Community Based Rehabilitation after Knee Arthroplasty (CORKA) Trial

Therapist Manual

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Chapter 1: Introduction

The Community-based Rehabilitation after Knee Arthroplasty (CORKA) trial was set up to investigate the effect of a community based rehabilitation programme on patients that are at risk of a poor outcome after total knee arthroplasty. It compares a community, home based rehabilitation programme with current usual care. It is only possible to evaluate the effect of any treatment if it is delivered in a standard way according to the study protocol. This manual is designed to guide healthcare professionals providing treatment for the trial participants to allow the intervention to be delivered in a standardised, systematic way. It will provide some background information about knee arthroplasty and an overview of the CORKA trial. It includes detailed descriptions of each aspect of the intervention and explanations about what the treating clinicians are expected to do throughout the intervention period.

1.1 Aims of the therapist manual

- To provide general information about osteoarthritis, knee replacement and the study population.

- To provide an overview of the CORKA trial including the flow of participants through the trial and its procedures.

- To provide a procedure and reference that explains what needs to be carried out for both groups in the trial: 'Usual Care' and 'Community Home Based Rehabilitation.'

- To supplement the material and explanations provided during the therapist training sessions.

Chapter 2: Overview of Knee Osteoarthritis and Arthroplasty

Osteoarthritis (OA) refers to a clinical syndrome of joint pain which commonly affects joints of the knee, hip and hands. Opposite to popular belief, OA is not caused by ageing and does not necessarily deteriorate over time (NICE 2014). The pathological changes found with the condition include degeneration of articular cartilage, remodelling of subchondral bone and joint space narrowing: see Figure 1 (Poole 1999). There is some disparity between the clinical and radiographic definitions of the condition due to the variation between radiographic findings and patient reported symptoms. The typical clinical presentation of knee osteoarthritis is an adult over the age of 55 who shows symptoms of knee pain, morning stiffness and joint crepitus (Hochberg et al 1995). For a radiographic diagnosis to be made joint space narrowing, subchondral sclerosis, and osteophyte formation should be identified on x-ray (Peat et al 2001).

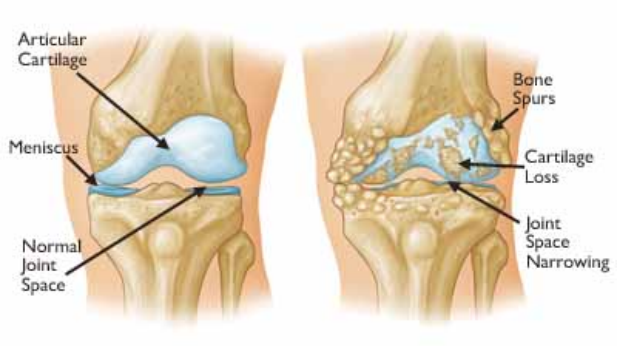


Figure 1: Typical knee joint compared to OA knee joint (AAOS 2014)

2.1 Epidemiology and Aetiology

Osteoarthritis is the most common cause of disability in older people (Martin et al 1988), with painful knee OA affecting 10% of people over 55 in the UK (Peat et al 2001). The causes of the condition are multifactorial with knee OA being classified as either primary or secondary. Primary knee OA is of an idiopathic and insidious onset whereas secondary knee OA results from a previous trauma or a developmental condition which can increase the rate of disease progression (Joern et al 2010).

Various risk factors have been linked with OA and they can be divided into systematic factors, which are linked with the development of OA; and local factors which alter the biomechanical loading within the joint (Garstang and Stitik 2006). Systematic factors include gender and age. Women are

disproportionately affected by OA and the prevalence and incidence of OA increases with age. Local factors can include joint injury, occupation or obesity e.g.; overweight people develop knee OA more often than people who are not overweight (Felson and Zhang 1998).

When a diagnosis of knee OA arises conservative management strategies are applied to help reduce pain and improve functional ability. This includes both non-pharmacological and pharmacological therapies. Non-pharmacological therapy may include patient education with emphasis on self-management of the condition, regular range of motion and strengthening exercises, weight reduction, orthotics or mobility aids and referral to physiotherapy if required. Pharmacological therapies can include non-steroidal anti-inflammatory drugs, analgesics or intra-articular injections of corticosteroids (Zhang et al 2007).

2.2 Knee Arthroplasty

Where conservative techniques are no longer managing the effects of OA, knee replacement surgery can be an option. The number of knee replacements carried out in the UK is continuously rising with over 84,000 replacements being carried out in the UK in 2011, an increase of over 3% from 2010 (Clement et al 2011). Of all knee replacements carried out in the UK between 2003 and 2013, 96% were due to OA with the median age for replacement being 70 years (NJR 2014).

There are two main types of knee replacement surgery; total knee replacement and unicompartmental replacement. Total knee replacement involves firstly the debridement of damaged cartilage and bone. Surgeons will then replace the joint surfaces of the femur and tibia with metal components and insert a plastic spacer in place of the meniscus to allow for smooth gliding of the joint (See Figure 2). The patella may be resurfaced if required. Cement may be used to keep the component parts in place. Alternatively in cement-less knee replacements the components are textured or coated to encourage bone to grow to the replacement giving a natural bond (McCaskie et al 1997).

In contrast if OA has only affected one condyle of the knee joint, a unicompartmental replacement can be carried out. Usually the medial condyle of the knee is affected (Ronn, 2011). A unicompartmental procedure is less complicated than a total knee replacement which potentially can reduce post-operative pain and improve knee function (Liddle et al 2014, Price et al 2001). Through a smaller incision only one of the femoral and tibial condyles are replaced with a metal component and a plastic spacer is inserted (See Figure 2). It is preferable that both cruciate ligaments are left intact for a unicompartmental replacement; however it is possible for this type of replacement to take place even if the anterior cruciate ligament is removed. Studies of outcomes of

participants following knee placement suggest that return to functional activities and reduction in pain levels is much slower for those patients who have total knee replacement compared to unicompartmental knee replacement (Munk et al 2012).

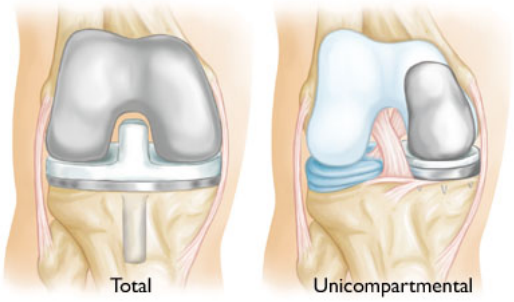


Figure 2: Total KR compared to unicompartmental KR (AAOS 2014)

2.3 Current practice

Pre-operative and inpatient care of knee replacement patients often involves assessments from both occupational therapists and physiotherapists. They aim to ensure the patient is safe for discharge by providing the necessary equipment, exercises and advice. The way that this care is delivered however can vary significantly from site to site.

The rehabilitation offered to patients following knee surgery also varies significantly. A survey of 24 Orthopaedic centres throughout the UK found that around 70% offered routine outpatient physiotherapy in either a group or one to one setting, with the other 30% offering little to no routine physiotherapy. However those centres that did not routinely offer physiotherapy would refer patients onto outpatient physiotherapy sessions if it had been identified that there was a clinical need (Artz et al 2013). This variability between sites can in part be explained by the lack of clear research into the most effective way of providing post-discharge physiotherapy after knee replacement (Minns Lowe et al 2007). Consensus work carried out by the CORKA team from sites across the UK confirmed this variability and found a range in procedures from no routinely organised physiotherapy following discharge to interventions of up to 12 routine sessions of outpatient physiotherapy. From this it is apparent that there is no agreed practice with regards to physiotherapy following knee replacement. Evidence also suggests that the number of sessions given to patients does not necessarily equate to better outcomes and recovery (Mitchell et al 2005).

Little published information is available about the provision of occupational therapy following knee surgery. Consensus work by the CORKA team showed variation in service offered to patients.

However, it was common practice for departments to offer at least one pre or post-operative occupational therapy assessment and where applicable a home visit. Where this is not carried out routinely, those with a clinical need for an assessment are highlighted and would be seen by an occupational therapist for an assessment.

Chapter 3: Overview of the CORKA trial

Outcome following knee replacement is multi-faceted with around 15% of patients reporting a poor outcome with continuing pain and mobility problems (Jones et al 2007). Even those who have good outcomes in terms of pain relief can have persistent problems in terms of gait speed, balance and muscle strength (Westby et al 2008). It is believed that by developing an effective rehabilitation intervention this post-operative return to functional activities may be improved.

In 2007 a systematic review evaluating the effectiveness of exercise supported the use of functional physiotherapy exercise interventions following discharge to obtain short term benefits following elective primary knee arthroplasty (Minns Lowe et al 2007). The exercises carried out within the intervention arm were similar in all studies, often using functional weight bearing exercises or simple strengthening exercises e.g.; sit to stand, walking or static quadriceps exercises. The review found that functional exercise for three to four months postoperatively had a small to moderate effect on functional outcome. There was also a small to moderate effect of functional exercises on quality of life and joint range of movement at three to four months postoperatively. No benefits of such an intervention were found at one year postoperatively. The review revealed the complexity involved in deciding the best rehabilitation after knee replacement (Minns Lowe et al 2007).

Current research has compared a variety of physiotherapy settings including; outpatient, group based and supervised home exercise programmes. They found that setting had little influence on patient recovery with participants reporting similar outcomes (Madsen et al 2013, Ko et al 2013). Patients report being equally satisfied with outpatient and home based physiotherapy interventions, however more would choose to have the intervention delivered in their home (Mitchell et al 2005).

Rehabilitation assistants are often involved in patient care to help facilitate rehabilitation and extend therapists roles. A study evaluating their role found that they could operate at a higher level of reasoning than would be expected for support staff, being able to effectively progress patients, issue mobility aids and provide motivation (Knight et al 2004). Further to this, outcomes from a set rehabilitation programme do not necessarily alter when delivered by either a qualified therapist or rehabilitation assistant. The outcomes from a rehabilitation programme for stroke patients were

analysed when delivered by an assistant and qualified therapist and showed no significant difference between the two (Lincoln et al 1999). Caution is needed as positive outcomes depend on providing adequate supervision and training for assistants (Lizarondo et al 2010). If adequate supervision and training can be provided then rehabilitation assistants can be a useful and cost-effective way to aid in the delivery of rehabilitation programmes.

Literature surrounding occupational therapy following knee replacement is sparse. The studies that do include occupational therapy use it within a package of rehabilitation. This pragmatic approach reflects clinical practice well but makes it difficult to extrapolate occupational therapy's exact contribution. Two studies found that a combined occupational therapy and physiotherapy rehabilitation programme for patients undergoing either a hip or knee replacement reduced hospital stay whilst also improving function (Munin et al 1998, Siggeirsdottir et al 2005).

3.1 Aims and objectives of the CORKA trial

The principle aim of the CORKA study is to assess the effectiveness of a community, home-based rehabilitation programme in comparison to usual care rehabilitation following knee arthroplasty. This will entail:

- *Developing a screening tool to identify those at risk of poor outcome following knee replacement.*
- *Developing an evidence based home based rehabilitation programme for those highlighted at risk that can be delivered easily within the provisions of the NHS.*

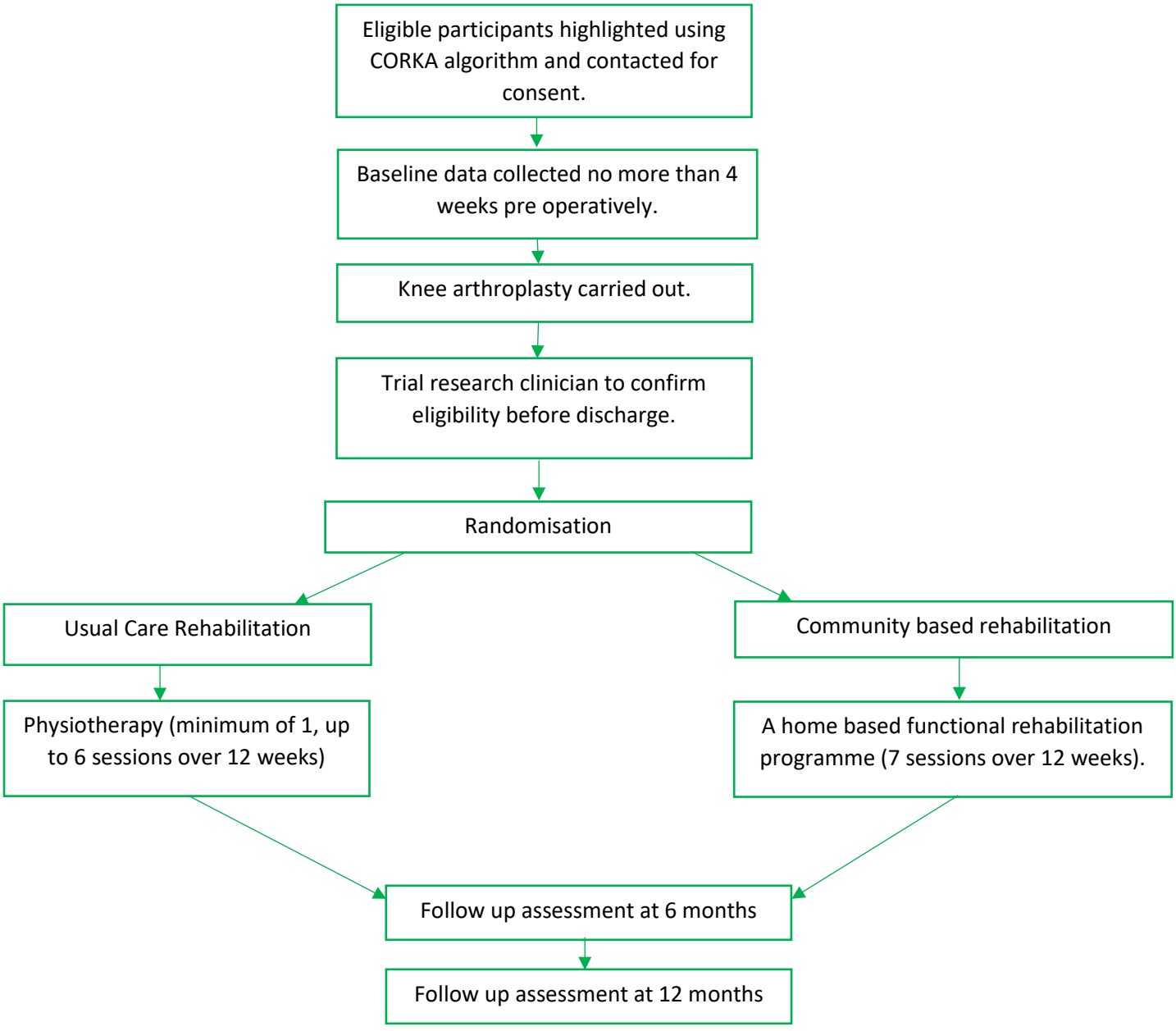
These aims will be achieved using the following objectives:

- *Evaluate the impact of a bespoke home based rehabilitation programme for those indicated at risk.*
- *Assess the acceptability and adherence to the treatment programme for patients and therapists using a randomised controlled trial with a nested qualitative study.*
- *Assess the cost effectiveness of the community based rehabilitation strategy*

3.2 Study Design

The CORKA trial is a prospective individually randomised controlled trial with blinded outcome assessment at baseline, 6 and 12 months. Patients who are having a knee replacement and are highlighted to be at risk of poor outcome by the CORKA screening algorithm will take part to determine if the home based rehabilitation programme is better than current usual care. The study will also include a qualitative assessment to determine what makes the intervention acceptable to patients and a health economic analysis. Figure 3 below gives an overview of the flow of participants through the trial.

Figure 3. Study design with flow of participant



3.3 Eligibility for the CORKA trial

3.3.1 Study participants

People scheduled to undergo knee replacement will be screened to see if they are suitable to take part in the CORKA trial by a trial research clinician (TRC). The TRC will carry out screening using the inclusion and exclusion criteria below and a specific screening tool developed for the CORKA trial that aims to identify people at risk of a poor outcome. The TRC will provide information to potential participants about the trial and obtain informed consent from those who are eligible and willing to participate.

3.3.2 Inclusion criteria

The inclusion criteria are as follows:

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

3.3.3 Exclusion criteria

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

- Severe cardiovascular or pulmonary disease (New York Heart Association III-IV)
- Severe dementia, assessed using their local hospital dementia screening tool
- Rheumatoid arthritis
- Further lower limb arthroplasty surgery planned within 12 months

If participants are eligible for the study the TRC will undertake consenting and carry out a baseline assessment. They will also confirm eligibility post operation, if the participant remains eligible then their details will be handed over to an identified staff member to randomise the participant and to pass their details on to the correct physiotherapist or administration staff for appointments to be made. This is in order to keep the TRC blinded, which is important for the rigour of the trial. The participant and therapist will be aware of the group the subject has been allocated to. It is important

not to reveal this information to the TRC, who will need to undertake follow up assessments without knowing treatment allocation.

3.4 Outcome measures

3.4.1 Primary Outcome

All trial outcome measures will be completed by the trial research clinician.

The primary outcome measure will be the Late Life Function and Disability Instrument (LLFDI) score. The score will be used at baseline assessment as well as 6 and 12 months post-surgery.

3.4.2 Secondary Outcomes

A number of secondary outcome measures will also be used at baseline, 6 and 12 months post randomisation including the:

- Oxford Knee Score
- Physical Activity Scale for the Elderly (PASE) questionnaire.
- EQ-5D
- Functional comorbidities index
- Physical measures including the figure of 8 walking test single leg stance, chair rise
- Health resource diary recording medication taken and use of healthcare services and personnel
- Record of complications or adverse events

Table 1: Outcome measure timeline

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		✓	✓

Chapter 4: Usual care

During the pre-operative and inpatient stage all patients involved in the trial will be assessed and receive the usual level of care as delivered by their local site. This includes input from both occupational therapists and physiotherapists who will assess and equip patients with the necessary advice, exercises and aids to allow for a safe discharge.

Following discharge the current intensity and type of physiotherapy input varies geographically and depends upon the patient's level of function. For the purpose of this trial it is necessary to provide a measure of standardisation to the usual care arm following discharge, whilst also ensuring that patients receive a similar standard of care to that they would have been given had they not taken part in the study, to ensure people are not disadvantaged by participating in the trial and to allow for the results of the trial to be analysed in a meaningful way. Consequently, participants allocated to usual care will all be offered physiotherapy up to a maximum of 6 sessions. Individual centres will follow their normal practice regarding mode of delivery i.e. individual or group, number of sessions and setting.

4.1 Summary of the usual care intervention

The usual care programme will include:

- Pre or post-operative occupational therapy assessment and issue of appropriate aids.
- Written advice on exercises to do at home.
- At least one physiotherapy outpatient session up to a maximum of 6, delivered by a qualified physiotherapist.

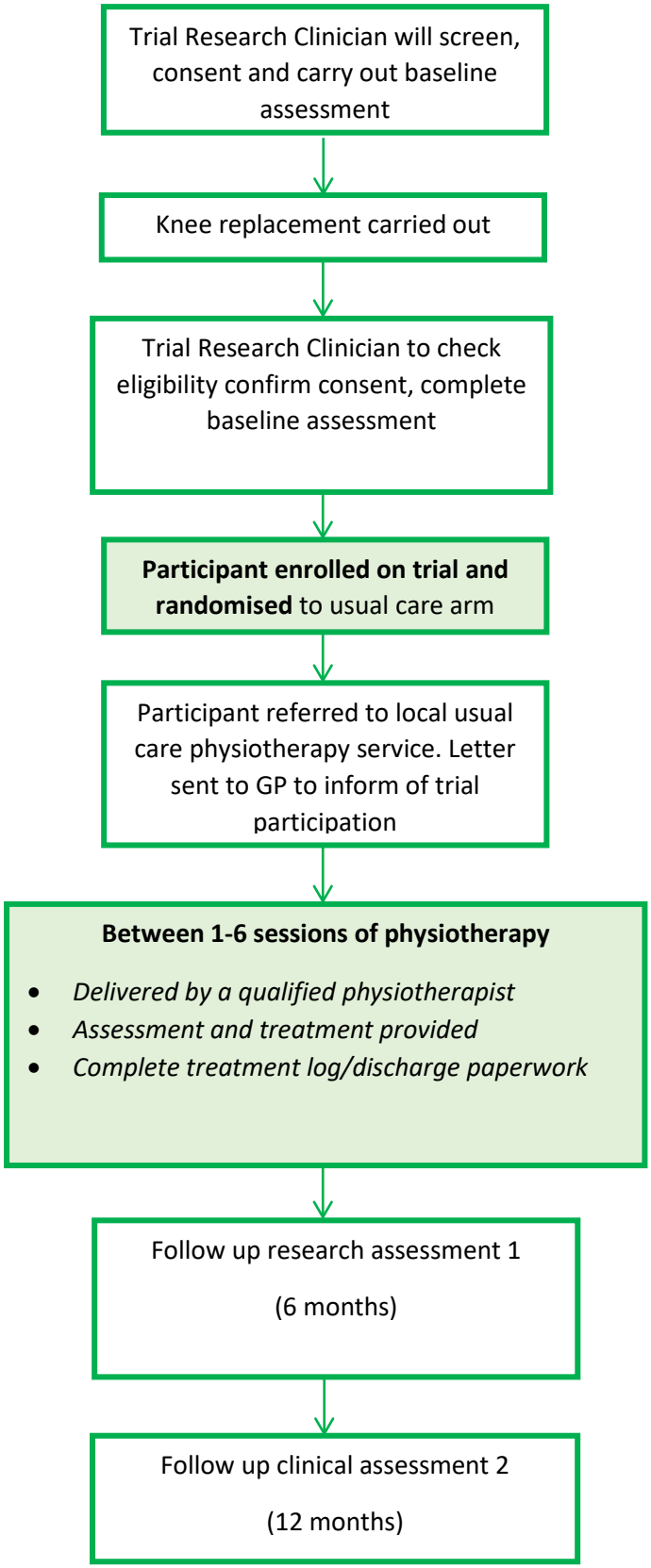
Although the number and setting for the outpatient sessions is specified; the content of each session is not defined so as to allow the physiotherapist to tailor the session to each individual patient's needs. This is a realistic representation of what is currently practised.

4.2 Why is it necessary to 'define' usual care?

A standardised usual care intervention is important to understanding the effects of the novel community based intervention. Physiotherapy after discharge is typically individualised with the amount of sessions required varying from patient to patient. To allow participants allocated to usual care provided by different clinicians and between areas to be grouped together and then compared to the community based intervention it is necessary to deliver a standardised intervention in line with the study protocol.

It is possible that physiotherapists treating patients on the CORKA study are used to offering a more comprehensive usual care treatment or feel that a patient would benefit from additional physiotherapy sessions. It is also quite possible that physiotherapists may find this level of 'usual care' excessive for an individual patient. Offering different or additional physiotherapy from the stated level of 'usual care' in the protocol may compromise the trial, making it difficult to distinguish any additional effects of the community based intervention. In other words if the treatment effects are lost or underestimated this may affect study conclusions and hence the care physiotherapists may provide to future patients following knee arthroplasty. If physiotherapists do have to deviate from the usual care protocol this should be recorded and will be classified as a protocol deviation with additional sessions being included in the final analysis.

Figure 4. Usual care arm: Flow of participants



Chapter 5: Community Based Rehabilitation Intervention

The next two chapters will describe the intervention for the CORKA trial. This chapter will present both a rationale for the components of the intervention, and also for the method of delivering the intervention. The following chapter will provide a detailed bullet point guide of how to deliver each session of the intervention.

5.1 Overview

The intervention is a structured package of rehabilitation with several components including; functional task practice, a graduated walking programme, gait re-education and a home exercise programme which will address range of movement, strength, balance and aerobic fitness. The programme will also consider pain management, confidence building, adherence strategies, the provision of appropriate aids and appliances and the home environment.

5.1.1 Home Exercise Programme

This section will consist of exercises to maintain or increase range of movement at the knee joint. In addition to exercises that aim to increase or maintain quadriceps, hamstring, hip abductor and calf muscle strength and balance exercises. The rationale for each of these components is given below.

5.1.2 Range of Movement

Prior to joint replacement people may have limited range of movement. Steultjens et al (2000) reported that in those with hip or knee osteoarthritis this restricted movement is linked with disability. Movement problems continue to be present following surgery. Stiffness has been reported as a common complication post knee replacement (Su et al 2010) with both loss of flexion and extension (flexion contracture) potential problems (Bhave et al 2005, Stratford et al 2010). It is thought that up to 60% of patients undergoing total knee replacement experience stiffness after surgery (Fitzsimmons et al 2010). Loss of active movement secondary to muscle weakness adds to loss of functional range of movement. This loss of range of movement is problematic as sufficient range of movement at the knee is essential to performing normal activities of daily living. It is suggested that neutral extension of 0 degrees and 110 degrees of flexion will allow normal function for most activities, including walking and standing from sitting (Rowe et al 2000).

A large proportion of any increase in range of movement is likely to take place in the first 12 weeks post-surgery (Stratford et al 2010), making it important to include activities and exercises that target

improving range in post-operative rehabilitation. Previous studies investigating rehabilitation after knee replacement have included range of movement exercises in their interventions (Piva et al 2010, Bade et al 2011, Liao et al 2013). Participants will be asked to practice exercises for both knee flexion and extension to improve both passive and active range of movement e.g.; hamstring stretches, active assisted knee flexion.

5.1.3 Strengthening

It is common for patients to present with strength deficits in the affected limb after knee replacement (Pozzi et al 2013). Stevens et al (2003) reported a decrease in quadriceps strength in those with knee osteoarthritis both prior to and after knee replacement. This decrease in strength can persist long after surgery. Walsh et al (1998) measured peak muscle torque for both knee flexors and extensors one year after knee replacement and found decreased strength in participants compared to age matched controls. This is particularly important in the light of the correlation between quadriceps muscle strength and functional performance e.g.; the ability to move from sitting to standing or climbing stairs (Mizner et al 2005). Further consideration is needed of other muscle groups. Piva et al (2011) suggest that hip abductor muscle strength is also reduced and affects physical function after total knee replacement in particular rising from a chair, climbing stairs and walking and changing direction. Additionally calf strength may also be reduced in this patient group (Ciolac and Greve 2011). Hip and calf muscle strength play a key role in gait and balance (Pandy and Andriacchi 2010, Lee et al 2014). Strengthening is therefore a key part of rehabilitation following knee replacement.

Previous studies investigating rehabilitation after knee replacement have included strengthening exercises mainly focusing on quadriceps, hamstrings and hip abductor muscle groups and at times included calf strengthening (Moffet et al 2004, Coulter et al 2009, Piva 2010, Bade et al 2011). These interventions are similar to strengthening programmes used in exercise trials for elderly participants with impaired mobility who are not post-surgery in both the UK (Clegg et al 2011) and the USA (Fielding et al 2011). Considering the evidence from trials of elderly populations is relevant considering that the median age for all knee replacements performed in England, Wales and Northern Ireland in 2014 was 70 years old (NJR 2014).

The strengthening exercises used in the CORKA intervention will target the following muscle groups; quadriceps, hamstrings, hip abductors and ankle plantar-flexors. The strengthening exercises will combine specific exercises targeting one muscle group such as inner range quadriceps sets, and exercises that may target several muscle groups with a functional emphasis such as sit to stand.

Strengthening exercises will be individually assessed and progressed, participants will be started and progressed on their strengthening exercises according to a treatment algorithm.

5.1.4 Balance

There is evidence that balance and proprioception are altered in people with knee osteoarthritis compared to aged-matched health controls (Knoop et al 2011). Furthermore, knee replacement surgery itself can affect gait stability and balance (Mandeville et al 2008). Decreased proprioception has been linked to changes in soft tissue and ligament balance post knee replacement surgery (Attfield et al 1996, Wada et al 2002). Reductions in joint range of movement and muscle strength also impact balance. These factors may increase the risk of falls in this population. Kearns et al (2008) found that out of 1135 patients who underwent total knee replacement, 7% experienced falling.

Previous studies have explored balance training in participants post knee replacement. Piva et al (2010) conducted a pilot RCT investigating adding balance exercises to functional training in those with total knee replacement. Although the pilot study was underpowered to detect a difference in functional outcomes, the authors report that the balance training group demonstrated high adherence, low drop outs and no adverse events. In 2013 a RCT investigated the effects of functional training with or without balance training in participants after total knee replacement. It found that the group who underwent additional balance training had significantly better functional outcomes, including 10m walk, Timed Up and Go, stair climb test and chair rise test (Liao et al 2013). Therefore, the CORKA intervention will include balance training. A functional approach will be adopted to recognise the specificity of motor learning. Consequently, some exercises will combine balance and strengthening such as single leg stance, or balance and functional activity such as side stepping along the kitchen work-surface or walking with a turn.

5.1.5 Functional activity and task based practice

Following knee replacement people typically experience functional limitations and these can persist beyond the immediate post-operative period (Meier et al 2008, Bade and Stevens-Lapsley 2012). At one year post knee replacement people are likely to be significantly slower when walking and climbing the stairs and have greater functional impairments, particularly on tasks that involve kneeling or squatting compared to matched control groups (Walsh et al 1998, Noble et al 2005). These results are in line with Bade et al (2010) who found that function at 1, 3 and 6 months post-

surgery, as assessed using the stair-climb test, TUG test, 6 minute walk test and single leg stance, was worse in those who had undergone knee replacement, compared to healthy adults.

In 2007 a systematic review evaluating the effectiveness of exercise supported the use of functional physiotherapy exercise interventions following discharge to obtain short term benefit following elective primary knee arthroplasty (Minns Lowe et al 2007). Functional exercises included practice of walking and sit to stand. The review found that functional exercise for three to four months postoperatively had a small to moderate effect on functional outcome. There was also a small to moderate effect of functional exercises on quality of life and joint range of movement at three to four months postoperatively. No benefits of such an intervention were found at one year post-operatively. Since this review, further studies have investigated rehabilitation post knee replacement (Bade and Stevens-Lapsley 2012) and a further systematic review of exercise post knee replacement conducted in 2013, recommended that physiotherapy post knee replacement should include both strengthening and intensive functional exercises (Pozzi and Snyder-Mackler 2013).

Therefore functional task based training will be an integral component of the CORKA treatment intervention. Tasks that are identified as being problematic in the initial assessment will be focused on to tailor the program to the individual's needs and goals and aid motivation and adherence. These tasks are likely to include things such as standing from a low chair or getting out of a car, stairs or picking up an object from a low height such as the bottom shelf of the cupboard. Techniques such as task analysis, i.e. breaking down the task and identifying specific components or issues will be used as part of a practical problem solving approach to improve function. Tasks will be demonstrated and practiced (patterning) in treatment sessions with an emphasis on quality of movement and function to build skill and confidence. Participants will be asked to employ techniques whenever they carry out these activities within the day e.g.; stand from a chair sharing weight equally between operated and non-operated leg as much as possible. This approach will be re-inforced with written advice in the patient exercise diary. These tasks will also be linked to the specific exercise programme that the participants are prescribed to aid motivation and adherence. For example if a participant is struggling with getting off a lower chair or toilet, it will be explained that in addition to practicing the task itself the knee flexion range of movement exercises and inner range quadriceps strengthening and sit to stand exercise within their specific home programme are likely to improve this task.

5.1.6 Mobility

It is expected that participants will have problems with functional mobility including gait and climbing stairs. Therefore the intervention will contain a mobility section that will consist of two parts. The first part will focus on improving gait skills such turning when walking. The second part will involve a graduated walking programme.

5.1.7 Gait skills

Patients often have problems with walking post knee replacement; these include specific gait deficits linked to underlying problems such as persistent pain or lack of knee range of movement as well as general problems such as decreased walking speed and endurance (McClelland et al 2007, Walsh et al 1998, Heiberg et al 2010). In 2007 a systematic review investigating gait analysis post total knee replacement, concluded that patients post total knee replacement have altered gait patterns compared to controls (McClelland et al 2007). Although a uni-compartmental knee replacement is likely to allow a gait pattern closer to normal than a total knee replacement, they still have an altered gait pattern compared to 'normal' (Wiik et al 2013). Walsh et al (1998) emphasise that these difficulties can remain at one year post surgery. Addressing these deficits is important, gait outcome contributes to patient's satisfaction after knee replacement (Turcot et al 2013). It is also likely to affect functional independence, including people's ability to work and participate in activities within the community.

The importance of including adequate mobility skills practice is illustrated by a RCT by Brunn-Olsen et al (2013). They compared a walking skills programme with usual physiotherapy and reported that both short and longer term functional mobility was better in the walking skills group. An essential part of the CORKA rehabilitation intervention will to work on gait skills. Early in the sub-acute stage this will focus on developing a normal gait pattern, weaning off walking aids as appropriate and progressing the ability to walk indoors and outdoors.

5.1.8 Graduated walking programme

People with end stage lower limb arthritis are likely to be physically deconditioned with lower levels of cardiovascular fitness (Philbin et al 1995, Ries et al 1996). Reduced mobility in the immediate post-op period will exacerbate these problems. Lack of fitness is a contributing factor in functional walking impairments e.g.; limiting distance and therefore the ability to participate in community activities. It is therefore important to consider the cardiovascular fitness of people after knee

replacement. If the CORKA intervention is going to increase participant's participation in the community, then increasing fitness and improving walking endurance as well as gait skill is needed.

In 2012 a study investigated heart rate responses and other factors affecting exercise performance in participants after knee replacement and found moderate intensity exercise was safe and tolerable (Naylor and Ko 2012). Aerobic exercise such as cycling on a static bike and walking on a treadmill have formed part of trial exercise interventions given post knee replacement (Coulter et al 2009, Harmer et al 2009). Additionally studies investigating exercise in older people have included exercise to improve aerobic capacity within the study interventions in order to combat frailty or the effects of aging (Clegg et al 2011, Fielding et al 2011). Guidelines for exercise relevant to people post knee arthroplasty surgery recommend accumulating 5 lots of 30 minutes of moderate intensity physical activity in a week in at least 10 minute bouts (Nelson et al 2007). These guidelines are specifically for adults aged 65 years and older, or adults aged 50-64 who have either a chronic condition or functional limitation that affects one of the following: movement ability, fitness, or physical activity.

5.2 Delivery of the intervention

The sections below will outline how the different components of the intervention are to be delivered. For a guide to each individual session, please see Chapter 6: CORKA Intervention Detailed Guide.

5.2.1 Prescription and progression

Prescribing the right amount of exercise for each of the sections is important. Below, each section of the intervention is reviewed and the way to prescribe the different exercises is discussed. There are no exercise guidelines specifically for people after knee replacement. Therefore exercise prescription guidelines for older adults have been considered when designing the intervention (Nelson et al 2007, Garber et al 2011)

5.2.2 Range of movement exercises

The first part of the home exercise programme is range of movement exercises. These exercises are ordered into two sections, a section of knee flexion exercises and a section of knee extension exercises (Appendix 1). The sections contain different types of range of movement exercises, active range of movement, active-assisted range of movement, passive range of movement and stretches. This gives the opportunity to provide an exercise that you feel is appropriate based on assessment of the participant. Select one exercise from each section for the participant, observe them performing

the exercise. When the participant and therapist are happy the exercise is being performed correctly the exercise can be added to the home exercise programme and recorded in the participant's treatment diary. Once the exercises have been selected, advise the participant to perform 3 sets of 10-15 repetitions, unless a stretch has been selected, here advise the participant to perform 3 sets of 3-5 repetitions with a 30 to 60 second hold. These sets can be spread out throughout the day.

5.2.3 Strengthening

This part of the intervention includes strengthening exercises for quadriceps, hamstrings, hip abductor and calf muscle groups (See Appendix 1). In order to prompt adaptation of muscle the exercises need to be of sufficient intensity.

For each muscle group there are a number of exercises to choose from. The exercises progress from easier to harder within each section. For each muscle group participants will be given one exercise, with the exception of the quadriceps muscle group, here participants will be given one exercise from the quadriceps exercise section (Appendix 1, section 4), in addition to an inner range quadriceps exercise and a static quadriceps exercise (Appendix 1, section 5). This is to ensure that we are working towards full knee extension, in addition to reflecting the volume of evidence highlighting the importance of quadriceps strength post knee replacement.

The participant should be given an exercise that they can perform for 6-12 repetitions with good form at a moderate intensity. From the assessment and using your judgement select an exercise from the programme for one muscle group and ask the participant to do up to 3 repetitions of this exercise. Observe and ask them to rate the intensity using the 10 point Rating of Perceived Exertion (RPE) scale (Borg 1998). The RPE scale (See Appendix 2) is an appropriate measure to use to adjust the intensity of resistance exercise (Garber et al 2011). The participant should be given an exercise where they feel they are working at RPE of 3-4 (moderate to somewhat hard).

Participants need to be able to complete at least 1 set of 6 repetitions of an exercise with good form, if they are unable to complete this, or if they are working at a RPE of 5 or higher, then an easier exercise should be selected. The therapist should record the exercise selected on the exercise record sheet and ask the participant to complete a set of 6 to 12 repetitions, holding for 5 seconds for each repetition of an exercise. Participants can be asked to perform from 1 to 3 sets of an exercise. It may be appropriate to start on the first session with one set of exercises, progressing to 2-3 sets as you see the patient on subsequent visits, but the patient should always feel that they are working at a RPE of 3 to 4.

During subsequent visits the exercise programme should be reviewed and the level and intensity of exercises adjusted as necessary. A lower intensity or easier exercise should be chosen if participants report experiencing an increase in pain lasting longer than 2 hours post exercise, or if they experience a significant increase in swelling or if their RPE is more than 3-4 when completing an exercise or if they are unable to perform 6 repetitions of the exercise with good form. Participants should maintain their current exercise level and intensity if their RPE is 3-4 and if they are able to perform 6-12 repetitions with good form. Participants will be asked to increase the level of exercise if their RPE is less than 3-4 and if they can complete over 12 repetitions with good form. These points are outlined in table 2 below.

Table 2: changing the intensity/difficulty of strengthening exercises

Decrease intensity/difficulty	**Maintain intensity/difficulty**	**Increase intensity/difficulty**
Increase in pain lasting longer than 2 hours post exercise	RPE 3-4	RPE < 3
Significant increase in swelling	Able to complete 6-12 repetitions with good form	Can complete more than 12 repetitions with good form
Unable to complete 6 repetitions of exercise with good form		
RPE >4		

5.2.4 Balance

The balance exercises prescribed need to be sufficiently challenging to prompt adaptation and progression without putting the participant at risk of falling. If the participants need to perform these exercises with support e.g.; kitchen work surface or back of a sturdy chair, this should be recommended. The balance exercises are listed in order of difficulty (Appendix 1, section 8). Participants should be prescribed one balance exercise as part of the home programme. The appropriate starting exercise chosen should be identified from the assessment. With each exercise participants will be asked to hold the position for up to 30 seconds, to repeat with both legs if appropriate, i.e. with single leg stance, and to perform 3 repetitions. Observe the participant performing the exercise to make sure the exercises is challenging but safe. The exercise can be progressed or made easier at subsequent appointments.

5.2.5 Gait skills

At each treatment session the participant should receive gait re-education, including providing advice on improving gait patterns e.g.; such as making sure both step lengths are equal, that time spent on each leg is equal and to put the heel of each foot on the ground first. It will include advice on the use of walking aids, practicing walking indoors and outdoors and turning. Gait re-education can also include practising negotiating a single step or kerb, stepping over objects and stairs as relevant. To re-enforce advice and practice done in sessions notes can be made in the participants home exercise record and participants should be asked to incorporate practice in daily life.

In addition some specific gait skill exercises have been included in the trial home exercise programme. The gait skills exercise prescribed for the home exercise programme needs to be sufficiently challenging to prompt adaptation and progression without putting the participant at risk of falling. If the participant needs to perform these exercise with support e.g.; kitchen work surface, this should be recommended. The gait skills exercises are roughly listed in order of difficulty (Appendix 1, section 9). The exercise selected from that listed needs to be one that challenges the patient without putting them at risk. This can be reviewed in assessment. Participants will be given one exercise from this section. Observe the participant performing the exercise to make sure that the exercise is challenging without being unsafe to include in the unsupervised home exercise programme. The can be progressed or made easier at subsequent appointments. The number of repetitions or time to perform these activities could vary significantly by participant and exercise selected. This can be based on assessment of the participant, for example you may ask a participant to practice marching on the spot for 6 – 12 marches, 2-3 times a day, or figure of 8 walking 3 times, 2-3 times a day along with the rest of the home programme.

5.2.6 Graduated Walking Programme

The most practical and relevant way to include aerobic moderate intensity exercise and to improve walking endurance in this study is through a graduated walking programme. It is recognised that individuals within the CORKA trial are likely to have a wide range of mobility levels at baseline and reflecting this the overall aim of the graduated walking programme will be to increase an individual's walking time and distance.

However for the majority of participants aiming to achieve recommended exercise guidelines is likely to be relevant. Hence for many the long term goal of the graduated walking programme will be to be able to walk for 30 minutes at a moderate intensity 3 to 5 times a week by the end of the 12 week

intervention. Although this will not be possible for all participants, it is a reasonable goal in relation to current exercise guidelines for this population. Participants will be asked to include a walking programme within their daily routines across a week. For some, walking for 30 minutes in one session will be possible, for others this may not be realistic but it may be possible to accumulate walking in short bursts e.g.; 10 minutes of walking 3 times a day.

It is important to introduce the walking programme gradually; as gait skills are improving and post-operative pain is reducing. For most people this is expected to be by session 3. If people are not currently walking longer distances and if it is felt unsafe to advise them to do so, then the walking programme should be introduced when these conditions are met.

To introduce the walking programme, at the end of session 2 participants will be asked to record the maximum distance or time they have walked on any one occasion e.g.; to the post box or to a neighbour's house, 10 minutes to the bus stop and back home comfortably etc. They should record this in their home exercise diary before the next session.

At session 3 the treating therapist will use this information to set up the graduated walking programme. Participants will be asked to try to increase their walking distance gradually, in small increments. A relevant long term goal should be set as well as short term goals to be achieved before the next session. To promote adherence, goals should relate to daily life and a plan to achieve the walking programme should be discussed and agreed. For example if the participant reports being able to walk once a day for 5 minutes comfortably, the goal might be include a second walk in the day of a similar distance or if they can walk to the post box and back comfortably the goal might be to walk further, to the bus stop etc.

Participants will to be encouraged to monitor their knee and tailor increases in activity accordingly. Consideration will be taken of pain and swelling and participants will be advised not increase their walking distance if they have an increase in pain for 2 hours post-walking, or a significant increase in swelling. Participants will be encouraged to walk at a moderate intensity; that is a rating of 3 to 4 (moderate to somewhat hard) on the RPE scale (Appendix 2). There are a number of factors that the patient and clinician can use to help determine if walking intensity needs to increase, decrease or stay the same. These are listed in table 3 below.

Table 3: changing the intensity of walking

Decrease walking intensity	Maintain walking intensity	Increase walking intensity
Pain lasting longer than 2 hours post exercise	RPE 3 to 4	RPE less than 3

A significant increase in swelling		
RPE 5 or more		

5.2.7 Task practice

Participants will be asked to practice 1 to 3 functional tasks that have been identified as relevant and potentially difficult through the initial assessment visit. These task/(s) need to be safe for the participant to practice independently or with supervision of a carer at home, if available. This is likely to be an activity of daily living. The participant will be encouraged to practice an activity that is currently problematic and therefore may be challenging. However the practice of this activity needs to be safe and consideration needs to be given to avoiding falls. The task or tasks will be practised with the patient during the treatment session. The therapist or assistant should make suggestions or pointers to help the patient with practicing the task, demonstrating the activity as needed. For example trying to have equal weight on both feet or come forward and up when attempting sit to stand. Other factors that could help with practicing a task would be to consider if some equipment might help, for example a perching stool, or to try and problem solve an alternative way of doing the task, for example using hands when rising from sitting, using a cushion when kneeling or using a 'step to' gait rather than a step through gait when negotiating the stairs. These pointers can be recorded in the participant's diary. The participant will be asked to think about the advice given when they are performing the activity in daily life. At each subsequent session the tasks practiced can be reviewed and if the participant and the clinician feel that the subject is now competent with the task(s), new task(s) can be practiced in the same way.

5.2.8 Exercise duration

When participants are asked to perform their home exercise programme including strengthening, ROM, balance and mobility exercises, it is envisaged that is will take between 15-25 minutes to complete. This can be done either in one block of time, or can be spread out throughout the day, whichever suits the participant the best.

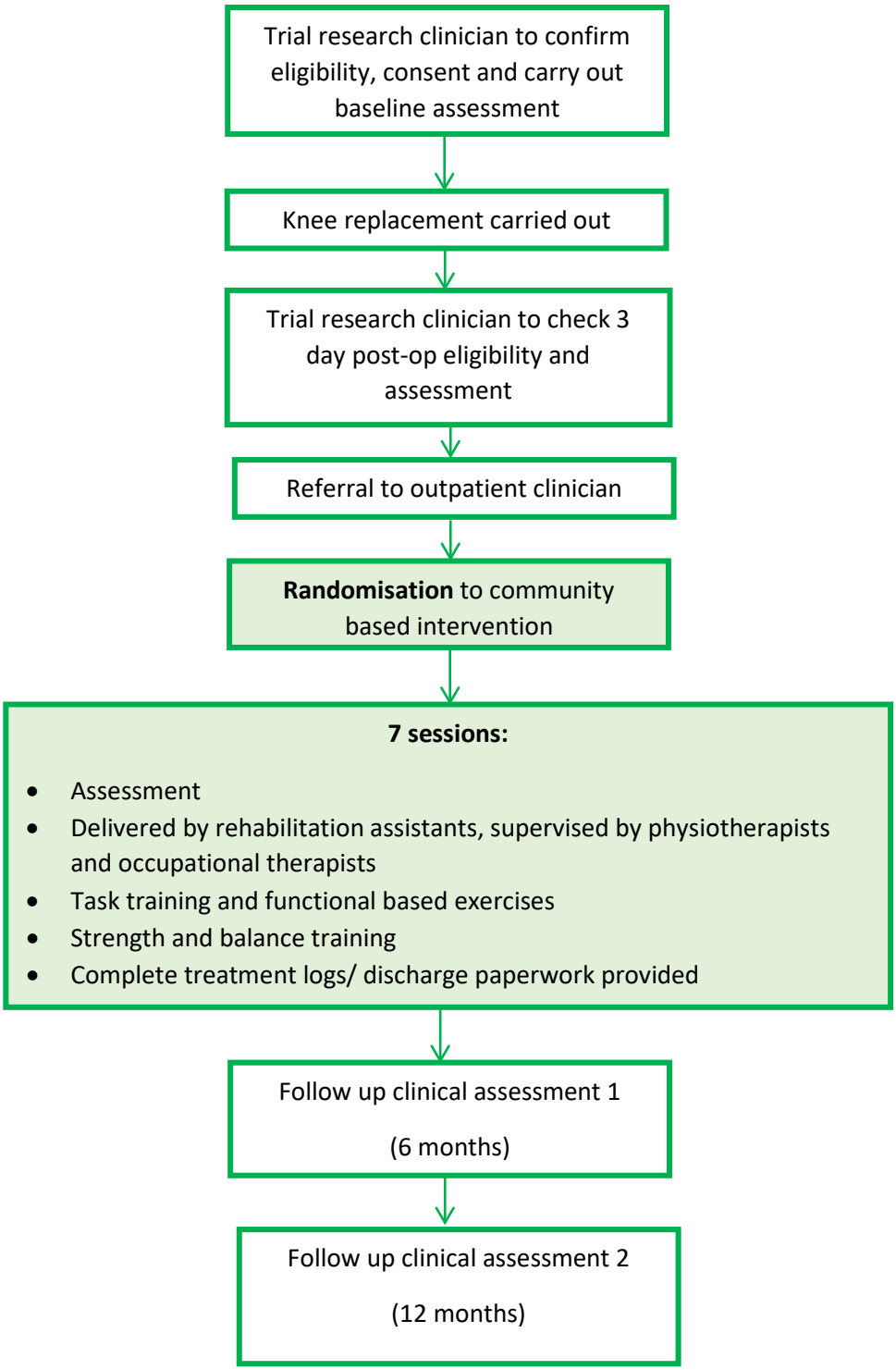
5.2.9 Exercise frequency

The participants will be asked to perform their home exercise programme daily, this may not be possible with all participants, but most people post knee replacement will be asked to exercise daily in physiotherapy as part of standard treatment. For walking, people will be encourage to walk or take part in an aerobic activity 3 to 5 times a week, in line with current exercise guidelines.

5.3 Assistants

Once the physiotherapist and assistance have visited the participant in session one to assess the participant and start the programme, the intervention will be carried out mainly by the rehabilitation assistant. Assistants will be trained beforehand by a member of the CORKA research team. Additionally assistants will be asked to feedback to the physiotherapist after every treatment session.

Figure 5. Community based rehabilitation: flow of participants.



Chapter 6: CORKA Intervention detailed guide

This section contains a detailed guide of the steps that need to be taken in delivering each of the seven treatment sessions. Table 4 provides a summary of which exercises should be prescribed in each session. It might be helpful to review appendix 6 a thumbnail version of the exercise programme, whilst reading this chapter.

6.1 Session 1: Initial assessment

In this session you will assess the participant and start them on their gait and functional task retraining. The home exercise programme may begin depending on time. It is recommended that this session lasts 90 minutes.

Assessment

- Use the CORKA assessment form (Appendix 3)

Intervention

- Give the participant the information booklet (see Appendix 4).
- Ask the participant if they have any questions and, point out that there is lots of relevant advice in the information booklet.
- Give the participant their home exercise book and go through the sections.
- Help the participant to complete the goal setting section in the participants exercise diary.
- Work on gait skills and 1 to 3 functional task/s with participants that have been identified in the assessment.
- Offer any points to consider or advice and record this in the participants exercise diary. Ask the patient to consider these points when performing the task in daily living.
- Prescribe a home exercise programme as time allows.
    - Give the participant their range of movement exercises, one exercise from section 1, knee flexion exercises, and one from section 2, knee extension exercises (See Appendix 1). If the participant is already doing these as part of their discharge advice, tell them to continue.
    - Give the participant both basic quadriceps exercises from section 3 and basic quadriceps exercises (see Appendix 1). If the participant is already doing these as part of their discharge advice, tell them to continue.
    - Give the participant their strengthening exercises, one exercise from section 4, quadriceps strengthening, one from section 5, hamstring strengthening, one from

section 6, hip abduction strengthening, and one from section 7, calf strengthening. Use the treatment algorithm (See Appendix 1) to help choose the appropriate level of exercise (the participant should be able to perform 6-12 repetitions of the exercise with good form, and should report a RPE of 4-5)

    - Give the participant a gait skills exercise and a balance exercise.
- If there is not enough time available to prescribe the entire home programme the participant can be started on part of the programme or continue with some or all the home exercises they were prescribed on discharge.
- Write all the exercises given in the participants exercise diary and place a copy of the relevant exercise sheets in their trial folder.
- Make sure the exercises given have been practiced when you are present.

To finish

- Book a follow up appointment
- Fill in session 1 treatment log and return it to the CORKA team

6.2 Session 2

In this session participant's will be reviewed and will continue with their gait and functional task retraining and the home programme should be started. This session should last 60 minutes

Assessment

- Re-assess participant; check ROM, strength, gait and functional tasks as needed. How did the participant get on with their home exercise programme if introduced? Check the participants treatment diary.
- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises.
- Once the participant has full active extension they can stop performing their exercise from section 2, knee extension exercises, and their basic quads exercise from section 3

Intervention

- Review how the participant is getting on with the task/(s) identified in session 1. If necessary continue to practice these tasks, review the pointers and advice given in session 1 and add to it if needed.

- If able identify a new task offer any points to consider or advice on technique of task, these can be recorded in the participants exercise diary. Ask the patient to consider these points when performing the task in daily living
- Review participants walking, offer appropriate advice based on your assessment regarding gait, walking aids and steps etc.
- Introduce or continue with the home exercise programme.
    - Continue with strengthening exercises as in session 1, progress to a new exercise if needed using the treatment algorithm (See Appendix 5). If there was not enough time last session, start the strengthening exercise as described in session 1
    - Add a gait skills exercise and a balance exercise to the participants programme if there was not enough time previously.
    - Write all the exercises given in the participants treatment diary and give them a copy of the relevant exercise sheets
    - Make sure the exercises given have been practised when you are present.
    - If you feel that the participant would benefit from an additional exercise, e.g. you would like to give them 2 exercises from section 3, add the additional exercise to the participants exercise diary and give them the relevant exercise sheet
- Ask the participant if they have any questions

To finish

- Book a follow up appointment
- Ask the participant to record the longest walking (distance or time) managed between session 2 and 3 in the home exercise diary
- Fill in session 2 treatment log and return to the CORKA team.
- Rehabilitation assistant feedback to physiotherapist after the session.

6.3 Session 3

In this session participants will continue with their gait and functional task practice and home programme. In addition the graduated walking programme may be introduced.

Assessment

- Re-assess participant, check ROM, strength, balance and functional tasks as needed. How did the participant get on with their home exercise programme? Check the patients treatment diary

- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises
- Once the participant has full extension they can stop performing their exercise from section 2, knee extension exercises and their basic quadriceps exercise from section 3
- In session 3 or 4 when the physiotherapist revisits, complete the goal review page of the participant's diary.

Intervention

- Review how the participant is getting on with the task/s identified in session 2, if necessary continue to practice these tasks, review the pointers and advice given in previous sessions and add to it if needed. If able, identify a new task/s, offer any points to consider or advice on technique of task, these can be recorded in the participants exercise diary. Ask the patient to consider these points when performing the task in daily living
- Review the participants walking, offer appropriate advice based on your assessment regarding gait, walking aids and stairs etc.
- Continue with the home exercise programme.
    - Continue with strengthening exercises as in session 2, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with balance exercises as in session 2, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with gait skills exercise as in session 2, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Ask the participant how far they are currently walking either in time or distance record this in the participants exercise diary, encourage the participant to try to increase this time or distance by a small amount (e.g. 10%) prior to the next appointment, but remind the participant to be mindful of pain and swelling and to adjust their walking accordingly. If you feel that the participant is not safe walking outdoors, leave out the walking programme and consider it in a subsequent session.
    - Make sure the exercises given have been practised when you are present
    - If you feel that the participant would benefit from an additional exercise add the additional exercise to the participants exercise diary and give them the relevant exercise sheet
- Ask the participant if they have any questions

To finish

- Book a follow up appointment
- Fill in session 3 treatment log and return to the CORKA team
- Rehabilitation assistant feedback to physiotherapist

6.4 Session 4

In this session participant will continue with their gait and functional task practice and home exercise programme, in addition to continue graduated walking programme, if able.

Assessment

- Re-assess participant, check ROM, strength, balance, gait skills, walking programme and functional tasks as needed. How did the participant get on with their home exercise programme? Check the patients treatment diary
- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises
- Once the participant has full extension they can stop performing their exercise from section 2 knee extension exercises and their basic quadriceps exercise from section 3
- In session 3 or 4 when the physiotherapist revisits, complete the goal review page of the participants treatment diary

Intervention

- Review how the participant is getting on with the task/s identified in session 3, if necessary continue to practise these tasks, review the pointers and advice given in previous sessions and add to it if needed. If able, identify a new task/s, offer any points to consider or advice on technique of task, these can be recorded in the participants treatment diary. Ask the patient to consider these points when performing the task in daily living.
- Review participants walking, offer appropriate advice based on your assessment regarding gait, walking aids and transfers.
- Continue with the home exercise programme
    - Continue with strengthening exercises as in session 3, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with balance exercises as in session 3, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)

- Continue with gait skills exercises as in session 3, progress to a new exercise if needed (See Appendix 5)
- Ask the participant how far they are currently walking either in time or distance, encourage the participant to try to increase this time or distance by a small amount (e.g. 10%) prior to the next appointment, but remind the participant to be mindful of pain and swelling and to adjust their walking accordingly
- Make sure the exercises given have been practised when you are present
- If you feel that the participant would benefit from an additional exercise, e.g. you would like to add the additional exercise to the participants exercise diary and give them the relevant exercise sheet

- Ask the participant if they have any questions

To finish

- Book a follow up appointment
- Fill in session 4 treatment log and return to the CORKA team
- Rehabilitation assistant feedback to physiotherapist

6.5 Session 5

In this session participants will continue with their gait and functional task practice, home exercise programme and if able, their graduated walking programme.

Assessment

- Re-assess participant, check ROM, strength, balance, gait skills, walking programme and functional tasks as needed. How did the participant get on with their home exercise programme? Check the patient's exercise diary
- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises
- Once the participant has full extension they can stop performing their exercise from section 2 knee extension exercises and their basic quadriceps exercise from section 3

Intervention

- Review how the participant is getting on with the task/(s) identified in session 4. If necessary continue to practice these tasks, review the pointers and advice given in previous sessions and add to it if needed. If able identify a new task/(s), offer any points to consider or advice

on technique of task, theses can be recorded in the participants exercise diary. Ask the patient to consider these points when performing the task in daily living

- Review participants walking, offer appropriate advice based on your assessment regarding gait, walking aids and transfers
- Continue with home exercise programme
    - Continue with strengthening exercises as in session 4, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with balance exercises as in session 4, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with gait skills exercises as in session 4, progress to a new exercise if needed
    - Ask the participant how far they are currently walking either in time or distance, encourage the participant to try to increase this time or distance by a small amount (e.g. 10%) prior to the next appointment, but remind the participant to be mindful of pain and swelling and to adjust their walking accordingly
    - Make sure the exercises given have been practised when you are present
    - If you feel that the participant would benefit from an additional exercise, add the additional exercise to the participants exercise diary and give them the relevant exercise sheet
- Ask the participant if they have any questions

To finish

- Book a follow up appointment
- Fill in session 5 treatment log and return to the CORKA team
- Rehabilitation assistant feedback to physiotherapist

6.6 Session 6

In this session participant will continue with their gait and functional task practice, home exercise programme and if able, their graduated walking programme.

Assessment

- Re-assess participant, check ROM, strength, balance, gait skills, walking programme and functional tasks as needed. How did the participant get on with their home exercise programme? Check the patient's exercise diary

- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises
- Once the participant has full extension they can stop performing their exercise from section 2 knee extension exercises and their basic quadriceps exercise from section 3

Intervention

- Review how the participant is getting on with the task/s identified in session 5, if necessary continue to practise these tasks, review the pointers and advice given in previous sessions and add to it if needed. If able identify a new task/s, offer any points to consider or advice on technique of task, these can be recorded in the participants exercise diary. Ask the patient to consider these points when performing the task in daily living
- Review participants walking, offer appropriate advice based on your assessment regarding gait, walking aids and transfers
- Continue with home exercise programme
    - Continue with strengthening exercises as in session 5, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with balance exercises as in session 5, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with gait skills exercises as in session 5, progress to a new exercise if needed
    - Ask the participant how far they are currently walking either in time or distance, encourage the participant to try to increase this time or distance by a small amount (e.g. 10%) prior to the next appointment, but remind the participant to be mindful of pain and swelling and to adjust their walking accordingly
    - Make sure the exercises given have been practised when you are present
    - If you feel that the participant would benefit from an additional exercise, add the additional exercise to the participants exercise diary and give them the relevant exercise sheet
- Ask the participant if they have any questions

To finish

- Book a follow up appointment
- Fill in session 6 treatment log and return to the CORKA team
- Rehabilitation assistant feedback to physiotherapist

6.7 Session 7

In this session participants will continue with their gait and functional task practice, home exercise programme and graduated walking programme if able.

Assessment

- Re-assess participant, check ROM, strength, balance, gait skills, walking programme and functional tasks as needed. How did the participant get on with their home exercise programme? Check the patient's exercise diary
- If the participant has knee flexion of 110 degrees or more, they can stop performing their exercise from section 1, knee flexion exercises
- Once the participant has full extension they can stop performing their exercise from section 2 knee extension exercises and their basic quadriceps exercise from section 3

Intervention

- Review how the participant is getting on with the task/s identified in session 6, if necessary continue to practise these tasks, review the pointers and advice given in previous sessions and add to it if needed. If able to identify a new task/s, offer any points to consider or advice on technique of task, theses can be recorded in the participant's exercise diary. Ask the patient to consider these points when performing the task in daily living
- Review participant's walking, offer appropriate advice based on your assessment regarding gait, walking aids and transfers
- Continue with home exercise programme
    - Continue with strengthening exercises as in session 6, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with balance exercises as in session 6, progress to a new exercise if needed using the treatment algorithm (See Appendix 5)
    - Continue with gait skills exercises as in session 6, progress to a new exercise if needed
    - Ask the participant how far they are currently walking either in time or distance, encourage the participant to try to increase this time or distance gradually but remind the participant to be mindful of pain and swelling and to adjust their walking accordingly
    - Make sure the exercises given have been practised when you are present

- **Table 4: CORKA intervention exercise prescription time points**

	Range of Movement Exercise	Basic quadriceps strengthening	Strengthening Exercise	Balance Exercise	Gait skills	Task Practice	Walking programme
Session 1	✓	✓	✓	✓	✓	✓	
Session 2	×	×	⇧	⇧	⇧	⇧	
Session 3	×	×	⇧	⇧	⇧	⇧	✓
Session 4	×	×	⇧	⇧	⇧	⇧	⇧
Session 5	×	×	⇧	⇧	⇧	⇧	⇧
Session 6	×	×	⇧	⇧	⇧	⇧	⇧
Session 7	×	×	⇧	⇧	⇧	⇧	⇧

Key:
✓ = Issue exercise **⇧ = Progress exercise if needed** **× = Stop exercise once appropriate level of function reached**

    - If you feel that the participant would benefit from an additional exercise, add the additional exercise to the participants exercise diary and give them the relevant exercise sheet
- Ask the participant if they have any questions
- Rehabilitation assistant feedback to physiotherapist

To finish

- Fill in session 7 treatment log and return to the CORKA team
- D/C the participant
- Remind the participant that they can continue with the exercise programme after they have been discharged

Chapter 7: Trial procedures

The control and community based rehabilitation interventions will be delivered by therapists and rehabilitation assistants who are independent of the assessment and randomisation procedures. They are known as Treating Therapists.

7.1 Treating Therapist and Therapy Assistant duties

The CORKA trial is large and is taking place over multiple sites. The Treating Therapist and therapy assistant are being asked to undertake the following duties within the trial:

- To treat eligible patients recruited into the trial based on the group they have been allotted through randomization.
- To document the treatment using the specific treatment forms provided.
- To encourage the patient to adhere to the protocol and continue their participation for the full trial duration.
- To report any adverse reactions/events as necessary.

Participants who are highlighted to be at risk of poor outcome will be contacted and asked to give their consent to participate in the study. Assessing therapists will carry out baseline and pre-discharge assessments. To ensure they remain blinded to the participant's treatment allocation the assessing therapist will then hand the randomisation information to a research clinician. This research clinician will telephone the independent randomisation centre who will allocate a treatment group. They will then ensure that the referral is passed onto the appropriate treating clinician or administration staff who will arrange an appointment to provide the participant's intended treatment allocation (usual care or community based rehabilitation). Participants will receive their allocated treatment based on the information from the Randomisation Office at the Clinical Trials Unit detailing which treatment they will receive. The treating therapist and therapy assistant will then treat the patient according to the study protocol outlined in the previous chapter.

Further duties include,

- To advise the patient's GP of their inclusion in the trial by sending the GP advisory letter.
- To undertake the planning and execution of the treatment within the agreed protocol ('Usual Care' or 'Community Based Rehabilitation').
- To complete all documentation associated with the trial.

- To maintain stocks of equipment and Trial Forms. To report any adverse events immediately to the local Trial Co-ordinator.
- To return Treatment Logs to the trial office.
- To act within recognised good clinical practice and core standards of professional practice as defined by their regulatory body (Health Professions Council) and professional bodies (Chartered Society of Physiotherapists and British Association of Occupational Therapists). This involves issues regarding appropriate assessment and management, record keeping, scope of practice, confidentiality, patient and professional interactions etc.

Prior to referral to the Treating Therapist, the patient will have:

- Received information and advice about knee replacement surgery.
- Received information about the CORKA trial.
- Provided written informed consent to participate in the clinical trial.
- Been screened for eligibility to participate in the trial by the local Trial Research Clinician.

The screening process will include a check for appropriateness for receiving therapy. However, this does not negate your clinical responsibility for the patient. You may find that the patient will ask your opinion or questions about the trial. You should feel confident and sufficiently informed to answer simple questions but, if not, refer back to your local Trial Research Clinician (see the front of this manual for details) or the Trial team.

7.2 Rationale for standardised protocol

In accordance with normal physiotherapy/occupational therapy practice, the intervention is tailored according to each patient's needs, and based on a clinical reasoning model that will be very familiar to therapists. We have designed the package using best available evidence, expert consensus and core components of good practice.

All efforts have been made to ensure that this treatment protocol is safe and appropriate. The most promising treatments have been selected. We have not selected treatments that require extended scope practice – all the proposed treatments are within the scope of the majority of therapists and therapy assistants working in the NHS. Traditional models of clinical reasoning are at the centre of the exercise package.

Therapists treating patients in the trial retain their professional autonomy, responsibility and freedom to individualize treatments based on clinical reasoning. However, due to the nature of clinical trials it is important for the choice of interventions to be standardised.

The reasons for standardising the interventions are:

1. To allow the results of the trial to be analysed in a meaningful way If too many types of treatment are included then it is difficult to proportion clinical effects to specific treatments – it helps us to know what works and what doesn't. Clinicians can critically appraise the treatment package used in order to assess its relevance to their clinical setting. Clinicians can see exactly which treatments are useful to help guide their practice.
2. To make the trial reproducible. If the trial protocol is clearly defined then it will be reproducible. This is essential to training and dissemination. Other researchers may wish to reproduce our intervention in the future and if the number and type of treatments are documented this is much easier.

7.3 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.

7.4 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.

7.4.1 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 OUH 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.

7.4.2 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.

7.4.3 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.

7.4.4 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.

7.5 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.

7.6 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.

7.7 Assessment

Once a referral has been received from the lead clinician, an appointment will need to be made within eight weeks but ideally within four weeks. As described previously, the patient will already have been assessed and consented to be included in the study. For the purposes of the trial, information regarding disease activity, impairment and function will have been gathered by the assessing therapist from the patient prior to your initial session. You will not be required to forward any of the details of your assessment from this first contact, or subsequent sessions, to the trial team. However, you will need to perform an assessment for your own notes as well as to comply with legal and ethical requirements. It is also possible that a patient suffering from a serious complication or adverse event may have slipped through the screening process or may have arisen since being seen by the assessing therapist.

To assist you in this you will have access to the initial assessment done by the assessing therapist. It is expected that this will not differ greatly from the normal assessment format used by therapists. This is for your own use and it is designed to be included in the hospital notes for each patient. Although we are providing a standardised assessment form, the actual assessment should still be guided by each individual patient's presentation.

It is hoped that information from the subjective examination and objective measurements taken during the assessment will better inform you as to the initial level of loading for individual patients who will be undertaking the exercise regime, and that subsequent re-assessments will aid in progression. Information regarding work, leisure and home activities will assist in the setting of general goals as well as 'when' and 'where' they will do their exercises.

7.8 DNAS / Non-attendance

Each department has their own method of dealing with non-attendance. However, every CORKA participant is precious to us and we need to make every effort that they attend for treatment. For the purposes of the CORKA trial we request that any trial participant in the usual care arm who doesn't attend an appointment is followed up by you (or on your behalf) and an attempt made to re-book them. If the patient fails to attend the re-booked appointment then your normal department

DNA policy will prevail. For participants in the treatment arm, if the appointment is cancelled for any reason please attempt to reschedule appointments.

Please note that even if a patient does not attend, you must complete the relevant Treatment Log for that session (tick the DNA box) with the date of the missed appointment. If the participant subsequently attends, please complete a new Treatment Log for that session. Every participant must have a Treatment Log completed for each session and returned to the Oxford Clinical Trials Research Unit, CORKA Trial Office, Room 101, Botnar Research Centre, Old Road, Oxford, OX3 7LD – even if they fail to attend!

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