PROTOCOL

Manual arthroplasty versus VELYS robot-assisted functional alignment in total knee arthroplasty (MARVEL): Protocol for a pragmatic, multicentre, blinded randomised controlled trial with multidomain investigations

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ABSTRACT

Aims

Robot-assisted total knee arthroplasty (raTKA) may improve implant positioning, soft-tissue balance, and early recovery, but high-quality randomised evidence is limited for raTKA in general, and imageless raTKA systems in particular. The MARVEL trial aims to compare robot-assisted TKA following a functional alignment strategy using the imageless VELYS Robot Assisted Solution with conventional manual jig-based TKA in patients undergoing primary TKA for osteoarthritis.

The study is specifically designed to address the principal UK National Institute for Health and Care Excellence (NICE) 2025 Early Value Assessment evidence domains for robot-assisted orthopaedic surgery, including patient-reported outcomes, safety, subgroup effectiveness, healthcare resource use, cost-effectiveness, and implementation-related outcomes.

Methods

MARVEL is a pragmatic, multicentre, parallel-group, participant- and outcome assessor-blinded randomised controlled trial. Adults undergoing primary TKA for knee osteoarthritis will be randomised 1:1 to manual TKA or VELYS raTKA using the same implant platform. The primary outcome is change in Forgotten Joint Score from baseline to six months postoperatively.

Secondary outcomes include additional patient-reported outcome measures, radiographic alignment, intraoperative digital metrics, adverse events, subgroup analyses, health service resource use, surgical efficiency, clinician task load, and health economic outcomes. A nested motion analysis laboratory sub-study will assess objective biomechanical outcomes, and an internal pilot will assess feasibility, retention, intervention fidelity, safety, and completeness of primary outcome data. The target sample size is 346 participants in total, with 173 participants per group.

Discussion

MARVEL is designed to provide randomised evidence on the clinical effectiveness, safety, biomechanical effects, implementation impact, and economic value of imageless robot-assisted functional alignment TKA compared with conventional manual TKA. By integrating patient-reported outcomes with radiographic, intraoperative, biomechanical, efficiency, and cost-effectiveness data, the study is intended to address major current evidence gaps and inform future adoption of raTKA in routine orthopaedic practice.

TAKE HOME MESSAGE

MARVEL is a large, investigator-initiated, multicentre, blinded randomised controlled trial with multidomain investigations evaluating whether imageless robot-assisted functional alignment TKA using VELYS Robot Assisted Solution improves patient outcomes over standard manual jig-based TKA. It is designed to address the UK National Institute for Health and Care Excellence 2025 Early Value Assessment evidence domains for robot-assisted orthopaedic surgery: patient-reported outcomes, safety, subgroup effectiveness, healthcare resource use, cost-effectiveness, and implementation-related outcomes.

SPIRIT-COMPLIANT STRUCTURED SUMMARY

Title

Manual arthroplasty versus VELYS robot-assisted functional alignment in total knee arthroplasty (MARVEL): a pragmatic, multicentre, blinded randomised controlled trial with multidomain investigations.

Trial design

Pragmatic, multicentre, parallel-group, superiority randomised controlled trial with 1:1 allocation. Nested components include an internal pilot, a motion analysis laboratory sub-study, and evaluations of surgical efficiency, task load, and clinician experience.

Setting

Secondary care orthopaedic centres in the United Kingdom. The coordinating centre is Golden Jubilee University National Hospital, Clydebank, UK.

Participants

Adults aged 18 years or older with primary knee osteoarthritis requiring primary total knee arthroplasty, suitable for either robot-assisted or manual TKA, able to provide written informed consent, and able and willing to complete follow-up assessments. Key exclusions include inflammatory arthritis, significant symptomatic hip/ankle/contralateral knee osteoarthritis, prior major surgery or injury to the index knee, neuromuscular gait disorders, BMI > 45 kg/m², major coronal or fixed flexion deformity, likely need for non-standard implants or constraint, inability to comply with follow-up, or contraindications to the surgical technique.

Interventions

Participants will be randomised to manual TKA using conventional jig-based instrumentation or VELYS robot-assisted TKA using a functional alignment strategy. All patients will receive a cemented Attune prosthesis with a medial stabilised polyethylene insert. Perioperative care will otherwise be standardised across groups.

Primary outcome

Change in Forgotten Joint Score from baseline to six months postoperatively.

Secondary outcomes

Secondary outcomes include additional PROMs, radiographic alignment, intraoperative metrics, surgical efficiency, clinician task load, health service resource use, adverse events, and biomechanical outcomes in the motion analysis laboratory sub-study.

Sample size

346 participants in total, with 173 per group, allowing for 15% loss to follow-up. The motion analysis laboratory sub-study will recruit 52 participants.

Randomisation and blinding

Randomisation will be performed 1:1 using a secure web-based REDCap system with computer-generated permuted blocks, stratified by recruitment centre. Participants and outcome assessors will be blinded; surgeons cannot be blinded. Unblinding will occur only if required for urgent clinical management or participant safety.

Recruitment and follow-up

Recruitment is planned from 01 April 2026 to 01 April 2029. Participants will be followed for 12 months, with the primary endpoint assessed at six months. Longer-term survivorship observation will continue for at least 10 years through follow-up and registry linkage.

Trial registration

ClinicalTrials.gov, registration pending.

Sponsor and funding

The sponsor is Golden Jubilee University National Hospital, Clydebank, UK. The study is investigator-initiated and funded by DePuy International Ltd, with the design, conduct, analysis, and reporting remaining under the control of the academic investigators.

Data availability

The statistical analysis plan will be available on reasonable request. Following publication of the primary results, de-identified individual participant data, the data dictionary, and statistical code will be considered for sharing with bona fide researchers on reasonable request, subject to sponsor approval and governance requirements.

INTRODUCTION

Osteoarthritis (OA) of the knee is one of the most prevalent causes of pain and disability globally.[1] Total knee arthroplasty (TKA) is a highly effective treatment for end-stage disease, providing excellent long-term implant survivorship.[2] However, despite advances in implant design and surgical techniques, between 10-20% of patients remain dissatisfied following surgery, citing persistent pain, stiffness, or limitations in function.[3–5] An evolving body of research suggests that clinical and functional outcomes may be improved by the adoption of modern alignment and balancing strategies facilitated by robot-assisted systems (RAS) in arthroplasty.[6–10]

Conventionally, TKA is performed using manual instrumentation to determine limb alignment, bone resection, component sizing, and joint balance evaluation, with cutting blocks and a handheld oscillating saw to execute a preoperative plan.[11] While this approach remains the standard of care and has produced excellent long-term outcomes, it is inherently limited by its reliance on indirect anatomical references and manual execution.[6,12] Deviations in guide positioning, sawblade control, or instrument calibration can result in alignment errors and variable bone resections, and intraoperative assessment of ligament balance and joint gaps is subjective.[12–15] This may produce variability in component positioning, limb alignment, and soft-tissue balance, which can influence functional outcomes and implant longevity.[12,16,17]

Manual (m) TKA is most commonly executed in accordance with a mechanical alignment (MA) philosophy, which aims to achieve a neutral hip-knee-ankle (HKA) axis and horizontal knee joint line obliquity (JLO) by making bone resections perpendicular to the mechanical axes of the femur and tibia and using soft tissue releases to achieve a balanced joint.[11,18–22] This standardised approach evolved because implant design and fixation methods were believed to have greater longevity when positioned perpendicular to the mechanical load-bearing axis, thereby minimising asymmetric stresses across the prosthesis during ambulation.[21–23] Additionally, the inherent variability associated with conventional manual instrumentation made it prudent to aim for a neutral alignment 'middle ground,' reducing the risk of extreme malposition that could compromise implant fixation, wear characteristics, or overall limb mechanics.[6,12,17] However, MA does not account for the considerable individual variation in constitutional limb alignment and JLO seen in the population, with only 15% of healthy knees exhibiting neutral HKA and JLO.[23] This may be associated with suboptimal outcomes in some patients, and explains why the number of patients that are dissatisfied after TKA remains at 10% to 20%.[3,4,17,21,23–26]

Kinematic alignment (KA) has gained popularity as an alternative to MA and aims to replicate the pre-arthritic anatomy and kinematic axes, with some evidence suggesting this leads to better knee function, and variations are described based on the surgical process by which it is achieved.[6,19,20,22,27–31] However, KA suffers the same limitations as MA when using conventional instrumentation, and these may even be of greater consequence when employing a KA strategy because of the limited accuracy and reproducibility of manual tools when evaluating knee balance and executing bony resections.[9,12,32,33] Furthermore, inaccuracies made when following KA rather than MA strategy may occur further from the mechanical axis of the limb, and therefore be of greater consequence.[13,16,34] In practice, most modern mTKA strategies borrow principles from multiple philosophies along the MA-KA spectrum to produce a safely positioned, balanced prosthetic joint.[6,35]

The introduction of robot-assisted surgery in arthroplasty has provided surgeons with tools for multi-dimensional reconstructive modelling and precise bone resection that preserves the soft tissue envelope, and these systems can be used with any TKA philosophy.[7,10,15,36] Suggested benefits of RAS include fewer errors of resection, balance, iatrogenic injury, and implant position, which may improve short and long-term outcomes.[7,8,10,37] Systems that permit precise, dynamic intraoperative evaluation of knee function have allowed surgeons to move away from conventional MA towards more 'personalised' arthroplasty strategies.[6,9,38,39] This has facilitated the evolution of functional alignment (FA), which builds on the KA principles of restoration of native knee kinematics while prioritising accurate restoration of soft tissue balance. [19,30,40]

There is good evidence suggesting that robot-assisted TKA (raTKA) is associated with improved early postoperative recovery and a reduction of errors in component positioning. The literature is limited by heterogeneous techniques, a lack of standardisation, and a shortage of large, high-quality randomised controlled trials (RCTs).[9,10,32] Additionally, previous studies have seldom included objective assessments of biomechanics or explored the relationship between intra-operative alignment and post-operative outcomes.[10,32] Furthermore, much of the literature evaluating RAS in knee arthroplasty is focused on computerised tomography (CT) guided systems such as Mako Robot-arm Assisted Surgery (Styker Inc., Kalamazoo, MI, USA).[9,41] Imageless systems like the VELYS Robot-assisted Solution (VRAS; Johnson & Johnson MedTech, Warsaw, IN, USA) capture all data intraoperatively, with a focus on real-time assessment of landmarks, stability, and soft tissue envelope tracking through a range of motion.[42] It is possible that such systems could guide safe, consistent joint replacement surgery that prioritises the restoration of native knee kinematic function, and negates the economic, time, resource, and radiation costs associated with CT-guided

systems.[38,42–46] However as imageless systems become widespread, more research is required to address key evidence gaps.

The current literature on the use of VRAS in TKA demonstrates early promise, though the evidence base remains limited.[46–48] Most available studies are small retrospective cohort analyses, with no RCTs published to date. Existing data suggest that VRAS improves the precision of component positioning compared with both manual and navigated TKA.[38,49] Additional reported benefits include improved early functional outcomes, a relatively short learning curve, a safety profile at least equivalent to manual TKA, and reduced rates of soft tissue release and inadvertent injury.[46,47,50–52] Despite these encouraging findings, higher-quality research, particularly adequately powered RCTs assessing appropriate patient-reported outcome measures (PROMs) and enabling subgroup analyses, remains essential.[53]

Many patients believe RAS guarantees better outcomes or faster recovery; however, current evidence is insufficient to support such claims.[54–59] Alongside these misconceptions, concerns are expressed regarding the radiation exposure associated with pre-operative CT scans required for certain RAS systems.[56,60] Notably, despite these concerns, a majority of patients indicate a preference for raTKA over mTKA when given the choice.[55,56,61] This highlights a substantial cohort who would favour an imageless system, emphasising the importance of providing accurate, transparent information about such technologies.

Guidance on the information that should be generated and communicated has been outlined by the UK National Institute for Health and Clinical Excellence in its ‘early value assessment’ of RAS for orthopaedic procedures.[62] This assessment identifies key evidence priorities for the six major orthopaedic RAS technologies over the next three years, including: the impact on patient quality of life and healthcare resource use; technology-specific utilities data and additional resource use data to inform economic modelling; and the clinical effectiveness of RAS in defined patient subgroups. These priorities align closely with the current knowledge gaps relating to the VELYS system in particular. The MARVEL Project (manual arthroplasty versus VELYS robot-assisted functional alignment in total knee arthroplasty) aims to address these gaps with a comprehensive evaluation of VRAS.

This multicentre, pragmatic, parallel-group, blinded RCT will compare VELYS robot-assisted functional alignment with conventional mTKA. The trial will employ a clearly defined, reproducible surgical protocol that will incorporate evaluation of the study cohort using: established clinical and patient-reported outcome measures (PROMs); gold-standard three-dimensional (3D) motion analysis

to objectively evaluate functional outcomes; detailed examination of intraoperative knee kinematics, pre-/post-operative hip-knee-ankle radiographic data, and healthcare system effects including economic, efficiency, and human factor measures.

Objectives

The primary objective is to compare knee-specific health outcomes in patients undergoing TKA performed with VELYS robot-assisted (raTKA) using functional alignment versus TKA performed manually (mTKA) using conventional instrumentation. The primary outcome measure will be differences between the two intervention groups (using an intention-to-treat approach) with regard to change in Forgotten Joint Score (FJS) preoperatively versus 6 months post-surgery. The secondary objectives are to:

1) Compare PROMs (FJS, EQ-5D-5L, Oxford Knee Score [OKS], satisfaction [numeric rating scale; NRS], 4-part Likert scale], pain [101-point scale VAS]) at 6 weeks, 6 months, and 12 months;
2) Correlate these outcomes with radiographic alignment and intra-operative data;
3) Evaluate biomechanical outcomes using motion analysis laboratory assessment;
4) Functional and activity-related outcomes;
5) Evaluate the economic and efficiency effects of imageless raTKA relative to mTKA;
6) Evaluate the human factor effects of introducing a new RAS into healthcare teams;
7) Assess surgical safety and the incidence of adverse events in both groups.

Null hypothesis

The null hypothesis is that functionally aligned raTKA using the VELYS imageless system does not result in a greater early improvement in knee-specific outcomes, as measured by change in Forgotten Joint Score at 6 months, compared with conventional mTKA.

METHODS

Study design

The study is designed as a multicentre, pragmatic, parallel-group blinded RCT. There are nested modular study components, including: an internal pilot to determine safety and practicability; a motion analysis evaluation, and a task load, efficiency, and clinician perspective evaluation. The lead centre for the study will be the Golden Jubilee University National Hospital (GJUNH). Additional centres will be based in the United Kingdom and Irish regions. All participating surgeons are high-volume arthroplasty surgeons (performing approximately 100 knee arthroplasties annually) and have extensive experience with robot-assisted surgery.

Surgeons and training

All participating surgeons are high-volume arthroplasty surgeons (performing approximately 100 knee arthroplasties annually) and have extensive experience with robot-assisted surgery. Studies evaluating the learning curve of the VELYS system found that proficiency was reached after between 5-9 cases, and there was no significant difference in outcomes for patients that underwent raTKA early versus late on the operator's experience curve.[13,43,52,63,64]

To minimise any learning curve effects and variability between centres, all surgeons will have completed manufacturer-delivered training and credentialling using both the manual and robotic systems, and a minimum of 20 Attune TKA non-trial cases will have been completed by all surgeons (comprising 10 manual Attune and 10 VELYS-assisted cases) before they recruit trial participants. A subgroup analysis of TKA performed early versus late on the clinical experience will be performed as part of the interim pilot study to evaluate for differences in outcomes and adverse events, and a sensitivity analysis will be performed if indicated.

Sample size

The sample size calculation is based on detecting a minimum clinically important difference (MCID) of 7 points in the FJS at six months post-operatively. This is informed by Alton et al (2025), and a standard deviation of 24 points, as reported in Clement et al., 2021.[46,65] Using a one-sided alpha of 0.05 and a power of 80%, it was calculated that 147 participants per group would be required. To account for an anticipated 15% loss to follow-up, the final recruitment target is 173 participants per group, yielding a total study population of 346 participants.

Outcome data from the internal pilot (the first 100 study participants who have completed their 6-month follow-up) will be analysed. A blinded pooled estimate of the outcome variance will be computed and used in a pre-specified sample size re-estimation algorithm. The analysis team will remain blinded to treatment allocation; any sample size adjustments will be made according to the pre-specified rules to preserve type I error.

For the motion analysis sub-study, a sample size of 52 participants (26 in the raTKA and mTKA groups respectively) has been determined to provide sufficient power to detect expected differences in peak medial knee contact force compared with matched healthy controls.

Recruitment

Participants will be identified through routine NHS orthopaedic outpatient clinics at the participating centres, in accordance with the eligibility criteria by the clinical team. Potentially eligible patients will be highlighted by the research team who will provide patient information relating to the study, with adequate time for consideration of the relevant materials and discussion with the clinical team before consent is sought. Participants will be randomised on a 1:1 basis to receive either: mTKA or raTKA. A separate consent form will be provided for the MAL sub-study.

Recruitment is planned to take place over 36 months, with each participant followed for 12 months post-operatively. Due to the use of the Attune Medial Stabilized (MS) polyethylene insert, long-term observation will be conducted for a minimum of 10 years to evaluate survivorship and cross-validated with national registry data.[66,67] The final phase of data analysis and dissemination will be conducted in year 5 of the study. The trial protocol is aligned with SPIRIT 2025 guidelines.[68] The study conduct will be reported according to CONSORT 2025 guidelines.[69]

Eligibility

Eligible participants will be aged 18 years or older, with a diagnosis of primary knee osteoarthritis requiring primary TKA. Participants must be suitable for either raTKA or mTKA, capable of providing written informed consent, and capable and willing to complete clinical and patient-reported outcome measures throughout the study period. (Figure 1)

Eligibility

Inclusion Criteria

- Aged >18 years
- Primary knee OA
- Requiring TKA
- Suitable for either raTKA or mTKA
- Capable to provide written informed consent
- Capable and willing to complete outcome measures throughout study period

Exclusion Criteria

- Inflammatory arthritis
- Significant symptomatic hip, ankle, or contralateral knee OA
- Prior TKA or major injury or major surgery on the index knee
- Neuromuscular gait disorders
- BMI >45 kg/m^2
- Coronal plane deformity >15° varus/valgus on pre-op HKA radiograph
- Fixed flexion deformity greater than 15°
- Bone loss likely to require non-standard implants (e.g. stems, augments)
- Severe deformity or ligament insufficiency likely to require constraint
- Inability to comply with the required follow-up assessments or complete PROMs
- Contraindications to any aspect of the surgical technique

Fig 1. *Eligibility criteria.*

OA: osteoarthritis, TKA: total knee arthroplasty, raTKA: robot-assisted TKA, mTKA: manual TKA, BMI: body mass index, PROMs: patient-reported outcome measures.

Randomisation

Participants will be randomised in a 1:1 ratio to receive either manual TKA or VELYS robot-assisted functional alignment TKA. Randomisation will be performed using a secure web-based system (Research Electronic Data Capture [REDCap], Vanderbilt University, USA) incorporating computer-generated permuted block randomisation, stratified by recruitment centre.[70] Block sizes will be randomly varied and concealed to ensure allocation concealment. Following written informed consent and collection of baseline data, site research staff will enrol and randomise participants.

Blinding

The study is a randomised controlled trial with patient and outcome assessor blinding for the duration of trial conduct and follow-up period. It is not possible to blind surgeons given the nature of the interventions. Non-surgical clinical staff (e.g. ward nurses and allied health professionals) will be

blinded. Femoral and tibial tracker pins will be placed within the surgical incision, avoiding the need for accessory incisions in raTKA cases or sham incisions to aid blinding in mTKA cases. Documentation will be redacted appropriately to prevent inadvertent unblinding of clinicians. PROMs will be completed independently by participants. Radiographic assessments and biomechanical analyses will be performed by assessors who are blinded to treatment allocation. All study data will be anonymised and the study arm concealed before the conduct of data analysis.

Routine unblinding is not planned. Unblinding will be permitted only where knowledge of treatment allocation is considered necessary for urgent clinical management or participant safety. Any request for unblinding should be made by the treating clinician to the Chief Investigator or delegated medically qualified investigator. The reason for unblinding, the date, the person authorising it, and the person informed will be documented in the trial records. The Sponsor will be informed, and the event will be reviewed by the Trial Steering Committee. Wherever possible, unblinding of one participant will not result in unblinding of outcome assessors or the wider trial team.

Retention and withdrawal of participants

Participants have the right to withdraw from the trial at any point and for any reason, without providing an explanation. Withdrawal from the study will not affect their routine clinical care. The Principal Investigators (or delegate) may also withdraw participants from the study intervention if it is deemed in their best interest, including but not limited to:

- Development of a medical condition making continuation inappropriate;
- Adverse Events (AEs) or Serious Adverse Events (SAEs) that necessitate discontinuation;
- Significant protocol violations that compromise study integrity or participant safety;
- Participant request or non-compliance with study procedures.

Data collected up to the point of withdrawal will be retained and included in analyses, unless the participant specifically requests data removal in line with GDPR provisions. Participants who withdraw before randomisation or before any study procedures will be replaced to ensure an adequate sample size. Participants who withdraw after randomisation will not be routinely replaced, unless withdrawal rates threaten study power, in which case replacement will be considered. If

withdrawal occurs due to an AE or SAE, appropriate medical care will be provided and relevant safety follow-up conducted until the event has resolved or stabilised. All such cases will be reported in accordance with regulatory requirements. Participants will be informed of these arrangements during the consent process, and all efforts will be made to minimise the burden of continued safety follow-up for those who withdraw from the intervention arm of the study.

Follow-up will be promoted through alignment of study assessments with routine clinical care wherever possible, use of electronic, postal, telephone, or in-person data collection methods, and reminder contact from the research team for outstanding questionnaires or visits. Participants who discontinue the allocated intervention or deviate from the protocol will be invited to remain in follow-up unless they withdraw consent for further data collection. Where full follow-up is not possible, the study team will seek to collect a minimum dataset comprising the primary outcome where feasible, key safety outcomes including adverse events and reoperations, and relevant routine clinical data available from the medical record.

Surgical technique

A thigh tourniquet will be used for the full case until closure of the arthrotomy, and a medial parapatellar approach to the knee will be used in all cases. A cemented Attune prosthesis with medial stabilised (MS) polyethylene insert will be implanted in all patients. Perioperative care will be delivered in a standardised fashion in accordance with safe established practice and will not vary according to treatment arm.

Manual TKA

Participants randomised to this group will undergo manual TKA performed with conventional jig-based instrumentation using cemented Attune Knee System components (Johnson & Johnson MedTech) and a medial stabilised (MS) polyethylene insert.[63,66] The aim will be to correct deformity towards a neutral limb alignment and achieve a TKA that is stable throughout the flexion-extension arc.[18]

Extramedullary referencing will be used to align the proximal tibial resection perpendicular to the axis of the tibia. Intramedullary referencing will be used to align the distal femoral resection based on pre-operative planning and intra-operative assessment. Femoral axial alignment will be set initially at 3 degrees of external rotation relative to the posterior condylar axis, typically perpendicular to

Whiteside's line, and adjusted based on the flexion gap and patellar tracking. Measured bone resections will be made using the standard cutting guides for the Attune TKA system.

VELYS robot-assisted functional alignment TKA

Participants allocated to the raTKA group will undergo TKA using the VELYS system following a functional alignment (FA) strategy that uses technology-assisted intraoperative evaluation to restore ligament balance and stability throughout the flexion-extension arc while reconstructing the native kinematic axes of the pre-arthritic knee.[6,8,19,20] This is achieved by precise assessment of the soft tissue envelope using the VELYS system with subsequent adjustments to the planned bone resections to achieve an optimally sized, aligned, and balanced TKA using minimal bone resections to accommodate the thinnest necessary polyethylene insert and minimising the need for soft tissue releases. Bone resections and implant positioning will be guided by the VELYS Robot-assisted Solution within safe target ranges: tibial resection 0° to 7° varus; overall limb alignment (HKA) 173°–183° (i.e. HKA between 7° varus and 3° valgus).[41,71] The femoral and tibial robotic arrays will be placed intra-incisional according to the standard VELYS technique to avoid the need for additional incisions.

It is possible to achieve FA either from a mechanically-aligned pre-operative plan, where bone resections are planned to produce neutral alignment in the coronal plane, or a kinematically-aligned pre-operative plan, where anatomical bone resections are planned to resurface the native anatomy. The latter accounts for bone loss, and thus restores the constitutional [pre-arthritic] limb alignment and joint line obliquity.[6,8,19,20] FA is then achieved by technology-assisted intraoperative assessment of the soft tissues and subsequent adjustments made to the planned resections to achieve a balanced knee. Soft tissue release is only utilised as a last resort if satisfactory alignment or balance is not achieved by modifying the bone resections alone.[18,19,22,28,72] For consistency in this study, all raTKA patients will be treated according to a KA-based FA philosophy. VELYS-acquired intra-operative data will be captured for correlation with post-operative outcomes.

Technical consistency

The Surgical Lead will chair a surgeon's group to review the surgical and perioperative techniques to ensure consistency of practice across all participating sites. Any deviations from the defined surgical protocol will be documented and will require prior approval by the CI and site PIs, Trial Steering Committee (TSC) and Research Ethics Committee (REC). Adherence to the intervention protocol will be monitored via surgical records and VELYS system logs.

Outcomes

The primary outcome will be the change in Forgotten Joint Score (FJS) at two timepoints, preoperatively versus 6 months post-surgery.[73,74] Secondary outcome measures will include PROMs; clinical outcomes; functional, physiological, and technology-enabled activity measures; health service and economic outcomes; technical surgical/radiographic measures, and biomechanical outcomes using motion analysis laboratory assessment. A dedicated motion analysis laboratory (MAL) study will be conducted as a nested sub-study. (Figure 2)

Outcomes	
Primary measure	
	Change in FJS [pre-surgery, 6 months][73,74]
Secondary Measures	
	Change in FJS [pre-surgery, 6 weeks, 12 months]
	Absolute FJS [6 weeks, 6 months, 12 months]
	OKS [pre-operative, 6 weeks, 6 months, 12 months][75]
	EQ-5D-5L [pre-operative, 6 weeks, 6 months, and 12 months][76]
	Satisfaction Score (NRS, Likert scale) [6 weeks, 6 months, 12 months][77]
	Pain score (VAS) [6 weeks, 6 months, 12 months][78]
	PROM anchor questions[79]
	Functional, physiological and technology-enabled activity measures
	Change in radiographic parameters
	Alignment measures (HKA, JLO, CPAK, component size and position)[21]
	Surgical time (preparation, case, tourniquet & turnaround)
	NASA TLX & clinician experience (after 1st and every 5th case)[80–82]
	Health service resource utilisation (clinical contacts, analgesic use)

***Fig 2**. Primary and secondary outcome measures. Time points are relative to date of surgery.*

FJS: Forgotten Joint Score, OKS: Oxford Knee Score, EQ-5D-5L; EuroQol EQ-5D 5-Level, NRS: numeric rating scale, VAS: visual analogue scale, HKA: hip-knee-ankle axis, JLO: joint line obliquity, CPAK: coronal plane alignment of the knee, NASA TLX: NASA Task Load Index.

Subgroup analyses

Predefined subgroup analyses will explore potential differences in outcomes according to: age; sex; BMI; socioeconomic deprivation level; primary compartment involved (medial, lateral, or patellofemoral); CPAK group and restoration; VELYS-acquired intra-operative data (for raTKA group).[41]

These subgroup analyses will extend the primary models by including interaction terms and will be considered exploratory. A generalised linear model will be applied, incorporating allocation group, age, site, surgeon, gender, BMI (≥35 kg/m^2), and the primary compartment affected (medial, lateral, or patellofemoral) as covariates. Both fixed- and random-effects modelling will be employed to assess robustness. Sensitivity analyses will explore model assumptions and include both modelling approaches. Other subgroup analyses may be pre-specified as appropriate.

Data collection

Study data will be collected using a bespoke portal on REDCap (Research Electronic Data Capture, Vanderbilt University, USA) at predefined time points, aligned with the clinical care pathway. An option for in-person, postal, and telephone collection will also be available to participants at each time point. (Table 1)

At the pre-operative baseline visit, participants will complete the PROMs questionnaires (FJS, OKS, EQ-5D-5L, satisfaction scores, and pain score). Pre-operative bilateral hip-knee-ankle (HKA) radiographs will be obtained to assess coronal alignment, joint line obliquity, and enable CPAK classification. For participants enrolled in the motion analysis laboratory (MAL) sub-study, a baseline assessment will be conducted during the same hospital visit.

During surgery, data will be collected relating to surgical workflow and efficiency (including case time, tourniquet time, operating room preparation and turnaround times). For the raTKA group, VELYS-acquired intra-operative data will be collected. Data from inpatient medical records will be collected. Routine postoperative radiographs will be taken in line with standard clinical practice.

At six weeks post-operatively, participants will complete the PROMs questionnaires. In addition, participants will complete a health service resource use questionnaire, which will capture clinical service contacts (including frequency and reason) and analgesic use during the follow-up period.

At six months post-operatively, participants will complete the FJS (primary outcome), and secondary PROMs questionnaires, and post-operative bilateral HKA radiographs will be obtained to assess implant positioning and limb alignment. A further health service resource use questionnaire will also be completed. MAL sub-study participants will undergo a repeat assessment.

At 12 months post-operatively, participants will complete the full set of PROMs, along with a final health service resource use questionnaire.

Data management

All study data will be recorded using case report forms (CRFs) and entered into the secure, password-protected REDCap platform. Access will be restricted to authorised members of the trial team and sponsor representatives. Personal identifiers will be replaced with coded participant IDs to ensure data confidentiality. De-identified data will be used for all statistical analyses. Data will be managed in accordance with the UK Caldicott principles, and data will be retained in excess of the minimum

eight years in accordance with sponsor policy and UK regulatory requirements.[83] Data quality will be safeguarded through range checks, source data verification, and ongoing data monitoring by the trial team. Audits may be conducted by the Sponsor in line with routine NHS research governance.

Statistical analysis

All analyses will adhere to CONSORT reporting standards.[69] A detailed statistical analysis plan will be finalised with the Trial Steering Committee before any formal analyses are undertaken. Baseline characteristics will be summarised to assess comparability between treatment groups. Simple descriptive statistics will follow standard conventions, including means and standard deviations or medians and interquartile ranges as appropriate for continuous variables, and counts and percentages for categorical data.

The primary analysis will examine differences between the two intervention groups (using an intention-to-treat approach) with regard to their change in FJS (preoperatively versus 6 months post-surgery).[73,74] A Student's independent t-test will be used to compare mean scores between groups. Assumptions of normality and equality of variances will be assessed using diagnostic plots and Levene's test. If variances are unequal, the Welch's t-test will be applied. The results will be reported as mean differences with 95% confidence intervals and p-values.

Secondary outcomes will be analysed similarly, appropriate to the type and distribution of the data. Categorical outcomes, such as patient satisfaction and complication rates, will be compared between groups using the chi-square test. If any expected cell count is less than five, Fisher's exact test will be applied. Effect sizes will be reported alongside these comparisons using risk ratios or odds ratios with 95% confidence intervals to provide a measure of the magnitude and precision of differences between groups.

Multiple testing

Formal adjustment for multiple comparisons will be applied only to analyses of the primary outcome. Secondary outcome analyses will be considered exploratory and will not undergo multiplicity correction, as such adjustments may be overly conservative and risk masking clinically meaningful effects. Results for secondary outcomes will therefore be presented with unadjusted p-values, effect sizes, and 95% confidence intervals to support interpretation rather than definitive inference.

Handling of missing data

Missing data will be carefully evaluated, and reasons for missingness recorded wherever possible. Where appropriate, multiple imputation will be used, and analyses of imputed datasets will be presented alongside sensitivity analyses tailored to the type of missing data.

Internal pilot

This study will include an internal pilot phase, during which feasibility parameters will be assessed in an interim analysis of the first 100 participants, followed up to 6 months. Data from this phase will contribute to the definitive trial analysis. Pre-specified progression criteria will guide continuation: recruitment ("Go" ≥75% of target rate; "Amend" 50–74%; "Stop" <50%), retention at the primary endpoint ("Go" ≥90%; "Amend" 75–89%; "Stop" <75%), intervention delivery fidelity ("Go" ≥85%; "Amend" 60–84%; "Stop" <60%), and completeness of primary outcome data ("Go" ≥90%; "Amend" 70–89%; "Stop" <70%). Safety signals or unexpected serious adverse events will prompt immediate review by the Trial Steering Committee. At the end of the internal pilot, the Trial Steering Committee will review feasibility data and determine whether to proceed without modification, continue with protocol amendments, or stop the trial.

Motion analysis laboratory (MAL) evaluation

A subset of 26 participants in the VELYS-assisted group and 26 participants in the manual group will undergo gold-standard 3D motion analysis (Vicon, Oxford, UK) to provide objective biomechanical (kinematic, kinetic and electromyographic) data which will be compared between groups and with a reference population of 52 age- and sex-matched healthy (native knee) controls using a 1:1:2 comparison ratio.[84–86]

The primary outcome measure will be knee adduction moment (KAM), which is a validated biomechanical indicator of medial compartment loading, with elevated KAM values associated with increased medial knee contact forces and implant wear.[31,87–89] Systematic review evidence demonstrates that manual TKA procedures consistently reduce peak KAM.[90] However, not many studies have systematically evaluated KAM patterns following raTKA or compared these outcomes to healthy individuals, representing a significant gap in understanding the biomechanical benefits of this advanced surgical technique.[85,91] Secondary outcomes will include:

- Spatiotemporal gait parameters (gait speed, step length);[92,93]
- Kinematic parameters (knee range of motion in sagittal and frontal planes);[90,94]
- Kinetic parameters, including peak hip flexion and adduction moments, peak knee flexion moment, knee adduction moment impulse, peak ankle dorsiflexion moment, and plantar loading symmetry;[90,92,93,95]
- Joint power parameters, including hip, knee, and ankle power;[85,86,93]
- Electromyographical assessment.

A sample size of 52 participants (26 in the raTKA and mTKA groups, respectively) has been determined to provide sufficient power to detect expected differences in medial knee contact force compared with matched healthy controls. The sample size calculation is based on peak knee adduction moment (KAM). Peak KAM for healthy controls is described as being 0.46 ± 0.13 Nm/kg, and for prosthetic knees at six months after mTKA, it is 0.61 ± 0.13 Nm/kg.[90,96] Only one study has investigated peak KAM in patients who have undergone raTKA, demonstrating values of 0.49 ± 0.31 Nm/kg at six months post-operatively.[91] A power calculation was performed (SPSS Sample Power) and demonstrated that with an independent samples t-test, a sample of 26 subjects in each group (mTKA and raTKA) provided adequate power to detect a significant difference in peak KAM (large effect size [0.80], $\alpha = 0.05$). Complementary MAL and technology-enabled assessments of real-world function, additional timepoints, and a larger sample may be added according to the availability of resources.

The motion analysis laboratory is based at the GJUNH, and subjects for the MAL study will be recruited from the GJUNH cohort of trial subjects. Patients will be invited to participate in the MAL study at the point of recruitment to the trial until the full sample (26 patients in each experimental arm) is complete. Recruitment to the MAL study will require separate informed consent due to the additional requirements for in-person attendance and testing pre-operatively and at 6 months post-operatively. Patients with a BMI of >40 kg/m2 will be excluded from the MAL study due to potential line-of-sight issues and greater soft tissue artefacts associated with anatomical placement of the retro-reflective markers and their subsequent movement relative to underlying bone during trials.

Health economic analysis

A prospective economic evaluation will be conducted from the perspective of the NHS and personal social services. Participants' healthcare contacts related to knee arthroplasty will be collected at all follow-up points, along with time lost from paid or unpaid work. Differences in surgical resource use,

including operating time and facility utilisation, will be costed using the latest published national reference costs, adjusted to a common year.

Health-related quality of life will be measured using the EQ-5D-5L questionnaire, with scores converted to utility values based on the UK value set recommended by NICE. Patient-level QALYs over 12 months will be estimated using the area under the curve approach. Missing data mechanisms will be assessed, and multiple imputation applied as needed. Imputed datasets will be used for bivariate analyses of costs and QALYs to estimate incremental cost per QALY and associated confidence intervals. Results will be presented on the cost-effectiveness plane, through cost-effectiveness acceptability curves, net monetary benefit calculations, and value of information analyses.

Limitations of trial-based economic analyses include potential discrepancies between observed and real-world costs, particularly for emerging technologies such as robot-assisted surgery. Costs may vary depending on hospital throughput and market conditions, and sensitivity analyses will explore these variations. If initial 12-month trial data show convergent outcomes and costs or dominance of one surgical approach, analyses will remain within-trial; otherwise, a longer-term economic model incorporating extended trial follow-up and external epidemiological data will be developed.

Surgical efficiency and task load evaluation

An assessment of the surgical efficiency, learning curve, physical and cognitive task load costs associated with VRAS raTKA versus mTKA will be conducted. This will include an evaluation of intraoperative timings, NASA Task Load Index (TLX) scores reported by clinicians based on their perception of surgical cases (after the first and every fifth case, including non-trial training period; i.e. after 1st case, 5th, 10th, 15th etc.), and clinician-reported questionnaires.

Trial organisation, oversight and monitoring

The trial Sponsor is the Golden Jubilee University National Hospital (GJUNH; NHS Golden Jubilee, Clydebank, UK), with collaborative research support provided by the University of St Andrews, and delivered by the Trial Management Group (TMG): Professor Jon Clarke (Chief Investigator [CI]), Dr Nick Clement (Co-CI), Dr Andrew Hall (Deputy CI), Professor Christopher Gee (Sponsor Principal Investigator [PI]), Mr Nick Ohly (Surgical Lead), Mr Nick Holloway (Data Management Lead), Mr Scott Morrison (Research Operations Lead), and Dr Swati Chopra (Research Operations Support). Additional recruiting centres may be added and PIs for additional study centres will be confirmed on joining the

study. The Sponsor will be responsible for ensuring appropriate trial governance and oversight throughout the study.

Oversight of the trial will be provided by an independent Trial Steering Committee (TSC) which will include a chair independent of the trial centre(s), a clinician with relevant orthopaedic expertise, independent statistical expertise, and PPI representation where feasible. The CI and relevant members of the trial management group may attend TSC meetings in a non-independent capacity. The TSC will review trial conduct, recruitment, retention, protocol adherence, intervention fidelity, safety reporting, internal pilot progression criteria, and any proposed substantial amendments. The TSC will meet before or shortly after trial initiation, at the conclusion of the internal pilot, and thereafter at intervals determined by trial progress and risk, with additional meetings convened if required for safety or governance reasons.

Trial monitoring will be risk proportionate and performed under Sponsor oversight. This will include central review of recruitment, data completeness, protocol deviations, informed consent documentation, eligibility, randomisation, and adverse event reporting, with on-site or remote monitoring visits undertaken as required. Source data verification will focus on key variables, including informed consent, eligibility, randomisation, the primary outcome, and serious adverse events, with additional verification performed where concerns are identified. Any serious breaches, major protocol deviations, or urgent safety concerns will be escalated promptly to the Chief Investigator, Sponsor, and TSC, and reported to the Research Ethics Committee and other regulatory bodies where required.

A separate Data Monitoring Committee/Data Safety Monitoring Board will not be established because both interventions are established surgical approaches used within routine care, the study is considered low risk, and ongoing safety oversight will be undertaken through Sponsor processes and independent TSC review. Should unexpected safety concerns arise, the Sponsor and TSC may recommend additional independent review.

Ethics and dissemination

The protocol was examined and approved by three independent reviewers with experience of orthopaedic and non-orthopaedic clinical and academic practice (internal and external to the sponsoring institution): Mr Carl Green (Consultant Orthopaedic Surgeon at GJUNH), Professor Ben Shelley (Consultant and Honorary Professor of Anaesthetics at GJUNH and University of Glasgow),

and Professor Brian Devitt (Consultant and Chair of Orthopaedics and Surgical Biomechanics at UPMC Sports Surgery Clinic and Dublin City University).

Independent REC approval was granted following the established NHS Scotland Research & Development Integrated Research Application System (IRAS) process (REC Reference: 26/WS/0020, IRAS Project ID: 364581). Additional approvals were provided by information governance, and operational support services (including procurement, sterilisation, medical physics, and clinical services) at the sponsor institution.

The trial will be conducted in compliance with the principles of Good Clinical Practice (GCP; ISO 14155) and in accordance with the CONSORT 2025 guidelines.[69,97,98] Ethical approval for the study has been obtained from a UK NHS Research Ethics Committee (REC).

Written informed consent will be obtained by appropriately trained research staff or investigators at each participating site before any trial-specific procedures are undertaken. In addition, participants will be asked to provide consent for the use of de-identified individual participant data in future research related to TKA or surgical technology evaluation. Study findings will be disseminated through:

- Peer-reviewed publications;
- Presentations at scientific conferences and other relevant events;
- Public trial registries (a summary of the results following trial completion).

A plain-language summary of the main findings will be made available to participants and the public following publication of the primary results.

Patient and public involvement

Multi-stage Patient and Public Involvement (PPI) has informed the design of this study. An initial scoping review of the existing literature concerning patient and public perceptions of robot-assisted surgical systems in clinical and research orthopaedic settings was conducted according to the PRISMA-ScR guidelines and established best practice.[99–101] The findings of this review were combined with the findings of a further scoping review (conducted to the same research methodology standards) of the existing evidence and knowledge gaps specifically related to the VRAS. These results were correlated with the UK NICE 2025 Early Value Assessment (EVA) document.[62] A provisional study protocol and

supporting materials were produced based on this examination of the literature and indirect PPI process.

Subsequently, direct PPI was sought through a structured questionnaire that was conducted with consenting patients in arthroplasty outpatient clinic settings at the GJUNH. This evaluated patient perceptions of the research aims; the relative value and justification of the research; the acceptability of the study to prospective participants (including the clinical technique and the research methods); the appropriateness of the proposed patient information sheet (PIS), and if patients would be likely to participate. The study protocol and supporting materials were then reviewed in an open interview format by the PPI group at the GJUNH, which is an established service used for the design and delivery of research in this institution. Final versions of the protocol and PIS were produced.

Safety and adverse events

Both raTKA and conventional mTKA techniques are in routine clinical use within the NHS and internationally. Published literature demonstrates that the use of RAS in general, and the VELYS RAS specifically, do not confer an increased risk of adverse events or complications compared with conventional manual techniques.[6,13,18,102] Accordingly, no additional patient risks are anticipated beyond those inherent to standard TKA surgery. These will be monitored and recorded in accordance with standard NHS practice and institutional policies.[11,17,103,104]

AEs will be categorised as ‘unrelated’ or ‘related’ to the current study according to predetermined definitions. Related AEs include: surgical site infection; arthroplasty failure; related fracture, or any AE occurring during the surgical admission. AEs will be reported in line with Good Clinical Practice (GCP) and Health Research Authority (HRA) requirements, which will be via the NHS DATIX reporting system, and monitored by the TSC.[105] Device-related issues will be escalated through the institutional Medical Physics & Devices pathway and reported to the manufacturer and the Medicines and Healthcare Products Regulatory Agency (MHRA) where applicable. Auditing of trial conduct may be performed by the Sponsor, in accordance with UK research governance frameworks.

The study has undergone independent R&D governance approval through institutional review by the Medical Physics & Devices Department, Surgeon Group, Information Governance Team, Procurement and Operating Department. These have supported the view that the study poses no material increase in procedural risk and that all equipment and software comply with existing safety and regulatory frameworks.

Instances of injury or ill health that are unrelated or indirectly related to the study (such as comorbid conditions, aberrant findings on assessment/investigation, or physical/mental ill health identified through patient-related study data) will be managed as per the standard non-trial practice in the study centres. It is common for people with end-stage OA to report anxiety, depression, and poor quality of life, and this distress is usually anticipated, contextual, and self-limiting.[106] Nevertheless patients will be made aware during the consultation, consent, and data collection stages that they can escalate concerns along a 'distress pathway' that will include the local clinical and research teams (represented by the responsible consultant, a member of the research operations team, and the site PI). The clinical team will facilitate timely clinical assessment and initial management, with onward referral to specialist services if required. The research team will submit a report to the CI who will determine the degree of risk to other participants and act according to the safety monitoring procedure.

Concomitant and post-trial care, compensation and indemnity

All participants will receive standard perioperative and postoperative care according to local institutional practice, including anaesthesia, thromboprophylaxis, analgesia, mobilisation, physiotherapy, and routine follow-up. Concomitant care considered part of usual care is permitted. No additional trial-specific co-interventions are mandated other than the allocated surgical approach and study assessments. Use of alternative robotic systems, non-protocolised experimental surgical technologies, or non-standard implants or constraint not anticipated by the protocol will not be permitted unless clinically required in the interests of patient safety. Any such deviations and the reasons for them will be documented.

Participants will continue to receive standard NHS care following their involvement in the study. No additional or special post-trial care is required. The Sponsor will maintain appropriate indemnity arrangements for the conduct of the study in accordance with applicable NHS and institutional requirements. Participants who suffer harm arising from trial participation will receive appropriate clinical care and may have access to compensation or indemnity arrangements in line with Sponsor and NHS policies relating to institutional insurance and NHS indemnity.

Protocol amendments

Any substantial protocol amendments will require prior approval by the REC and the Sponsor. All approved amendments will be communicated to participating sites, investigators, and trial registries.

Confidentiality

Participant confidentiality will be strictly maintained. Identifiable data will be stored in secure NHS systems, accessible only to authorised members of the study team and the Sponsor. De-identified data will be accessible to trial investigators and Sponsor representatives. All data analyses will be performed on de-identified datasets.

Authorship eligibility

Authorship of any publications arising from the study will be determined in accordance with the criteria of the International Committee of Medical Journal Editors (ICMJE) for the manuscripts in question.[107] The Surgical Team and other supporting contributors will be recognised as part of the MARVEL Group.

Protocol and data availability, sharing and public access

The study protocol will be registered through ClinicalTrials.gov trial registration and submitted for publication ahead of recruitment. The final statistical analysis plan will be available on reasonable request from the corresponding author, subject to sponsor approval.

Following publication of the primary trial results, a summary of the trial results will be made available through the public trial registry. De-identified individual participant data underlying the reported results, together with the data dictionary and statistical code required to reproduce the primary analysis, will be considered for sharing with bona fide researchers on reasonable request. Requests must include a methodologically sound proposal and may require evidence of appropriate ethical and institutional approvals and completion of a data sharing agreement. Data will only be shared where this is consistent with participant consent, sponsor requirements, data protection legislation, and institutional information governance procedures. Requests should be directed to Jon.Clarke@gjnh.scot.nhs.uk.

Funding

This is an investigator-initiated study. The design, conduct, data analysis, and publication of the study will remain entirely under the control of the academic investigators. Data will be collected, stored, and analysed independently by the study team. All intellectual property and data generated remain the property of the investigators and the sponsoring institution (GJUNH). Results will be submitted

for peer-reviewed publication regardless of study outcome. Study costs will be funded by DePuy International Ltd (Leeds, UK), the manufacturer of the VELYS robot-assisted system and Attune Total Knee System. The funder has no role in trial design, participant recruitment, surgical decision-making, data collection, statistical analysis, data interpretation, or manuscript preparation.

Conflicts of interest

No payments, honoraria, or personal reimbursements have been received for participation in this trial. Any future relationships arising during the conduct of the study will be transparently declared to the Sponsor, REC, and in all publications.

AJH: No conflict of interest declared.

NDC: Recipient of NIHR & industry-funded research grants (unaffiliated medical devices company).

SRM: No conflict of interest declared.

SC: Involved in industry-funded research (unaffiliated medical devices company).

CWG: Paid educational role (unaffiliated medical devices company).

NEO: Involved in industry-funded research (unaffiliated medical devices company). Paid educational role (unaffiliated medical devices company).

NH: Involved in industry-funded research (unaffiliated medical devices company).

PW: Paid educational role with Johnson & Johnson MedTech.

BMD:

JVC: Industry-funded research (unaffiliated medical devices company).

Trial status

This protocol is version 5.1, dated 01 April 2026. Recruitment is planned to begin on 01 April 2026 and continue until 01 April 2029. Follow-up for the primary endpoint will continue to six months post-operatively, with final 12-month follow-up thereafter. Trial registration on ClinicalTrials.gov is pending and will be completed before enrolment of the first participant.

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Table 1. Participant timeline: schedule of enrolment, interventions, and assessments.

	ENROLMENT			POST-RANDOMIZATION				CLOSE-OUT
	Initial Identification	**Preoperative Clinic**	**Randomised to Group**	**Surgery**	**6w Assessment**	**6m Assessment**	**12m Assessment**	**Trial End**
Timepoint	$-t_i$	$-t_i$	$-t_i$	t_i	t_1	t_2	t_3	t_p
Time (tolerance)	*-6 weeks (±2)*	*-6 weeks (±2)*	*-6 weeks (±2)*	*0 weeks*	*+6 weeks (±2)*	*+26 weeks (±4)*	*+52 weeks (±4)*	*Post-t_3*
ENROLMENT								
Eligibility screen	x							
Information provision	x							
Confirm participation		x						
Informed consent		x						
Baseline data collection		x						
Randomization			x					
INTERVENTION								
Intervention (raTKA)				x				
Comparator (mTKA)				x				
ASSESSMENTS								
Baseline characteristics		x						
Baseline HKA		x						
Baseline MAL*		x						
Surgical/inpatient data				x				
PROM data		x			x	x	x	
Post-op HKA (6w/6m)						x		
Clinical assessment					x			
Post-op MAL*						x		
Complications / (S)AEs				x	x	x	x	
Health service use data					x	x	x	
CLOSE-OUT								
Data analysis & publication								x
Unblinding								x

EQ-5D-5L, EuroQol EQ-5D-5L; FJS, Forgotten Joint Score; HKA, Hip-Knee-Ankle; MAL, Motion Analysis Laboratory; mTKA, manual TKA; OKS, Oxford Knee Score; PROMs, patient-reported outcome measures; raTKA, robot-assisted TKA; (S)AEs, (serious) adverse events; TKA, total knee arthroplasty.

*Only for patients included in the MAL sub-study.