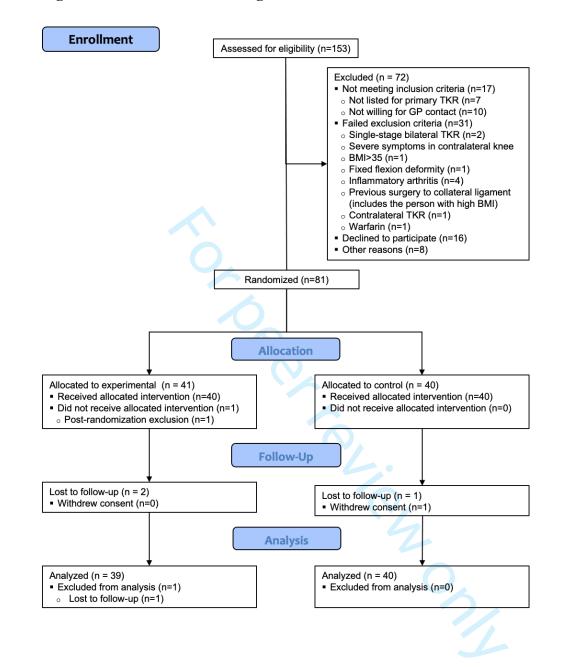


Figure 1. CONSORT Flow Diagram



Supplement	to
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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

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	surgery (primary timepoint)Double stance support (percentage of the gait cycle) from baseline to six months post-surgery (primary timepoint)Joint parameters from baseline to six months post-surgery (primary timepoint)Muscle activity during walking from baseline to six months post-surgery (primary timepoint)Balance parameters from baseline to six months post-surgery (primary timepoint)Table S8. Non-operated leg cadence (steps/minute), step length and stride length from baseline to six months post- surgery (primary timepoint)Post-operative clinical context: days of in-patient stay and consequences of surgeryComposition of out-patient physiotherapy treatment received following TKR by JII-BCS and Genesis II groups

OKS-APQ	(nur Baseline	mber of particip Two months	ants)				een grou	ps comparison				
	Baseline	True months	antsj		Two months					Six months		
OKS ABO	Baseline	I wo months	Six months	•	Unadjusted Adjusted ^a			Unadjæst	ted	Adjusted ^a		
OVE ADO		after surgery	after surgery	effect size (95% CI)	p- value	effect size (95% CI)	p- value	effect size (95% CI)လို	p- value	effect size (95% CI)	p- valu	
JNS-Ary				, ,		. ,		<u></u>		,		
JII-BCS	2.81 (6.63) (n=40)	36.09 (27.05) (n=40)	70.83 (23.81) (n=39)	11.63	0.09	12.09	0.08	3.66 000 (-7.53,14.86)	0.52	3.31	0.56	
Genesis II	1.41 (3.39) (n=40)	47.34 (32.50) (n=40)	74.14 (25.46) (n=40)	(-1.87,25.14)	0.09	(-1.63,25.8)	0.08	(-7.53,14.8 ⁵)	0.52	(-8.05,14.67)	0.30	
EQ5D Utility								m				
JII-BCS	0.52 (0.16) (n=40)	0.74 (0.10) (n=40)	0.90 (0.12) (n=39)	0.05 (-	0.11	0.05	0.05	0.00	0.89	0.00	0.95	
Genesis II	0.47 (0.20) (n=40)	0.78 (0.14) (n=40)	0.89 (0.13) (n=40)	0.01,0.1)		(0.00,0.11)	0.05	(-0.06,0.05)	0.89	(-0.06, 0.05)	0.95	
EQ5D VAS								n.br				
JII-BCS	59.78 (17.70) (n=40)	77.85 (14.12) (n=40)	89.03 (9.44) (n=39)	0.65	0.85	2.89	0.40	0.00 (-0.06,0.03)	0.50	-1.04	0.70	
Genesis II	51.30 (17.71) (n=40)	78.25 (16.11) (n=40	87.55 (12.75) (n=40)	(-6.18,7.48)	0.05	(-3.92,9.70)	0.40	(-6.77,3.35g) ♪	0.50	(-6.32,4.23)	0.70	
UCLA								April 17,				
JII-BCS	1.10 (0.78) (n=40)	4.82 (1.62) ^b (n=40)	6.87 (1.38) N=38)	0.23	0.53	0.25	0.49	,7 -0.13 (- 202	0.67	0.08 (-	0.79	
Genesis II	3.00 (0.85) (n=40)	5.05 (1.60) ^b (n=40)	6.68 (1.44) (n=40) baseline scores, ^b	(-0.5,0.95)	0.55	(-0.48,0.98)	0.49	-0.13 (-2024 by guest. Protected by copyright.	0.07	0.69,0.53)	0.79	

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

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								48 0	-						
		Means (SDs)				Means (SDs) Between groups comparison									
	(nu	mber of participa	ints)		Two n	nonths		$\frac{1}{\omega}$ Six months							
		Two months	Six months	Unadjus	ted	Adjuste	d ^a	Unadjus	ted	Adjusted ^a					
	Baseline	Two months after surgery	after surgery	effect size (95% CI)	p- value	effect size (95% CI)	p- value	effect size (95% ()	p- value	effect size (95% CI)	p-value				
Walking fun	ction							<u></u>							
Timed Up &	Go Test (secs)							Dow							
JII-BCS	11.34 (3.40) (n=40)	11.89 (3.92) (n=37)	10.30 (2.90) (n=35)	1.61	0.04	-1.32	0.03	-0.62d	0.34	-0.37	0.40				
Genesis II	11.04 (3.33) (n=40)	10.42 (2.45) (n=37)	9.76 (2.36) (n=34)	(-3.11,-0.1)	0.04	(-2.48,-0.16)	0.03	(-1.91,0.%) To	0.54	(-1.25,0.50)	0.40				
6-minute wal	lk test (metres)							n n							
JII-BCS	304.03 (79.95) (n=40)	272.20 (71.51) (n=39)	343.41 (73.44) (n=35)	30.12	0.06	32.2	0.02	22.24g	0.17	20.19	0.07				
Genesis II	299.09 (85.69) (n=40)	298.87 (65.23) (n=37)	363.39 (58.85) (n=34)	(-1.16,61.39	0.06	(5.74,58.65)	0.02	(-9.72,54 ² / ₆₂)	0.17	(-1.60,41.98)	0.07				

BMJ Open BMJ Open Table S2. Walking functional ability from baseline to six months post-surgery (print

^a adjusted for strata used in randomisation and for baseline scores.

^a adjusted for strata used in randomisation and for baseline scores.

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

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		Means (SDs)	
	(nui	nber of participa	· ·
	Baseline	Two months	Six months
	Dusenne	after surgery	after surgery
Anterior reach	n (cm)– non-opera	ated leg	
JII-BCS	40.98 (7.69)	43.20 (8.11)	43.09 (7.58)
JII-DCS	(n=37)	(n-33)	(n=31)
Genesis II	40.54 (6.12)	41.87 (6.18)	42.16 (9.37)
Genesis II	(n=36)	(n=34)	(n=32)
Anterior reach	n (cm) – operated	l leg	
	41.83 (6.85)	36.84 (7.45)	44.98 (21.54)
JII-BCS	(n=34)	(n=32)	(n=30)
	37.72 (7.41)	35.92 (6.94)	40.00 (7.47)
Genesis II	(n=36)	(n=35)	(n=32)
Postero-media	l reach (cm) – no	n-operated leg	
W D G G	63.79 (10.87)	65.10 (13.59)	67.74 (14.59)
JII-BCS	(n=36)	(n=33)	(n=31)
~ • •	63.57 (9.81)	65.11 (10.78)	66.44 (16.73)
Genesis II	(n=34)	(n=34)	(n=32)
Postero-media	l reach (cm) – op	· · · ·	()
	64.18 (11.69)	62.44 (12.74)	66.10 (14.10)
JII-BCS	(n=34)	(n-32)	(n=31)
	59.32 (10.23)	59.57 (8.87)	65.59 (11.43)
Genesis II	(n=36)	(n=34)	(n=32)
Postero-latera	l reach (cm) – noi		(11 02)
	60.10 (11.77)	62.03 (15.15)	63.21 (14.49)
JII-BCS	(n=34)	(n=31)	(n=29)
	59.86 (11.45)	62.16 (11.73)	62.81 (16.63)
Genesis II	(n=32)	(n=32)	(n=30)
Postero-latera	l reach (cm) – ope		(11 50)
	58.73 (11.01)	57.78 (14.08)	62.83 (14.86)
JII-BCS	(n=32)	(n=29)	(n=30)
	55.39 (10.78)	55.19 (8.02)	60.19 (12.70)
Genesis II	(n=33)	(n=31)	(n=30)
strata used in randomisa		. ,	(11 50)

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

^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.

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

								8 on				
						D. f		4				
	(Means (SDs)			Т		een grou	ips comparison	C'	41		
	(nt	umber of particip	ants)	Unadius	Two months Unadjusted Adjusted ^a			Unadjusted Adj			ustoda	
	Baseline	Two months	Six months	effect size	p-	effect size	p-	effect size	p-	Adjuste effect size	p-	
		after surgery	after surgery	(95% CI)	value	(95% CI)	value	effect size	value	(95% CI)	value	
Double stance	e support (% gai	it cycle)						OW				
JII-BCS	0.30 (0.07)	0.32 (0.11)	0.25 (0.08)	0.02		0.02		ownloaded -0.01 (-0.04,0.02from		0.00		
	(n=39) 0.32 (0.09)	(n=37) 0.30 (0.07)	(n=35) 0.25 (0.05)	-0.02 (-0.06,0.02)	0.33	-0.03 (-0.07,0.00)	0.07	-0.01 ਫ਼ਿ (-0.04,0.02	0.60	0.00 (-0.02,0.02)	0.69	
Genesis II	(n=40)	(n=37)	(n=34)	(0.00,0.02)		(0.07,0.00)		(0.04,0.024 ron		(0.02,0.02)		
adjusted for st	rata used in rando	omisation and for	baseline scores.					h http://bmjopen.bmj.com/ on April 17, 2024 by guest. Protected by copyright.				
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ouble stance s	support (% of gait	t cycle). A lower	value indicates be	etter performanc	e			Ĕ				
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	Tab	le S5. Joint p Means (SDs)	arameters fro	m baseline to	o six mo			primary tim ups compatison	• /		
	(nui	mber of participa	unts)		Two r	nonths	con grou			nonths	
	Baseline	Two months after surgery	Six months after surgery	Unadjust effect size (95% CI)	ed p- value	Adjustec effect size (95% CI)	l ^a p- value	Unadjus effect size (95% CT)	sted p- value	Adjust effect size (95% CI)	ed ^a p-valı
During walki	ng			() () () ()		(101001)		Ní		() () () ()	
Hip ROM (de	0							2023.			
JII-BCS	40.00 (6.04) (n=39)	38.90 (5.44) (n=38)	41.56 (6.01) (n=35)	2.24	0.11	1.93	0.07	3.01 回 (0.20,5.8智)	0.04	1.64	0.07
Genesis II	40.31 (5.93) (n=40)	41.03 (6.15) (n=37)	44.44 (5.48) (n=34)	(-0.48,4.95)	0.11	(-0.20,4.06)	0.07	(0.20,5.8)	0.04	(-0.11,3.39)	0.07
Ankle ROM	(degrees)							d from			
JII-BCS	24.84 (6.57) (n=39)	21.69 (4.54) (n=38)	24.54 (6.63) (n=35)	0.75		1.36		-1.37		0.08	
Genesis II	23.10 (5.52) (n=40)	22.43 (3.76) (n=37)	23.22 (3.77) (n=34)	(-1.21,2.71)	0.45	(0.22,2.94)	0.09	(-4.01,1.28)	0.31	(-1.89,2.04)	0.94
Knee peak ex	tension moment (I	Nm/Kg)	. ,					en.l			
JII-BCS	-0.34 (0.09) (n=37)	-0.30 (0.10) (n=38)	-0.41 (0.08) (n=34)	-0.03	0.16	-0.03	0.00	open.bmj. -0.028	0.45	-0.02	0.00
Genesis II	-0.32 (0.08) (n=40)	-0.33 (0.10) (n=37)	-0.42 (0.08) (n=34)	(-0.08,0.01)	0.16	(-0.07,0.02)	0.22	(-0.05,0.02)	0.45	(-0.05,0.02)	0.35
Knee peak fle	exion moment (Nm	· · · ·	(-)					Apr			
JII-BCS	0.52 (0.25) (n=37)	0.38 (0.22 (n=38)	0.55 (0.27) (n=34)	-0.06	0.22	-0.06	0.20	0.11 20 (-0.23,0.♥2)	0.10	-0.07	0.22
Genesis II	0.44 (0.21) (n=40)	0.34 (0.21) (n=37)	0.45 (0.25) (n=34)	(-0.16,0.04)	0.22	(-0.15,0.04)	0.26	(-0.23,0.02) g	0.10	(-0.19,0.05)	0.22
• • •	ing onto a stair gular velocity (deg	grees/sec)	-					by guest.			
JII-BCS	221.70 (88.35) (n=37)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31		51.63		50.01ec (5.97,94. 2 4)		35.15	
Genesis II	243.74 (84.05) (n=38)	251.04 (87.88) (n=34)	318.82(71.32) (n=30)	(16.67,91.96)	0.01	(15.36,87.89)	0.01	(5.97,94. 9 4) ङ्	0.03	(-3.09,73.39)	0.07

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Table S6. Muscle activity during walking from b	paseline to six months post-surgery (p	en- 2022- Emary timepoint)

		Means (SDs)				Betw	een gro	ups compa fi son	1																										
	(nu	mber of participa	unts)		Two r	nonths	_	inua	Six 1	nonths																									
		T	Six months	Unadjust	ed	Adjusted ^a		Unadjusted		Adjusted ^a																									
	Baseline	Baseline Two months after surgery	Six months after surgery	effect size (95% CI)	p- value	effect size (95% CI)	p- value	effect siæ (95% CI)	p- value	effect size (95% CI)	p-valu																								
Peak activation	on Vastus Mediali	s (% gait cycle)						– – – – – – – – – – – – – – – – – – –																											
III DCG	28.62 (27.23)	25.42 (24.93	23.20 (22.72)					nlo																											
JII-BCS	n=39	n=38	n=35	-1.22	0.82	-1.13	0.04	1.86 a	0.74	1.4	0.00																								
с . н	30.10 (27.73)	23.18 (22.66)	24.64 (24.94)	(-12.1,9.65)	0.82	(-11.98,9.72)	0.84	(-9.45,13 46)	0.74	(-9.43,12.22)	0.80																								
Genesis II	n=40	n=38	n=33					rom		(-)																									
Peak activation	on Vastus Laterali	is (% gait cycle)						htt																											
	18.44 (12.15)	17.29 (11.51)	13.03 (5.61)					5.59 m																											
JII-BCS	n=39	n=38	n=35	1.20	0.73	1.11	0.75	5.59	0.12	5.63	0.12																								
с . н	20.23 (20.35)	18.47 (17.46)	18.79 (19.89)	(-5.67,8.07)		0.75	(-5.78,8.01)	0.75	(-1.52,12)	0.12	(-1.65,12.9)	0.13																							
Genesis II	n=40	n=38	n=33					<u>e</u>																											
Peak activation	on Tibialis Anterio	or (% gait cycle)						4.68 or 4.68 (-3.92,13 248)																											
III DCG	23.46 (24.74)	18.97 (20.91)	15.20 (14.27)					G																											
JII-BCS	n=39	n=38	n=35	0.47	0.02	0.54	0.01	4.68	0.29	6.06	0.14																								
о · н	28.88 (27.88)	19.82 (20.76)	19.61 (20.32)	(-9.18,10.13)	0.92	(-9.21,10.28)	0.91	(-3.92,13,28)	0.28	(-2.14,14.26)	0.14																								
Genesis II	n=40	n=38	n=33					April 1																											
Peak activatio	on Biceps Femoris	(% gait cycle)						17																											
III DCC	25.03 (25.32)	21.87 (21.34)	35.77 (34.01)					, 20																											
JII-BCS	n=39	n=38	n=35	6.76	0.00	5.71	0.25	-9.784	0.01	-10.97	0.17																								
с . н	29.98 (28.00)	29.16 (31.55)	25.30 (28.86)	(-5.49,19.01) 0.28	0.28	0.28	.01) 0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	(-5.49,19.01) 0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	0.28	(-6.42,17.84)	0.35	(-25.33,5,\$,\$6)	0.21	(-26.69,4.74)	0.17
Genesis II	n=40	n=38	n=33					guest.																											
Peak activatio	on Lateral head of	Gastrocnemius	(% gait cycle)																																
III DCC	24.67 (17.24)	23.87 (19.34)	20.66 (15.99)					Protect																											
JII-BCS	n=39	n=38	n=35	-1.18	0.76	-1.01	0.70	-1.84 🗑	0.50	-1.89	0.50																								
а : н	25.23 (22.36)	23.39 (14.60)	20.00 (13.80)	(-8.9,6.53)	0.76	(-8.55,6.52)	0.79	(-8.61,4. 🗒	0.59	(-8.79,5.01)	0.59																								
Genesis II	n=40	n=38	n=33					by																											
adjusted for st	rata used in random	nisation and for ba	seline scores					copyright.																											
-								oyriç																											
								ght																											

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Table S7. Balance parameters from baseling	ne to six months post-surgery (prima	rs timepoint)

			Between groups comp g rison									
	(nu		Two months			Six months		onths				
		т	C'	Unadjust	ed	Adjusted	Adjusted ^a Urradjust		sted Adjus		sted ^a	
	Baseline	Two months after surgery	Six months after surgery	effect size	p-	effect size	р-	effec	p-	effect size	р-	
		alter surgery	alter surgery	(95% CI)	value	(95% CI)	value	(95%CI)	value	(95% CI)	value	
Can stand	d for 10 secs only o	n operated leg, eye	s open (number)					Dow				
JII-BCS	13/40 (32.5%)	13/39 (33.3%)	15/35 (42.9%)	0.92		1.17				0.62		
Genesis	10/40 (25.0%)	11/37 (29.7%)	10/34 (29.4%)	(0.34,2.49)	0.88	(0.34,4.07)	0.80	(0.20, g .51)	0.249	(0.17,2.28)	0.47	
II	10/40 (23.070)			(0.54,2.47)		(0.54,4.07)				(0.17,2.20)		
Seconds s	standing only on op	erated leg, eyes op						from				
JII-BCS	205.04 (176.11)	215.39 (99.27)	235.48 (176.94)					82.42				
JII-DC3	(n=38)	(n=39)	(n=35)	7.00	0.80	23.72	0.18	82.42	0.01	-59.91	0.01	
Genesis	188.25 (125.93)	226.09 (137.15)	158.14 (65.40)	(-48.53,62.53)	0.80	(-10.93,58.37)	0.16	$(-147.17\frac{3}{2}17.67)$	0.01	(-105.98,-13.85)	0.01	
II	(n=40)	(n=36)	(n=34)					ope				
COP path	h length standing o	•••	osed (mm)					n.b				
JII-BCS	205.04 (176.11)	215.39 (99.27)	235.48 (176.94)					<u>, 3</u> ,				
JII-DCS	(n=38)	(n=39)	(n=35)	7.00	0.80	23.72	0.18	82. <mark>4</mark> 2	0.01	-59.91	0.01	
Genesis	188.25 (125.93)	226.09 (137.15)	158.14 (65.40)	(-48.53,62.53)	0.80	(-10.93,58.37)	0.16	(-147.17 <mark>5</mark> 17.67)	0.01	(-105.98,-13.85)	0.01	
II	(n=40)	(n= 36)	(n=34)				\frown .	n A				
^a adjuste	ed for strata used in r	andomisation and f	or baseline scores					April 17,				
-								, 202				
Resultar	nt centre of pressure	path length (COP c	m) in double stance	with eyes closed:	lower pa	ath length indicate	es better b	palance ability.				
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		Means (SD	s)			
	(number of participants)					
	Baseline	Two months after surgery	Six months after surgery			
Cadence						
	107.37	103.09 (13.21)	113.09 (9.51)			
JII-BCS	(10.62)	N=37	N=35			
	N=39					
Constant. II	102.7(10.8	105.25(10.21)				
Genesis II	3) n=40 🧹	n=37	112.98(9.71) n=34			
Step length						
	0.53(0.08)					
JII-BCS	n=39	0.5(0.09) n=37	0.56(0.1) n=35			
Genesis II	0.54(0.09)					
Genesis II	n=40	0.55(0.08) n=37	0.6(0.08) n=34			
Stride length						
0	1.06(0.17)					
JII-BCS	n=39	1.04(0.18) n=37	1.15(0.21) n=35			
Genesis II	1.08(0.17)					
Genesis II	n=40	1.11(0.15) n=37	1.2(0.16) n=34			

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

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

urgery					
	JII-BCS	Genesis II	Effect size	p-valu	
	Number (%)	Number (%)	(95% CI)		
Length of in-					
patient stay					
Three days	14 (35%)	13 (33%)			
Four days	21 (53%)	21 (53%)			
Five days	4 (10%)	5 (13%)	NA	0.740	
Six days	1 (3%)	1 (3%)	NA	0.749	
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	NT A	
Yes	0	0	NA	NA	
Complications					
No	34 (85%)	35 (88%)	1.00	0 790	
Yes	6 (15%)	5 (13%)	0.83 (0.23,3.01)	0.780	
Change pain					
medication					
No	1 (3%)	4 (10%)	-7.5% (-18.0,3.0)	0 250	
Yes	39 (98%)	36 (90%)	-7.5% (-18.0,3.0)	0.359ª	

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

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.

	BCS and Genesis II groups.	Number of se exercises wer median	e performed: (IQR)
		JII-BCS	Genesis I
Īn	-patient sessions (JII-BCS n=27, Genesis II n=26)	(n=40)	(n=40)
11	Gait re-education	2.0 (2.0, 3.0)	2.0 (2.0, 3.
	Step exercise	1.0(1.0, 1.0)	1.0 (1.0,2.
	Knee ROM flexion exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.
	Static quadriceps exercise	2.0 (2.0, 3.0) 2.0 (2.0, 3.0)	2.0 (2.0, 3)
	Inner range quadriceps exercise	1.0 (0.0, 1.0)	1.0 (0.0, 2)
		0.0 (1.0, 1.0)	0.0 (1.0, 1.
	Straight leg raise exercise	· · · · · ·	
	Knee extension strengthening exercise in	1.0 (0.0, 1.0)	1.0 (0.0, 2
	sitting	10(0020)	10(00 2
	Ice treatment	1.0(0.0, 2.0)	1.0 (0.0, 2
	Advice and education	3.0 (2.0, 3.0)	2.5 (2.0, 3
~	Other body region rehabilitation exercises	3.0 (2.0, 3.0)	2.5 (2.0, 3
	ut-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
	Seat pedal exercises	0.0 (0.0, 1.0)	0.0 (0.0, 1
	Static bike exercises	1.0 (0.0, 3.0)	1.0 (0.0, 5
	Cross-trainer exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5
	Calf stretch exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5
	Gait re-education	1.0 (1.0, 2.0)	1.0 (1.0, 5
	Stair practice	1.0 (0.0, 1.0)	1.0 (0.0, 1
	Step exercise	1.0 (0.0, 4.0)	1.0 (1.0, 5
	Sit to stand exercise (without arms of chair)	1.0 (0.0, 4.0)	1.0 (0.0, 5
	Sit to stand exercise (with arms of chair)	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
	Knee strengthening extension exercise with	0.0 (0.0, 5.0)	1.0 (1.0, 5
	resistance band		
	Static quadriceps exercise	1.0 (1.0, 1.0)	1.0 (1.0, 4
	Straight leg raise exercise	1.0 (1.0, 1.0)	1.0 (1.0, 3
	Inner range quadriceps exercise	1.0 (1.0, 3.0)	1.0 (1.0, 3
	Proprioceptive exercises in standing	0.0 (0.0, 5.0)	1.0 (1.0, 5
	Proprioceptive exercises in standing (with	0.0 (0.0, 0.0)	0.0 (0.0, 0
		0.0(0.0, 0.0)	0.0 (0.0, 0
	support) Proprioconting exercises in standing (with		
	Proprioceptive exercises in standing (with	0.0 (0.0, 0.0)	0.0 (0.0, 1
	eyes shut)		
	Advice and education	0.0(0.0, 1.0)	0.0 (0.0, 1
	Glutei strengthening exercise	0.0 (0.0, 1.0)	0.0 (0.0, 1

Table S11. Complications and adverse events

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



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

Section/Topic	ltem No	Checklist item 1648 9	Reported on page No
Title and abstract		4 5 8	
	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	2a	Scientific background and explanation of rationale	6
objectives	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 2	N/A
Sample size	7a		7
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:		Method used to generate the random allocation sequence	
Sequence	8a	Method used to generate the random allocation sequence	7
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially automation because),	7
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned a	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who $a g$ signed participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, 🎽 re providers, those	7

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			assessing outcomes) and how 8	
1 2		11b	assessing outcomes) and how	6
2	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
5	Results			
6 7	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received in ended treatment, and	14
8	diagram is strongly	100	were analysed for the primary outcome	17
9	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	14, 15
10 11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
12		14b	Why the trial ended or was stopped	13
13	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16
14 15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and weether the analysis was	16
16			by original assigned groups	
17	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	19, 22,25
18 19	estimation		precision (such as 95% confidence interval)	29,31
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
21 22	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	As above
23 24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for barms)	33,
25				Supplementar
26			S S S S S S S S S S S S S S S S S S S	y table 9
27 28	Discussion		Apr <u>i</u>	
29	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	33
30	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	33
31 32	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	34,35
33	Other information			
34	Registration	23	Registration number and name of trial registry	4
35 36	Protocol	24	Where the full trial protocol can be appaged if evoluble	provided
37	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders $\frac{1}{6}$	35
38		20		
39 40				
40 41			by copyright.	
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43	CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Page 2
44 45				
46				

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*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. 61648 on 4 January 2023. Downloaded from http://bmjopen.bmj.com/ on April 17, 2024 by guest. Protected by copyright , van ,

CONSORT 2010 checklist