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

Trial Number ☐☐☐☐☐

Recruitment Pack

This pack contains the instructions, Case report forms and study procedures for Re-cruitment. If you have any queries please contact the central study team at:

Racer@warwick.ac.uk

STEPS TO REGISTER A PARTCIPANT INTO THE RACER STUDY:

☐ Ensure that the Eligibility Criteria has been assessed by a clinician.

☐ Ensure that Informed Consent have been obtained and appropriately recorded.

AFTER THAT YOU CAN COMPLETE THE REGISTRATION FORM AND USE THE LINK BELOW TO REGISTER THE PARTICIPANT ONLINE

☐ **Registration Form**

Link to Register participant online: https://ctu.warwick.ac.uk/racer

This must be completed in order to obtain the participants Trial Number

NOW THE REQUIRED BASELINE FORMS MUST BE COMPLETED.

☐ **Baseline Form**

☐ **Baseline Questionnaire***

☐ **Participant Contact Details**

*Baseline Questionnaire is a participant completed form, please schedule in the time with the participant to complete this.

After Registration

- **Obtain a surgery date for participant where possible**
- **Book participants first CT Scan for the Planning CT***

* **MUST** be within 3 months of planned date of surgery.

For a printable version of this pack go to: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/current/racer/

This form is to be filled in by the Research Associate/Nurse once informed consent has been obtained

Contact Details

Your Contact Details: **Site Code:** | | | **Participant TNO:** | | | | | |

Title: First Name: Surname:

1st Line of Address :

2nd Line of Address:

Town/City: Postcode:

Telephone: Mobile:

Email: Preferred time of contact:

Please provide details of two people who would be willing to be contacted by the research team if you were to changes address.

1. Is the participant happy to provide up to two additional contacts? **Yes** ☐ **No** ☐

2. Is the participant aware that they should inform these two additional contacts that they have been nominated to do this? **Yes** ☐ **No** ☐

Additional contact 1 :

Title:
First Name:
Surname:
Email:

Telephone
Home:
Work:
Mobile:

Additional contact 2 :

Title:
First Name:
Surname:
Email:

Telephone
Home:
Work:
Mobile:

GP Details:

Doctors Surgery Name:
Address:
Telephone:

Research Associate/Nurse Name (Print): .....

Research Associate/Nurse Signature: .....

Date Completed: d d - m o n - y y y y

Registration Form-Part 1
Eligibility confirmation

1. SITE DETAILS:

Registering Site:

2. CONFIRMATION OF ELIGIBILITY

PATIENT INCLUSION CHECKLIST: *(both answers must be **'YES'** to enter the trial)*	**No**	**Yes**
1. Osteoarthritis of the knee with pain, disability and changes on standard of care clinical images, that, in the opinion of the treating clinician, warrants total knee replacement (TKR)	☐	☐
2. Conservative therapy has been unsuccessful	☐	☐

PATIENT EXCLUSION CHECKLIST: *(all answers must be **'NO'** to enter the trial)*	**No**	**Yes**
3. Osteoarthritis secondary to inflammatory arthropathy or intra-articular fracture	☐	☐
4. Revision surgery or need for complex implants or any other implant than a standard Triathlon TKR	☐	☐
5. Age under 18 years	☐	☐
6. Unfit for TKR, or surgery is otherwise contraindicated	☐	☐
7. Previous randomisation in the present trial i.e. the other knee	☐	☐
8. Unable to take part in trial processes	☐	☐

Name of clinician confirming eligibility: .....

Please ensure that the clinician has recorded that they have confirmed eligibility in the clinic letter or clinical records

Registration Form—Part 2 Informed Consent Confirmation

3.INFORMED CONSENT CONFIRMATION

	No	Yes
1. Has the patient read the current Participant Information Sheet ? (Version……. Date…….)	■	☐
2. Has the patient provided informed consent to take part in the study? (Version……. Date…….)	■	☐
3. Has the patient provided a written and signed consent form?	☐	☐

If ***No***, complete to questions number **4 –7**

If ***Yes***, please confirm date consent was signed by participant d d - m o n - y y y y

4. Has verbal consent been collected remotely? ■ ☐

5. Please confirm date verbal consent was provided d d - m o n - y y y y

6. Has a witness countersigned the consent form? ☐ ☐

Please provide name of witness

7. Date the witness countersigned the consent form d d - m o n - y y y y

8. The patient has consented to receive text messages (not required for study entry) ☐ ☐

9. The patient has agreed for their GP to be contacted (not required for study entry) ☐ ☐

10. Name of the research staff or clinician who signed consent form *Please note, your name must be on the trial delegation log*

11. Date consent form was signed by the research staff or clinician d d - m o n - y y y y

12. Has the patient consent process and eligibility been documented in their medical notes? ■ ☐

TRIAL OFFICE USE:

Received:	Initial:	Checked:	Initial:

Informed Consent Checklist

This should be completed by the person who took consent.

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

	No	Yes
1. Has the patient consented and eligibility been documented in their medical notes?	■	☐
2. The patient has received and read the current version of the Participant Information Sheet (Version…… Date……)	■	☐
3. a. The patient has signed the current consent form (Version…… Date……..)	☐	☐
Date consent form was signed: d d - m o n - y y y y		
3. b. The patient has not signed the current consent form due to verbal consent being obtained - A witness signature is present on the consent form. (Version…… Date……..)	■	☐
4. The patient has consented to receive text messages (not required for study entry)	☐	☐
5. The patient has agreed for their GP to be contacted (not required for study entry)	☐	☐
6. Has the patient consented for the optional data sharing with Stryker Orthopaedics	☐	☐

Please note, your name must be on the trial delegation log

Form Completed by (print name): ……..

Signature: …… **Date signed:** d d - m o n - y y y y

Registration Form-Part 3
Participant details

4. REGISTRATION TYPE:

Is the participant being registered for the: **RACER Main Study** ☐
or
Learning Effects Study ☐

5. PARTICIPANT DETAILS:

1. Participant initials: ☐☐☐

2. Date of birth: d d – m o n – y y y y

3. NHS / CHI Number: ☐☐☐ ☐☐☐ ☐☐☐☐

4. Hospital Number: ☐☐☐☐☐☐☐☐☐☐

5. Sex: ☐ Male ☐ Female

6. What is the name of the consultant in charge of care? _____

7. Which knee is being entered for the study? Left ☐ Right ☐

8. If known, please provide date of planned total knee replacement: d d – m o n – y y y y

Now that you have completed the form you can REGISTER the patient

PARTICIPANT TRIAL NUMBER:

TNO - ☐☐☐☐☐

Form completed by (print name): _____

*(Please note: your name **must** be on the trial delegation log)*

Signature: _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE | *Received:* *Initial:* | *Checked:* *Initial:*

Baseline Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

KNEE HISTORY

1. Which is the affected knee (knee included in the study)? ☐ Left ☐ Right

2. Duration of symptoms in the affected knee (study knee)?
   - ☐ Less than a year
   - ☐ 1-5 years
   - ☐ 6-10 years
   - ☐ More than 10 years

3. Does the participant have a history of knee intra-articular fracture (i.e. fracture into the joint surface?) ☐ No ☐ Yes

   If Yes, please give approx. date of injury m o n – y y y y

4. Has the participant had a knee replacement on the other knee? ☐ No ☐ Yes

5. Has the participant had previous treatment to the affected knee (study knee)?

I. Physiotherapy in the last 12 months ☐ **No** ☐ **Yes**

a) If Yes, is physiotherapy still ongoing? ☐ No ☐ Yes

II. Steroid injection ☐ **No** ☐ **Yes**

a) If Yes, total number of injections in the affected knee ☐☐

b) Date of most recent injection (approx.) m o n – y y y y

III. Previous surgery ☐ **No** ☐ **Yes**

If Yes, was it:

a) Arthroscopy/Meniscal Surgery ☐ No ☐ Yes

No. of procedures: ☐☐

Date of most recent procedure: m o n – y y y y

Baseline Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

KNEE HISTORY

III. Previous surgery (cont.)

If Yes, was it:

b) Anterior Cruciate Ligament reconstruction ☐ No ☐ Yes

No. of procedures: ☐☐

Date of most recent procedure: m o n — y y y y

c) Cartilage Regeneration Surgery ☐ No ☐ Yes

No. of procedures: ☐☐

Date of most recent procedure: m o n — y y y y

d) High tibial osteotomy ☐ No ☐ Yes

No. of procedures: ☐☐

Date of most recent procedure: m o n — y y y y

e) Other, please give details: ☐ No ☐ Yes

Type of procedure: ☐

Date of most recent procedure: m o n — y y y y

MEDICAL IMAGING—available at baseline (copies of previous imaging in an anonymised form will be requested by the trial office)

1. What recent imaging has the participant had of the affected knee?

I. MRI ☐ No ☐ Yes

a) If Yes, please provide most recent date m o n — y y y y

II. X-ray ☐ No ☐ Yes

a) If Yes, please provide most recent date m o n — y y y y

III. CT scan ☐ No ☐ Yes

a) If Yes, please provide most recent date m o n — y y y y

Baseline Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

BACKGROUND INFORMATION

1. Please tick the box closest to the participant's ethnic background. (Tick one box only)

White	☐	Mixed/Multiple Ethnic Groups	☐
Asian/Asian British	☐	Black/African/Caribbean/Black British	☐
Other Ethnic Group	☐		

2. What is the participant's current employment status? (Tick one box only)

Full-time employed	☐	Unpaid work	☐
Part-time employed	☐	Unemployed	☐
Self-employed	☐	Full time student	☐
Retired	☐	Full time carer	☐

3. Does the participant have a history of any of the medical conditions listed below?

(Please tick all that apply)

Myocardial Infarction:		No ☐	Yes ☐
Congestive Heart Failure:		No ☐	Yes ☐
Peripheral Vascular Disease:		No ☐	Yes ☐
Stroke or TIA:		No ☐	Yes ☐
Dementia:		No ☐	Yes ☐
Hemiplegia:		No ☐	Yes ☐
COPD:		No ☐	Yes ☐
Connective Tissue Disease:		No ☐	Yes ☐
Peptic Ulcer Disease:		No ☐	Yes ☐
Liver Disease:		No ☐	Yes ☐
If yes:	Mild:	No ☐	Yes ☐
	Moderate to Severe:	No ☐	Yes ☐

Baseline Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

3. Does the participant have a history of any of the medical conditions listed below? (cont.)

(Please tick all that apply)

Diabetes:		No	☐	Yes	☐
If Yes:	Diet Controlled	No	☐	Yes	☐
	Oral drugs (Tablets)	No	☐	Yes	☐
	Insulin:	No	☐	Yes	☐
Moderate to severe CKD:		No	☐	Yes	☐
Solid Tumour:		No	☐	Yes	☐
If Yes:	Localised	No	☐	Yes	☐
	Metastatic	No	☐	Yes	☐
Leukaemia:		No	☐	Yes	☐
Lymphoma:		No	☐	Yes	☐
AIDS:		No	☐	Yes	☐

4. Does the participant *currently* smoke tobacco products e.g. cigarettes, pipe, cigars?

No ☐ Yes ☐

a) If Yes, how many per week? ☐☐☐

b) And for how many years? ☐☐

5. How many units of alcohol does the participant drink in a normal week? (A **unit** is approximately 1/2 pint of standard strength beer or cider, 1/2 a small 125ml glass of wine or 25ml of standard strength whiskey)

0-7 units ☐ 8-14 units ☐ 15-21 units ☐ More than 21 units ☐

6. Does the participant use a walking aid?

No ☐ Yes ☐

a) If Yes, please detail what walking aid is used:

☐	1 stick	☐	2 crutches
☐	2 sticks	☐	Walking frame
☐	1 crutch	☐	Wheelchair

TRIAL OFFICE | *Received:* *Initial:* | *Checked:* *Initial:*

Baseline Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site code: ☐☐☐

EXAMINATION:

1. Affected knee (study knee) range of motion (measured with a goniometer):

Flexion: ☐☐☐ degrees Extension: ☐☐☐ degrees

COVID-19:

1. Has the participant had any symptoms of COVID-19? No ☐ Yes ☐

If Yes, please tick all that apply: a) A high temperature ☐

b) A new continuous cough ☐

c) A loss or change in sense of smell or taste ☐

2. Has the participant had a positive test for COVID-19? No ☐ Yes ☐

a) If Yes, date sample was taken which returned a positive COVID-19 result

(if multiple, date of most recent positive test) d d – m o n – y y y y

Please note, your name must be on the trial delegation log

Form completed by (print name): ……..

Signature: …….. Date signed: d d – m o n – y y y y

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Participant Trial Number:

Site Code:

Collection Method (Tick):

Telephone In-person Post

Baseline Questionnaire

We would like to know about your: **Right knee** ☐

Left knee ☐

Please answer ALL of these questions with regard to the knee that was treated in the study, this is ticked above

Please read **ALL** the instructions carefully before completing the questionnaire.

Please use **BLACK** or **BLUE PEN** to complete the questionnaire.

Please **DO NOT** sign or add your name to this questionnaire.

Please **CHECK** that **ALL** the questions have been answered after you finish.

Please tell us the date you filled out this questionnaire: d d – m o n – y y y y

Funder acknowledgement:

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SECTION A: KNEE QUESTIONNAIRE

A healthy joint is not something you are aware of in everyday life. However, even the smallest problems can raise one's awareness of a joint. This means that you think of your joint or have your attention drawn to it. The following questions concern how often you are aware of your affected knee joint in everyday life. Please choose the most appropriate answer for each question.

Are you aware of your knee joint...	Never	Almost never	Seldom	Sometimes	Mostly
1. … in bed at night?	☐	☐	☐	☐	☐
2. … when you are sitting on a chair for more than one hour?	☐	☐	☐	☐	☐
3. … when you are walking for more than 15 minutes?	☐	☐	☐	☐	☐
4. … when you are taking a bath/shower?	☐	☐	☐	☐	☐
5. … when you are traveling in a car?	☐	☐	☐	☐	☐
6. … when you are climbing stairs?	☐	☐	☐	☐	☐
7. … when you are walking on uneven ground?	☐	☐	☐	☐	☐
8. … when you are standing up from a low sitting position?	☐	☐	☐	☐	☐
9. … when you are standing for long periods of time?	☐	☐	☐	☐	☐
10. … when you are doing house-work or gardening?	☐	☐	☐	☐	☐
11. … when you are taking a walk/hiking?	☐	☐	☐	☐	☐
12. … when you are doing your favourite sport?	☐	☐	☐	☐	☐

SECTION B: QUALITY OF LIFE

Under each heading, please tick the ONE box that best describes your health TODAY

Mobility

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

Self Care

- I have no problems with washing or dressing myself ☐
- I have slight problems with washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems with washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problem doing my usual activities ☐
- I have a slight problem doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

The best health you can imagine

The worst health you can imagine

- We would like to know how good or bad your health is **TODAY.**
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY.**
- Now, please write the number you marked on the scale in the box below.

PROBLEMS WITH YOUR KNEE

Tick (✓) one box for every question.

1. During the past 4 weeks…

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

2. During the past 4 weeks…

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks…

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks…

For how long have you been able to walk before pain from your knee becomes **severe**? (with or without a stick)

No pain/More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all/pain severe when walking
☐	☐	☐	☐	☐

5. During the past 4 weeks…

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
☐	☐	☐	☐	☐

6. During the past 4 weeks…

Have you been limping when walking, because of your knee?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

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7. During the past 4 weeks…

Could you kneel down and get up again afterwards?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks…

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

9. During the past 4 weeks…

How much has pain from your knee interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

10. During the past 4 weeks…

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

11. During the past 4 weeks…

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

12. During the past 4 weeks…

Could you walk down one flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

Finally, please check back that you have answered each question.
Thank you very much.

ACTIVITY & PARTICIPATION QUESTIONNAIRE

PLEASE TICK (✓) ONE BOX FOR EACH STATEMENT.

Please consider these statements thinking about the past 4 weeks:	Strongly agree	Tend to agree	Neither agree nor disagree	Tend to disagree	Strongly disagree
1. It is a problem for me to do activities (e.g. sports, dancing, walking) **to the level I want, because of my knee.**	☐	☐	☐	☐	☐
2. It is a problem for me to carry heavy things (e.g. items at work, shopping, or a child)**, because of my knee.**	☐	☐	☐	☐	☐
3. I need to modify my work or everyday activities, because of my knee.	☐	☐	☐	☐	☐
4. I need to plan carefully before going out for the day because of my knee (e.g. taking painkillers, using a knee brace or checking that there will be places to sit down)**.**	☐	☐	☐	☐	☐
5. It is a problem for me to fully take part in activities with friends and family, because of my knee.	☐	☐	☐	☐	☐
6. It is a problem for me to walk at the pace I would like, because of my knee.	☐	☐	☐	☐	☐
7. It is a problem for me to twist or turn, as my knee may give way or be painful.	☐	☐	☐	☐	☐
8. It is a problem for me that I need to take longer to do everyday activities, because of my knee.	☐	☐	☐	☐	☐

Finally, please check back that you have answered each question.

Thank you very much.

SECTION E: KNEE PAIN

Please respond to each question by marking one box per row.

During the past 7 days…	Had no pain	Mild	Moderate	Severe	Very severe
1. How intense was your pain at its worst?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. How intense was your average pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	No pain	**Mild**	**Moderate**	**Severe**	**Very severe**
3. What is your level of pain right now?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

SECTION F: OTHER PAIN

For each question, think about your pain **in the last month.**

Please **circle one number** for each question.

1. Have you had pain in your *left* knee?

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

2. Have you had pain in your *right* knee?

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

3. Have you had pain in your *left hip*?

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

4. Have you had pain in your *right hip*?

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

5. Have you had pain in your back or your spine?

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

6. Have you had pain elsewhere in your lower limbs? Please give details of the location of the pain in the box below i.e. ankles

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain

SECTION G: PAINKILLERS AND ANALGESIA

1. Are you taking any pain-killers or analgesia medicine for your knee? Yes ☐ No ☐

If **yes**, please tell us which drugs you are taking, the dose, and the approximate number of times you take that dose each day. If you do not know exactly, please give us your best guess on average, over the last week.

Please use **Table 1.** to record all **pain killer TABLETS, pain killer PATCHES and/or pain killer LIQUID medications** that you have taken **regularly over the last week.** Regular medication means you are taking the same dose every day.

Examples are given in the table.

Table 1: Pain killer tablets, patches and/or liquids that you have taken over the past week

Name of medication	Strength of medication	How many taken?	Taken how often?
Example: Paracetamol	*500mg*	*2 tablets*	*Four times per day*
Example: Fentanyl patch	*75mcg*	*1 patch*	*Every three days*
Example: Oramorph	*10mg/5ml*	*1 dose*	*Every four hours*

SECTION H: COVID-19

The COVID-19 pandemic has affected many people worldwide and we would like to know how many have been affected in this trial:

A. Do you think you have had COVID-19? ☐ No ☐ Yes

B. If **YES**, and you think you have had COVID-19, was this confirmed with a test? ☐ No ☐ Yes

SECTION I: MOBILE APP

Would you like to complete your future follow-up questionnaires using a mobile app? ☐ No ☐ Yes

Thank you for completing this questionnaire.