Community Based Rehabilitation after Knee Arthroplasty (CORKA) Trial

Research Clinician Manual

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CORKA Project Team

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Chapter 1: Overview of the CORKA trial

The COmmunity based Rehabilitation after Knee Arthroplasty (CORKA) trial was developed in response to a commissioned call by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme for research into a functional home based rehabilitation programme for patients who may be at risk of poor outcome after knee arthroplasty. The team developing the intervention included physiotherapists, medical consultants and health researchers.

The HTA provided specific direction to researchers in a number of areas e.g.; about relevant outcomes and this is reflected in the overall design of the project. The study also went through an extensive peer review process before being commissioned and has been adapted in response to feedback.

1.1 Aims of the study

There are a variety of physiotherapy interventions that have been trialled following knee arthroplasty. Currently little is known about the effects of a targeted home based functional rehabilitation programme for patients who may be at risk of poor outcome.

The primary objective for the CORKA trial is:

To compare patient reported functional and quality of life outcomes of the new CORKA rehabilitation protocol versus usual care and rehabilitation following knee arthroplasty surgery.

The secondary objectives for the CORKA trial are:

- To assess the safety and serious adverse events associated with the new treatment programme.
- To assess the acceptability and adherence to the treatment programme for patients and therapists through both a RCT and a nested qualitative study.
- To assess the cost effectiveness of the different treatment strategies.

1.2 Study design

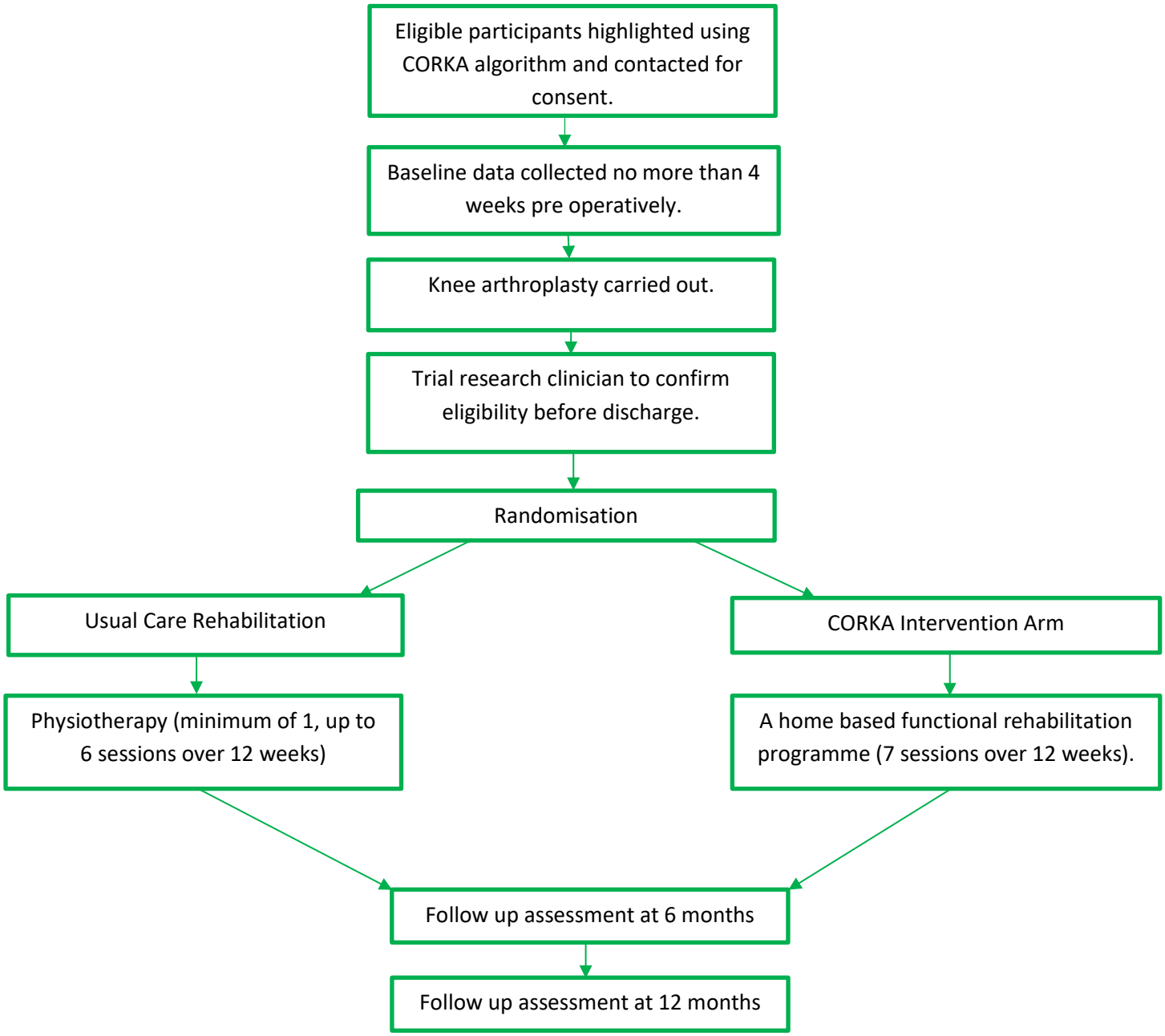
CORKA is a prospective individually randomised controlled trial with blinded outcome assessment at baseline, 6 and 12 months. Patients who are having a knee arthroplasty and are highlighted to be at risk of poor outcome by a screening algorithm specifically developed for the trial will take part to determine if the CORKA rehabilitation programme is better than current usual care. It will recruit up to 600 participants. The study will also include a qualitative assessment to determine what makes the intervention acceptable to patients and a health economic analysis.

During the trial people undergoing knee replacement will be screened for suitability in two phases; primarily during their pre-operative assessment (See Appendix 1) and secondarily post-operatively to ensure they remain suitable to participate. Eligible people that consent to participate pre-operatively (See Appendix 2) will undergo the first part of a baseline assessment (See Appendix 3) with a Trial Research Clinician (TRC). The first assessment will occur no more than 4 weeks before surgery at the participant's home. Following surgery participants will again be screened to check they remain suitable to participate in the trial using part D of the baseline case report form (CRF). Eligible people that confirm they are willing to participate will be enrolled on the trial by the TRC and the baseline assessment will be completed. An unblinded staff member will randomise the participant using either the website provided by the OCTRU randomisation service. Participants will be allocated to receive one of two rehabilitation options, either 'usual care rehabilitation' or the novel 'CORKA intervention arm'. An unblinded clinician will ensure that the referral and information about group allocation is passed to the treating therapist. Participants and those delivering rehabilitation will be aware of the treatment allocation due to the nature of the intervention.

Those in the usual care arm will receive a minimum of one and a maximum of 6 sessions of physiotherapy. Those in the intervention arm will receive 7 sessions of the home-based functional rehabilitation programme over 12 weeks. The first session will last up to 60 minutes, with subsequent sessions of 30 minutes. Follow-up clinical assessments will be performed by the TRC who will be unaware of group allocation at 6 and 12 months (See

Appendix 4). Figure 1 below gives an overview of the flow of participants through the trial together with the timing of assessment procedures.

1.3 Flow of participants through the trial



1.4 Eligible Participants

People scheduled to undergo knee arthroplasty who are assessed at risk of a poor outcome will be screened to see if they are suitable to take part in this trial and must meet the following criteria.

1.4.1 Inclusion criteria

The inclusion criteria are as follows:

- The person is willing and able to give informed consent for participation in the study.
- Male or Female, aged 55 years or above.
- Primary unilateral knee arthroplasty surgery as a scheduled procedure.
- Deemed by CORKA study screening tool to be at risk of poor outcome.
- Willing to allow the rehabilitation team to attend their home to deliver the CORKA intervention arm if randomised to the intervention arm.

1.4.2 Exclusion criteria

The participant may not enter the study if ANY of the following apply:

- Unable to take part safely in a supervised programme of rehabilitation and exercise due to severe cardiovascular or pulmonary disease (New York Heart Association III-IV).
- Severe dementia assessed using local hospital dementia screening tool.
- Rheumatoid arthritis
- Further lower limb arthroplasty surgery is planned within 12 months.

1.5 Outcome measures

1.5.1 Primary outcome measure

The primary outcome measure will be the Late Life Function and Disability Instrument (LLFDI) score (See appendix 5). The score will be used at baseline assessment as well as 6 and 12 months post-surgery. This self-reported questionnaire comprises of a 16-item disability component and a 32-item function component. This is an outcome instrument developed specifically for community-dwelling older adults, which assesses and responds to meaningful change in two distinct outcomes: function - a person's ability to do discrete actions or activities, and disability - a person's performance of socially defined life tasks (Jette 2002, Haley 2002).

1.5.2 Secondary outcome measures

Information about relevant physical characteristics will be collected at baseline. The Functional Co-morbidities Index questionnaire (See Appendix 5) will also be administered as other diseases are likely to be present in this older population which might affect physical outcomes. Other outcomes listed below include measures of knee pain, balance, lower limb strength, quality of life, mobility and physical activity. These are all areas affected by osteoarthritis in the knee joint. Each test is reliable and valid, has been used with older, community dwelling adults and is shown to be responsive in previous rehabilitation studies

- Oxford Knee Score - A disease specific measure to assess function and to allow comparison with data from large epidemiological cohort studies. It is a 12 item patient reported outcome measure, designed to measure pain and function after total knee replacement surgery (Murray 2007) (See Appendix 5).
- Physical Activity Scale for the Elderly (PASE) questionnaire - This assesses activity in the past week (See Appendix 5).

- EQ-5D - This generic measure of HRQoL and will be used to assist comparison with other conditions and assessment of health economics (EuroQoL Group 1990) (See Appendix 5).

- Figure of 8 Walking Test- designed to assess and compare straight path and curved path walking skills, and also to assess motor planning in gait (See Appendix 10).
- Chair Rise Test – used to assess lower body strength and endurance (See Appendix 11).
- Single Leg Stance Test – designed to assess postural stability and balance. Single leg stance time correlates well with risk of falls (See Appendix 12).
- Health Resource Diary to record the use of healthcare including visits to a GP, consultant, use of complimentry medicine or other therapy, as well as monitoring use of aids, analgaesia, and any adverse events.

Chapter 2: Research Clinician Responsibilities

As a research clinician, you will be responsible to the Principal Investigator at your site and ultimately the Chief Investigator (Dr Karen Barker). Should you encounter any difficulties you should discuss them with one of the CORKA trial management team at the OCTRU. See page 2 for a list of contacts.

For the duration of the CORKA trial you will be responsible for the following:

1. Stock control of trial materials e.g.; Patient information sheets and diaries, small equipment.

   OCTRU will supply all the necessary trial materials but you must ensure that there are adequate numbers of patient information sheets (PIS) and diaries located in appropriate clinical areas and inform the trial office if further are needed.

2. Collection of data from medical records.
   Patient data from medical records may be located in several forms depending on local systems. i.e.; you may have to liaise with pre-admission clinic and ward staff for the best method of collecting the data for entry into trial CRFs.

3. Screening and Recruitment.
   This involves identifying and screening patients for eligibility onto the CORKA trial, consenting suitable patients and confirming eligibility prior to enrolment.

4. Conducting CORKA research appointments.
   The TRC will need to arrange and carry out a baseline assessment at either the participant's home or local research facility and carry out assessments at both 6 and 12 months again at the patients preferred location. Guidelines for conducting the research assessments can be found in chapter 4: Outcome Measures Assessment Guide.

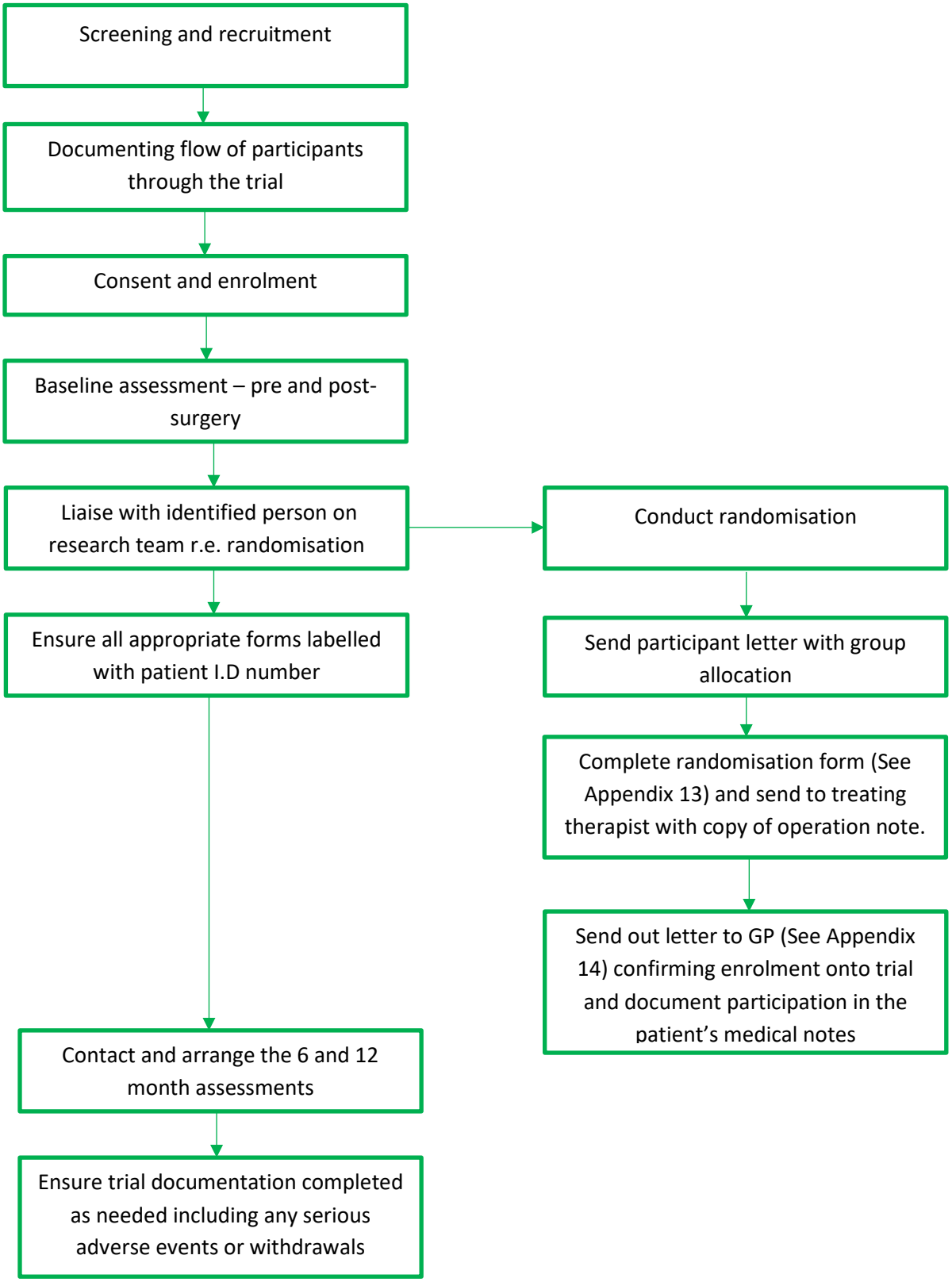
   You must ensure the safe storage of any trial materials and equipment needed for the research assessments and also return all completed assessment paperwork to

OCTRU. Assessments need to be carried out at the time points set in the protocol, if this is not possible e.g.; the patient is away on holiday, then this deviation and the reason for it needs to be recorded in the participant's CRF.

5. Dealing with withdrawals, complaints or adverse events.
   You are not expected to deal with major problems that occur as a result of the study; however you are expected to communicate any problems to the trial team at OCTRU in an efficient and timely manner, using appropriate trial forms and paperwork.

6. Helping to maintain trial site files.
   As part of Good Clinical Practice guidelines, the Chief Investigator is responsible for maintaining the trial site file, which contains information about the trial e.g.; Protocol, ethics and site approvals, delegation log and safety information. You may be asked to perform this role on behalf of the Chief Investigator and must ensure any amendments are completed as needed. You also need to maintain other trial documentation including screening logs, signed consent forms and CRFs. In addition to this, the trial site file delegation log should be completed and signed showing each clinicians role within the trial. To ensure as the TRC you do not become unblinded to the participant's treatment group, the enrolment logs should be completed by a second research clinician (named in the trial site file) and filed in a separate folder.

2.1 Flowchart of the Trial Research Clinicians role



Chapter 3: Screening and Recruitment

Patients attending pre-operative assessment clinic or pre-operative appointments with a consultant, nurse or physiotherapist can be screened by the TRC. This can be done in clinic or if the patient is missed in clinic by telephone. Those who are identified as being eligible for the trial will be provided with information (See Appendix 15) and given the opportunity to ask questions either in person or by telephone. A baseline assessment appointment and informed consent will be sought for those who remain eligible and willing to participate. All participants will need to provide informed consent before being enrolled; their willingness to continue with the trial and their suitability for the trial will be confirmed post-operatively.

3.1 Introducing the study to patient

Our ethical framework insists that all patients are able to give consent which is fully informed.

Therefore, before consent is sought it is important to provide sufficient information and opportunities to ask questions to allow a person to understand fully what taking part in the trial will involve. This may be by person or by telephone.

Once the person has been screened as eligible with the CORKA screening tool (See Appendix 16) provide the patient with a Patient Invitation letter (See Appendix 17), PIS and reply slip (See Appendix 18). Allow the patient a week to read through the information and return the reply form. After this time, if they have replied and are willing to participate or have failed to reply you should contact the patient by telephone using the telephone screening script (See Appendix 19). If the patient is not willing to participate this should be documented in the trial screening log (See Appendix 20).

The study eligibility checklist can then be completed over the telephone, allowing time to ask any questions. You should also provide a clear verbal explanation of the trial, including:

- Introducing the CORKA trial, explaining the study aims
- Describe what taking part will involve including:
    - The study assessment and follow up process (Baseline, 6 and 12 months).
    - That information will be collected from medical records.

- The randomisation process into one of two trial arms. The participant needs to be happy to receive either of the treatments.
- A letter will be sent informing the participant which treatment they will receive.
- If randomised into the CORKA intervention arm, the rehabilitation team will need to attend their home to deliver the home based rehabilitation programme.
- Length of the CORKA intervention (7 sessions over a period of 12 weeks).
- That if they are in the usual care arm they will receive usual therapy for that site

- If appropriate, making patients aware that they may claim back travel expenses for assessment appointments on production of a valid receipt.
- Informing the patient they are free to withdraw from the study at any stage, without having to give a reason.
- Asking the participant if he/she has any questions about the CORKA trial.

3.2 Screening documentation

As the TRC you must ensure all necessary documentation is completed during the screening process. This includes the CORKA screening tool form, baseline eligibility checklist and trial screening log.

As part of good research practice a register of all patients approached about the study needs to be maintained. Whenever you locate a potential participant from a clinic list or are referred a potential participant these patients need to be recorded in the trial screening log. You will need to record the screening number and date screened, patients initials, Date of Birth, eligibility, if not eligible a reason why, appointment for baseline assessment and any further comments.

3.3 Booking a baseline assessment appointment

If the patient appears to be eligible, has received an information sheet and had the trial explained to them, then a research clinic appointment can be booked.

Negotiate a mutually convenient time to see the patient taking into consideration the randomisation office opening times (9am to 5pm) and date of their surgery. Discuss with the patient a convenient place to carry out the assessment, either at their home or in an outpatient therapy department. If you are carrying out the assessment in the patient's home, ensure you have read and followed your local lone working policy.

Ensure the patient knows where and when their research clinic appointment is. Post or provide the standardised letter confirming their appointment. If they are attending an appointment in an outpatient setting prompt them to bring any glasses should they need them to complete the questionnaires.

Finally ensure the screening log is complete and that a research appointment has been made for no more than 4 weeks pre-operatively.

3.4 Confirming eligibility post-operatively

Following surgery and before discharge from hospital the TRC needs to confirm the participant's eligibility for the trial and that they continue to be willing to participate. This is done by completing the pre-discharge screening checklist and completing part D of the CRF. If the participant remains eligible then they should be enrolled on the trial. All their study information should be passed onto the second research clinician to contact OCTRU and carry out randomisation. Following surgery if a potential participant no longer meets all the eligibility criteria e.g.; has a post-operative complication that means they can no longer take part in the trial, this should be documented on the trial screening log and partially completed CRFs destroyed in line with site policies.

Chapter 4: Outcome Measures Assessment Guide

4.1 Equipment list

Test	Equipment required
Chair rise test	➢ Standard height 17" seat height chair ➢ Stopwatch
Figure of 8 walking test	➢ 2 cones ➢ Tape measure ➢ Stopwatch ➢ Step counter
Single leg stance test	➢ Stop watch ➢ Chair/Supporting surface
Equipment required to take to participants home	➢ Pen – black ➢ Clipboard ➢ Stadiometer ➢ Calibrated weighing scales

4.2 Pre-operative assessment

During this initial baseline assessment information will be collected about the participant's height, weight, age, current mobility and physical function using parts A, B and C of the CRF. This needs to be completed no more than four weeks before the operation date to ensure accurate up to date data about an individual's pre-operative status is used to evaluate the effect of interventions. A self-reported questionnaire pack will need to be completed. At baseline this will include the Functional Co-morbidities index as other diseases are likely to be present in this older population which might affect physical outcomes. Refer to the table below as a guide to completing the questionnaires and outcome measures according to the assessment protocol.

Table 1: Outcome Measures

Outcome assessment	**Time line**		
	Baseline	6 months	12 months
LLFDI	✓	✓	✓
Functional Comorbidities Index	✓		
Oxford Knee Score	✓	✓	✓
PASE	✓	✓	✓
EQ-5D	✓	✓	✓
Physical Tests	✓	✓	✓
Adverse Events/ Complications	✓	✓	✓
Health Resource Diary		✓	✓

4.3 Post-operative assessment

Before discharge the post-operative screening should be completed by the TRC to ensure the patient is still eligible for the study using part D of the CRF. Providing the participant meets the eligibility criteria the TRC can then complete the following sections in part D showing post-operative function and surgery details, including a copy of the operation note where possible. You will also provide them with their first participant health resource diary.

The TRC must remain blinded to the participant's treatment allocation. To allow this to be possible the participant's randomisation information will be handed over to a second research clinician. This research clinician will use the website provided by OCTRU to randomise the participant https://rramp.octru.ox.ac.uk/ this will allocate the participant to a treatment group and provide a study identification number. The designated research clinician will then complete the randomisation form and pass it onto the appropriate treating clinician or administration staff along with a copy of the operation note collected before discharge. They must also inform the TRC of the participants assigned study number so it can be added to all relevant paperwork. An appointment can then be arranged to provide the participant's intended treatment allocation (usual care or CORKA intervention arm).

4.4 Month 6 and 12 Outcome Assessment

At this stage in the trial the blinded TRC will carry out an assessment using the 6 and 12 month case report form and measure pack. The functional co-morbidities index will not be administered at this time but all other measures are collected: see Table 1. At 6 months the participant health resource diary will need to be re-issued by the TRC. Additionally at both the 6 and 12 month assessment the TRC must collect the completed participant health resource diary that was previously issued. The completed health resource diaries can be posted to **CORKA Trial Office, Room 101, Botnar Research Centre, Old Road, Oxford, OX3 7LD.** If they forget to bring it please remind them to bring it along to their next visit or post it to the above address.

The following outcome measures will be conducted at baseline, 6 and 12 month assessments.

i. Height and Weight

All participants will have their height and weight measured (See Appendix 21) to allow calculation of their Body mass Index (BMI).
Height is measured in centimetres using a stadiometer. This is placed against a wall and the participant is then shown how the movable plastic plate lowers until it gently touches the top of their head. They are then asked to remove their shoes and stand upright on the stadiometer base, facing away from the wall and the plastic plate is lowered slowly to touch the top of their head. The height measurement is read from the ruler on the upright and recorded in centimetres on the CRF.

Height: | | | | . | | cm

Weight is measured on a set of calibrated scales. Each participant is asked to remove their shoes; they are fully clothed though they are asked to remove coats and jackets. They step onto the weighing scales. They then stand still whilst their weight is recorded in kilograms and recorded on the CRF.

Weight (kg): | | | | . | | kgs

ii. Chair rise test

The chair rise test is designed to test lower body strength and dynamic balance. To conduct the test, carry out the following:

1. Set out a straight back chair on a flat surface ensuring there is enough room for the participant to undertake the test safely. If possible set the chair against a wall to prevent the chair sliding backwards.

2. Explain the measure:

"I want to see how many times you can sit down and stand up again in thirty seconds. I want you to sit in the middle of the chair and place your hands on the opposite shoulder crossed at the wrist. Keep your feet flat on the floor, your back straight and your arms against your chest. On "Go" rise to a full standing position and then sit back down again. Continue this for 30 seconds. Please watch whilst I demonstrate"

3. On **"Go"** begin the stopwatch.
4. The assessor records in the table provided how many sit to stands the participant is able to carry out in thirty seconds.
5. If the participant is unable to rise without support allow them to use their hands or mobility aid. Score this as an adapted test score (See table 2).
6. If the participant is over halfway to a standing position when the 30 seconds have elapsed, count it as a stand.
7. If the participant is unable to stand with support mark the appropriate box in the adaptations column and score a zero.

N.B. The same chair should be used for re-testing within sites

Table 2: Chair rise test scoring table

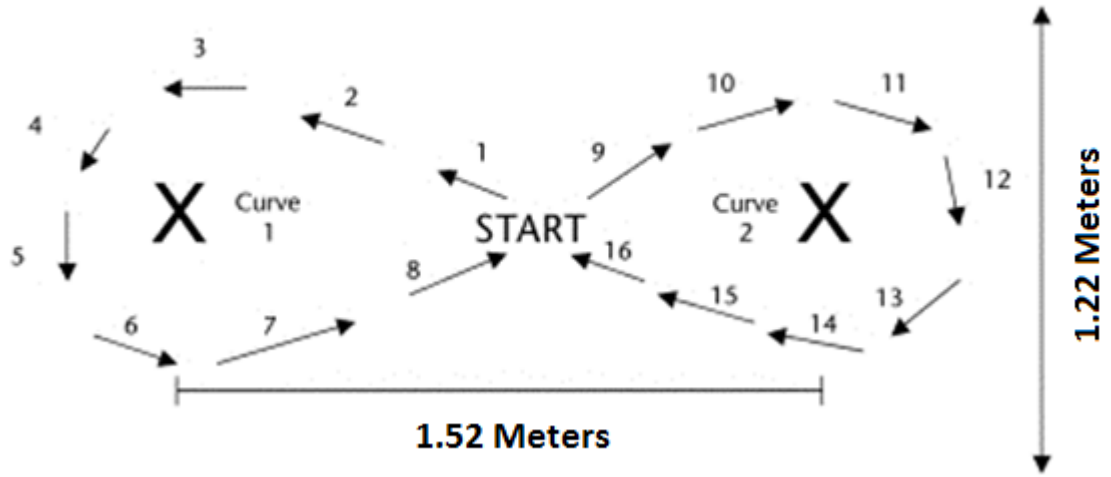
Score (Repetitions in 30 seconds)	Adaptations	Adapted score (Repetitions with adaptions in 30 seconds)
___ ___ stands	Uses hands on legs ☐ Uses walking aid ☐ Not tested - unable ☐ Not tested – refused ☐	___ ___ stands

iii. Figure of 8 Walk Test

The Figure of 8 Walk Test (F8WT) is designed to assess and compare straight path and curved path gait skills, and also to assess motor planning in gait. To conduct the test, carry out the following:

1. Set out two cones 1.52 meters apart from each other ensuring a 0.61m unmarked test boundary is present around the cones. See diagram 1 for the test layout. (Note the relationships of the unmarked testing space e.g. floor markings or landmarks prior to testing.)

Diagram 1: F8WT layout



2. With the participant sitting explain the measure:
   "*We are interested to see if you are able to walk on both straight and curved paths. I want you to stand in between the two cones and then begin walking at your usual pace in a figure of 8 around both cones. You may choose which direction you go and stop when you have returned to your start point. Use your walking aid as needed (if relevant). Please watch whilst I demonstrate"*

3. The stopwatch starts the moment the participant moves their foot in order to take a step.

4. The assessor records how many steps the participant is taking

5. The assessor notes if the participant steps outside the unmarked 2ft surround of the cones.

6. The assessor stops timing when the patient assumes a side-by-side stance of the feet back at the start position. Please record the number of seconds to one decimal place

7. The assessor scores the participant for smoothness using the three item smoothness component scale (See table 3). Mark one point for each of the three items that are successfully completed. If the participant has any difficulty completing an item, score a zero. Higher scores represent better performance.

8. If the participant is unable to complete the test, tick the box on the CRF (as shown below) to indicate they could not carry out the test and leave the table blank.

   Was the participant able to complete the Figure of 8 Walk Test? *Yes* ☐ *No* ☑

Table 3: F8WT scoring table

Time to complete	Number of steps	Did the patient stay within the 2ft surround of the cones?	Smoothness Score (Score each component one point and total)	
__ __ __. __ sec	___ ___ steps	Yes ☐ No ☐	Walk completed without stopping Walk completed without hesitancy (*includes sub movements or extra movements made to adjust position or to complete the curve about a marker*) Walk completed with no changes in pace (*a timing issue or interruption of a consistent pace of stepping for the entire walk pattern*)	☐ ☐ ☐
			Total	***/3***

iv. <u>Single leg Stance test</u>

The single leg stance test looks at postural stability and indicates the participant's falls risk. A single leg stance is required to perform turns, climb stairs and dress so is an important measure of functional ability. To conduct the test, carry out the following:

1. Ensure there is a clear space for the participant to carry out the test.

2. With the participant sitting explain the measure:

   "I want to see how long you are able to stand on one leg with your eyes open. When you're ready I need you to stand here and lift one leg without using any other support. You can choose which leg you wish to stand on. I will time how long you are able to maintain the stance for and stop the timer once you lose your balance. There will be a chair/support beside you should you feel you can no longer keep your balance and require support."

3. Demonstrate to the patient.
4. Ensure you stay within a close distance of the participant whilst they are carrying out the test and place a chair beside the participant for support should they lose their balance.

5. The stopwatch starts the moment the participant's foot leaves the floor.

6. The number of seconds the individual is able to maintain the position is recorded. Please record the seconds to one decimal place, i.e. 8.3 seconds

7. The timer should be stopped if any of the following occur:
    - ❖ The foot touches the support leg
    - ❖ Hopping occurs
    - ❖ The foot touches the floor
    - ❖ The arms touch something for support
    - ❖ If the participant reaches 45 seconds

8. If the participant is unable to carry out the test safely they will score a zero.

9. If the participant cannot complete all three trials, record the time of the completed trial/s in the appropriate box and score a zero for the remaining trial/s.

10. Repeat the test three times for each leg (See table 4).

Table 4: Single leg Stance scoring tables

Standing on **RIGHT** leg

	Trial 1	Trial 2	Trial 3
Time	☐☐ . ☐ Secs	☐☐ . ☐ Secs	☐☐ . ☐ Secs

Standing on **LEFT** leg

	Trial 1	Trial 2	Trial 3
Time	☐☐ . ☐ Secs	☐☐ . ☐ Secs	☐☐ . ☐ Secs

Chapter 5: Self Report Questionnaires Guidelines

Participants should be asked to complete the self-report questionnaire pack at baseline, 6 and 12 month assessments. The TRC must make sure they take time to go through the questionnaire with the patient, double checking that they have completed all questions and asking for further clarification on questions that they have not completed or on statements that they may have added. Once each questionnaire has been checked as indicated, the TRC should complete the tick box.

5.1 Co-morbidity Questionnaire

- Please ensure that participants have circled every section.

5.2 Late life function and disability instrument (LLFDI)

- The LLFDI is a two part questionnaire designed to assess change in either disability or function.
- There are 16 questions relating to disability and 32 relating to function.
- Two visual aids should be issued to the participant whilst filling out the function component of the questionnaire and a further two are to be issued whilst completing the disability component.
- All questions in the LLFDI are scored from 1-5, a higher score indicates less disability and better function.
- For example

How much difficulty do you have....? (Remember this is without the help of someone else and without the use of any assistive walking device.)	None	A little	Some	Quite a lot	Cannot do
F1. Unscrewing the lid off a previously unopened jar without using any devices	5	4	3	2	1

5.3 Oxford Knee Score

- A validated outcome measure focusing specifically on the knee joint, it is marked from 0-4 with 4 being the best outcome.
- A total of 12 questions scored out of 48 with higher scores indicating better knee function.

During the past 4 weeks**.....**

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

None	Very mild	Mild	Moderate	Severe
❑	❑	❑	❑	❑
4	**3**	**2**	**1**	**0**

5.4 EQ5D

Each section of the EQ5D is marked from 1-5, with higher scores representing worse outcomes. Thus for the example below statement one: I have no problems would score 1 and statement five: I am unable to walk about would score 5.

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	❑

5.5 Physical Activity Scale for the Elderly Questionnaire

This questionnaire was designed to measure activity in older adults. Please ensure that participants complete all sections of the questionnaire. PASE scores are calculated from weights and frequency values given for each of the 12 activities. The TRC will not need to calculate the scores.

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER	[1.] SELDOM (1-2 DAYS)	[2.] SOMETIMES (3-4 DAYS)	[3.] OFTEN (5-7 DAYS)
↓ GO TO Q.#3	↓	↓	↓

2a. On average, how many hours per day did you spend walking?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

5.6 Health Resource Diary

A health economic cost utility analysis will be conducted using the EQ-5D-5L and data from participant completed diaries. The diary is designed to collect data about the following:

- Visits to healthcare practitioners and admissions to hospital
- Any unpaid care provided by a relative or friend.
- Medicines
- Aids and Equipment use
- Falls
- Time taken off from employment
- Difficulties encountered following knee surgery (E.g. wound healing)

Please ensure each section is completed and that a diary is reissued at 6 months and collected at both the 6 and 12 month assessments. See Appendix 22 for further details.

Chapter 6 – Screening for serious complications

Serious complications after knee replacement surgery are rare and are highly unlikely to occur as a result of the therapy being evaluated in this trial. However, some serious events may spontaneously occur in this patient group, including deep infection, wound haematoma, periprosthetic fractures, bearing dislocations and deep vein thrombosis or pulmonary embolism. Patients will have been screened at various points in the trial: By an initial 'Eligibility Checklist' In the Pre Admissions Clinic, before discharge from the ward and then by yourself during the therapy assessment.

Patients with serious complications should have been screened out by the assessing therapist. However, if any serious complications do arise during the course of the treatment, they should be referred to their GPs or A&E department as appropriate and the Trial Co-ordinator informed.

6.1 Reporting of Adverse Events for CORKA

The accurate and timely reporting of adverse events is a requirement of Good Clinical Practice.

The Chief Investigator (Dr Karen Barker) is responsible for the reporting of relevant adverse events to the sponsor and producing a report on the safety of participants in annual progress reports.

All staff that have contact with trial participants have a responsibility to note any adverse events mentioned by participants and communicate these to the Principal Investigator via the trial team. This includes Adverse Events/Reactions or Serious Adverse Events/Reactions.

6.1.1 Serious Adverse Events/Reactions

A serious adverse event is any untoward medical occurrence that:

- Results in death,
- Is life-threatening.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Other important medical events*

*Other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgment, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. Any serious adverse event (SAE) occurring to participant/s during the study will be reported to the REC that gave a favourable opinion of the study where in the opinion of the Principal Investigator the event was: 'related' – that is, it resulted from administration of any of the research procedures; and 'unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence. Reports of related and unexpected SAEs will be submitted within 15 days of the Principal Investigator becoming aware of the event, using the NRES report of serious adverse event form.

In addition, the Serious Adverse Events reporting form will be completed, signed and faxed to the CORKA Trial office within one working day of the event. The original of this faxed copy will be filed in the Trial Master File and the event will be recorded in the patient's hospital notes and case report form.
All appropriate follow up reports will be completed, including annual safety reports.

6.1.2 Adverse Events/Reactions

For CORKA it is considered that an adverse event has occurred if a patient reports any of the following: a significant increase in any of their symptoms following treatment which fails to resolve within 1 week following treatment, onset of serious pathology, any complication that results in referral to the GP, or A&E department.

6.1.3 Reporting procedures

Adverse events and serious adverse events, which in the judgment of the Principal Investigator are 'related' and 'unexpected' and directly attributable to the study intervention or study assessments

should be reported if they occur during the time period of: getting to and from a treatment session and during a treatment session. If any directly attributable serious adverse events are identified, the research clinician should: Contact the study co-ordinator David Smith on 01865 237958 and fax the completed Event Notification Form to 01865 738043 or scan and email the form to CORKA@ndorms.ox.ac.uk within one working day of knowledge of the event. If the study co-ordinator is not available please telephone the Chief Investigator Dr Karen Barker on 01865 738080.

6.1.4 Possible scenarios

In order to assist you in deciding whether an adverse event has occurred as well as how to deal with possible situations you may face, the following guide has been developed.

What happens if the patient experiences an increase in pain or swelling?
If the onset was after an exercise session, get them to check if they have overstrained their knee and provide appropriate reassurance. Educate patients that exercises may be uncomfortable to begin with as joints and muscles need to get used to the new joint replacement and being stretched and strengthened. Find out the exercise barriers and address them. Discuss rationale for intervention; '...evidence suggests that doing these exercises will not harm your joints or soft tissues and will improve your strength and function.'

If pain or swelling lasts more than a couple of hours after performing exercises reduce the level of difficult of the exercise or/and number of sets for next session. Encourage them to use the VAS to document their pain and continue with their home programmes if possible. Ensure they are aware of the difference between pain and discomfort due to exercising. Gradually increase the number of repetitions over the next few sessions.

If the pain lasts longer than 1 week, is unproportionate to the level of exercise issued or is present in their calf with increased redness than this is an adverse event. Please advise them to stop all exercises and visit their GP. Fill out the adverse event form and notify the trial study team as mentioned above.

Please note that support and advice is available to all Treating Therapists from the CORKA Trial team at Oxford Clinical Trials Research Unit, CORKA Trial Office, Botnar Research Centre, Old Road, Oxford for any problems or queries you may have regarding the trial.

6.2 Withdrawals

Any request from a participant to withdraw from the study must be respected but encourage the patient to try their best to continue their participation till the end. Assure them of the useful contribution they are making by their participation.

It is important to ascertain if this is a complete withdrawal from the study (i.e. no longer wish any data to be collected or used by the study team) if the participant no longer wishes to take part in the treatment sessions but is happy to be reassessed by the assessing therapist, if the participant no longer wishes to take part in the treatment sessions and requests no further assessments, but is happy for the research team to use data already collected.

All withdrawals should be reported to the Trial team at the Oxford Clinical Trials Research Unit, CORKA Trial Office, Room 101, Botnar Research Centre, Old Road, Oxford, OX3 7LD using the Event Notification Form, with a clear description of the type of withdrawal.

6.3 Complaints

In the unlikely event that a participant, hospital staff member or relative should make a complaint about any aspect of the trial: Contact the Trial team at Oxford Clinical Trials Research Unit, CORKA Trial Office, Botnar Research Centre, Oxford, as soon as possible. Complete the Event Notification Form and fax the form to the Trial co-ordinator on 01865 738043. It is our experience that complaints are rare from trial participants. If a complaint does occur it can usually be dealt with most effectively if the Principal Investigator or Trial Lead contacts the participant, hospital staff member or relative as soon as possible to discuss the problem.

Appendices

1. Pre-operative Eligibility Checklist
2. Main Trial Consent Form
3. Baseline Case Report Form
4. 6-12 Month Case Report Form
5. CORKA Questionnaire Pack V1.0_ 20Feb2015
6. Figure of 8 Walk Test Instructions
7. Chair Rise Test Instructions
8. Single Leg Stance Instructions
9. Randomisation Form
10. GP letter
11. Patient Information Sheet
12. CORKA screening tool
13. Patient invitation letter
14. Participant Reply Slip
15. Telephone Screening Script
16. CORKA screening log
17. Height and Weight Standard Operating Procedure
18. Health Resource Diary

References

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