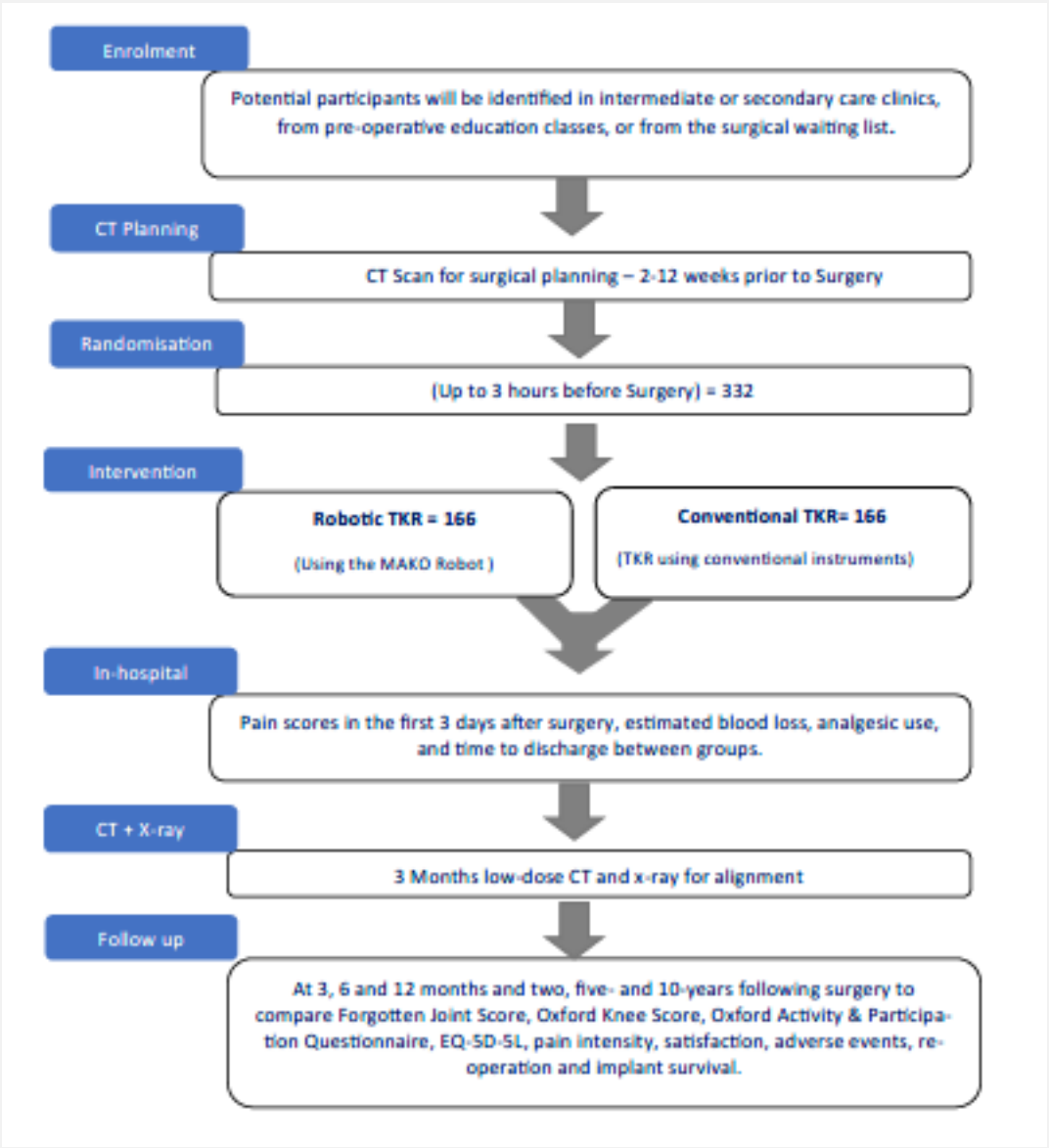
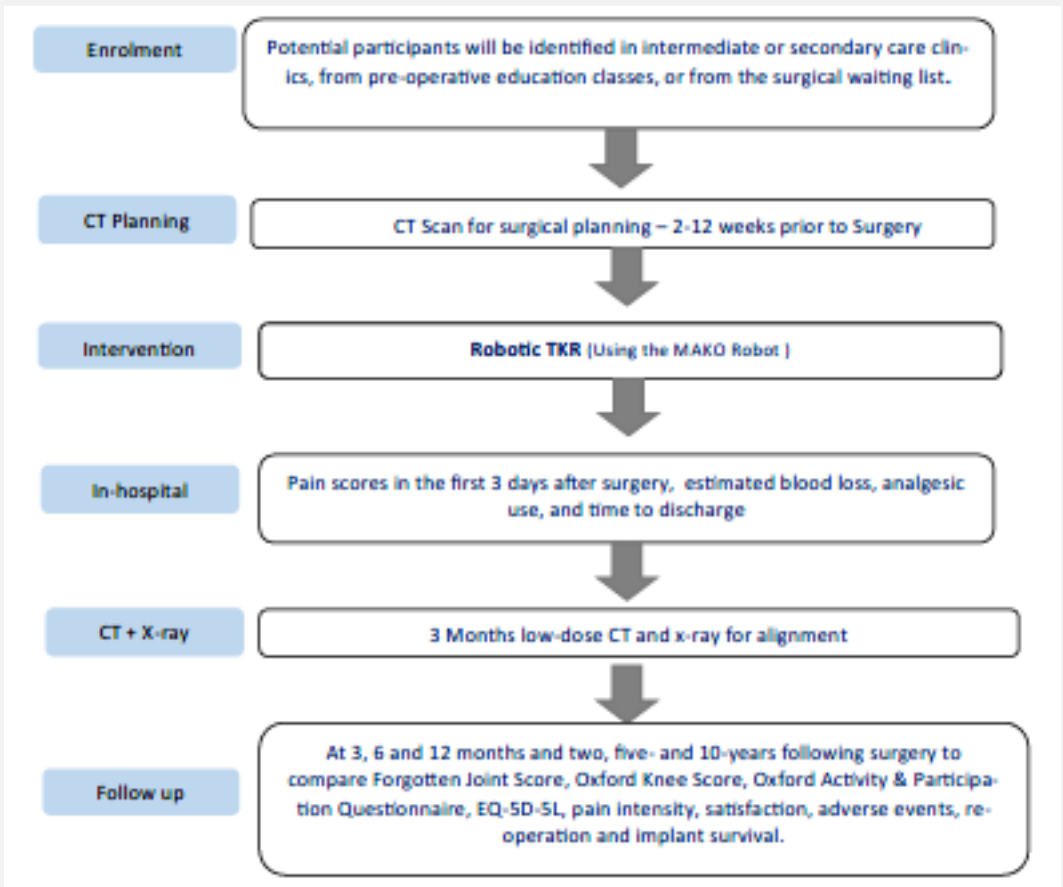
Study Summary Sheet

Robotic Arthroplasty: A Clinical and cost Effectiveness Randomised controlled trial (RACER)

ISRCTN27624068 | IRAS 278357

Study details	Short title**:** RACER Chief Investigator: Mr Andrew Metcalfe and Mr Edward Davis Sponsor: University of Warwick/ University Hospitals Coventry and Warwickshire Trial Management Centre: Warwick Clinical Trials Unit Funder: HTA programme, National Institute for Health Research
Study Overview	RACER is a blinded, multi-centre RCT comparing whether robotic TKR is clinically and cost-effective when compared to TKR using conventional instruments. Our primary objectives are to compare robotic TKR against TKR performed with conventional instruments on the Forgotten Joint Score, 12 months after surgery and to determine the cost-effectiveness of robotic TKR in a UK setting. We aim to compare differences in pain in the first three days after surgery, estimated blood loss, analgesic use, and time to discharge between groups. We will also compare the Forgotten Joint Score, Oxford Knee Score, Oxford Activity & Participation Questionnaire, EQ-5D-5L, pain intensity, satisfaction, adverse events, re-operation and implant survival at three, six and 12 months and two, five- and 10-years following surgery
Sample size	332
Approx. No. of sites	7 NHS Sites
Information for sites	• The participant and **all staff** bar the person who randomised the participant (except theatre staff involved in the operation itself) will be blinded to the allocation. • Randomisation will be performed up to 3 hours before surgery using a simple online system available 24-hours a day. Randomisation can be carried out by theatre staff or unblinded research staff. If the latter option is used, sites should ensure that some members of the research team remain blinded. • Consent and Eligibility must be reconfirmed on the day of surgery prior to Randomisation. • Sites will have the option to collect CRFs on paper or to enter onto the trial database by the Research team (Training will be provided for this). • CT Scans must occur after consent has been obtained, ensuring that the participant has had their scan a minimum of 2 weeks prior to surgery and a maximum of 12 weeks prior to surgery – this is for the CT surgical planning required.
Eligibility criteria	**Inclusion criteria:** • **Osteoarthritis of the knee** with pain, disability, and changes on standard of care clinical images (x-rays or MRI according to normal clinical practice) that, in the opinion of the treating clinician, warrants TKR. • **Conservative therapy has been unsuccessful**, as judged by the treating clinician. **Exclusion criteria:** • **Osteoarthritis secondary to inflammatory arthropathy or intra-articular fracture**, as determined by the treating clinician • **Revision surgery or need for complex implants**, or any other implant than a standard Triathlon TKR, as determined by the treating clinician. This includes nickel-free implants as well as those that require a long stem, augments, or custom-made devices. • **Age <18 years**. • **Unfit for TKR**, or surgery is otherwise contra-indicated (for example, concurrent infection). • **Previous randomisation** in the present trial (i.e. other knee). • **Unable to take part in trial processes**, including prisoners or people unable to communicate or complete questionnaires in English, or people unable to give informed consent.

Study Design	RACER MAIN STUDY FLOWCHART 
Learning Effect study	All lead surgeons operating on trial participants will have completed at least 10 cases using the robot system before they enrol a patient into the trial. Surgeons who have not reached this threshold will be expected, during their normal practice, to carry out robotic cases to achieve the ten cases required. In general terms, the procedure for these 'training' cases will follow the normal practice of the Trusts involved when a surgeon is learning a new technique. The pathway is similar to the main RACER study except for the randomisation and follow-up schedule. RACER LEARNING EFFECT STUDY FLOWCHART 
Rehabilitation	A standardised in-patient and out-patient physiotherapy programme for all participants across both arms of the study will be used. A physiotherapy manual and accompanying materials (including a booklet for participants and an exercise band) will be offered to each participant.
Contact Details	For any queries, contact our trial co-ordinating team on: RACER@warwick.ac.uk , Tel: 02476 968 629