OPAL

Occupational advice for Patients undergoing Arthroplasty of the Lower limb

(HTA Project Reference Number: NET SCC ID 15/28/02; HTA Call: Occupational advice initiated prior to planned surgery for lower limb joint replacement)

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1. Full title

Occupational advice for **P**atients undergoing **A**rthroplasty of the **L**ower limb (**OPAL**).

2. Summary of research

Importance: There are an increasing number of patients of working age undergoing hip and knee replacements. However, currently there is variation in the advice and support given about sickness absence, recovery to usual activities and return to work after these procedures. Earlier, sustainable, return to work improves the health of patients and benefits their employers and society. An intervention that encourages and supports early recovery to usual activities, including work, has the potential to reduce the health and socioeconomic burden of hip and knee replacements.

Objective: To develop an occupational advice manual to support early recovery to usual activities including work which is tailored to the requirements of patients undergoing hip and knee replacements. To test the acceptability, practicality and feasibility of this intervention within current care frameworks.

Design: Two phase research programme delivered over 27 months using a six-stage intervention mapping approach:

Phase 1 (Months 1-13): Intervention mapping stages 1-3:

1 Needs assessment (including rapid evidence synthesis, prospective cohort analysis and structured stakeholder interviews)
2 Identification of intended outcomes and performance objectives (PO)
3 Selection of theory-based methods and practical strategies

Phase 2: (Months 10-27): Intervention mapping stages 4-6:

4 Development of components and materials for the manualised occupational advice intervention using a modified Delphi process
5 Adoption and implementation of the intervention
6 Evaluation and feasibility testing

Setting: A minimum of three NHS hospitals in the UK and two Higher Education Institutions.

Participants & Exposures: Patients will be involved as research participants in Phases 1 and 2.

Phase 1 will commence with an assessment of current practice and an individual needs assessment related to occupational advice and return to work after hip and knee replacement surgery. This will involve a rapid review of existing evidence evaluating outcome tools measuring activity, participation, workplace disability, return to work and occupational advice interventions across surgical conditions. We will also conduct a prospective cohort study of patients on the waiting list for hip or knee replacement who are currently working. Patients that intend to return to work and patients that do not intend to return to work will be recruited to the cohort study. A minimum of 150 patients will be recruited from the participating centres. Information about pre-surgical activity, work roles, absenteeism and work place disability will be collected pre-operatively and at 8, 16 and 24 weeks post operatively using questionnaires. This data will enable recovery and return to usual activities to be mapped and provide information about current support and advice delivered at each of the recruiting centres. At each centre individual qualitative interviews will be undertaken in 10-15 patients in the 'return to work' group and 3 patients in the 'do not intend to return to work group'. Additionally, interviews with surgeons, allied health professionals (AHPs) and nurses, general practitioners (GPs) and employers will be undertaken. These interviews will provide detailed information about the shortcomings and difficulties in current care and support available and identify possible solutions and improvements to overcome them.

The information collected in Phase 1 will identify who and/or what needs to change in order for workers to make a successful return to work following surgery. We will then be able to generate a list of potential intervention components matched to each individual performance objective.

In Phase 2 the potential intervention components identified during Phase 1 will be reviewed by stakeholder groups using a modified 3-round Delphi consensus process to agree the content of the final intervention. The intervention will then be manualised and an implementation and evaluation plan will be designed. Following implementation at each centre, the intervention will then be evaluated using questionnaires and further stakeholder interviews. This will assess the fidelity of the intervention (the acceptability, practicality and feasibility of delivery) against defined intervention performance objectives. This process will allow the assessment of the intervention as both an intervention for clinical practice and as a potential trial intervention for any subsequent clinical trial. The final intervention will be revised and refined based on feedback from this process.

3. Background and Rationale

Lower limb joint replacement is an effective and cost-effective way of relieving pain, restoring physical function and improving health related quality of life for patients with hip and knee arthritis. Currently over one million hip and knee replacements are performed annually in the United States and over 170,000 in England, Wales and Northern Ireland (NJR 2014). Projections from 2005 suggest that by 2030, the demand for primary total hip (THR) and knee (TKR) replacements will increase by 174% and 673% respectively.

Decreased physical function associated with arthritis reduces the likelihood of employment, reduces household income and increases missed workdays for those who are employed (Li 2006). The magnitude of the impact varies dependent upon the degree of activity limitation and disease severity (Fautrel 2005). This observation, combined with an ageing workforce and changes to the pension age, has resulted in a steady increase in the numbers of hip and knee replacements being performed in patients of working age over the last decade. Currently 82% of people aged 35 to 49 and 67% aged 50 to 64 years are currently in employment (ONS 2013). In 2013 29,692 (19%) of all hip (n=76,760) and knee (n=82,723) replacements performed in England, Wales and Northern Ireland were in patients aged under 60 years; 52,130 (33%) were performed in patients aged between 60-69 years (NJR 2014).

A recent systematic review reported that 71-98% of patients returned to work after hip and knee replacement and the mean time varied substantially, from 2-14 weeks (Tilbury 2014). Ill health resulting in absence from work of 7 days or more, as seen following joint replacement, costs £8.4 billion/year at an average cost per case of £35,800 (HSE 2013). These costs are borne by the individual (impact of ill health on quality of life), employers and society (loss of productivity, need for health care, rehabilitation and compensation). Lengthy sickness absence can result in work disability, poorer general health, increased risk of mental health problems and higher mortality (Waddell 2006). Earlier return to work therefore has potential health benefits as well as socioeconomic value.

While major lower limb joint replacement includes hip, knee and ankle replacement we will focus on return to work after hip and knee replacement only. This is justified as 1) the number of ankle replacements performed annually is approximately 700/year (<1% of the annual number of hip or knee replacements) 2) the role of ankle replacement is not fully established and is currently being evaluated in a separate HTA funded trial (TARVA: Total Ankle Replacement Versus Arthrodesis).

4. Evidence explaining why this research is needed now

Current evidence suggests that:

a) A substantial proportion of patients undergoing hip and knee replacement are of working age and the majority are in work at the time of surgery. This number is set to increase as we support an increasingly aged workforce who will have to work for longer due to changes in the pension age.
b) Lengthy sickness absence can impact negatively upon individual patient's physical and mental health status.
c) The cost associated with sickness absence to the patient, employer and the state is significant.

In response to these concerns the HTA issued the current research call (15/28/02) to examine if it is feasible to undertake a trial to evaluate whether an occupational advice intervention delivered to working adults, commencing prior to primary hip or knee joint replacement surgery, improves speed of recovery to usual activities including work. Preliminary work to be undertaken as part of this research call will involve the research team a) defining the population to be studied in any subsequent clinical trial; b) developing and manualising an occupational advice intervention designed to expedite return to work; c) defining 'standard care' as the comparator in any clinical trial; d) determining a suitable 'return to work' outcome measure for use as the primary outcome.

The interaction between patients, employers and surgical intervention is complex. Return to work is influenced by a range of patient, health process and employment factors (Tilbury 2014). The underlying probability of employment also varies by age, gender, education level, and other factors, meaning the economic implications of musculoskeletal limitations vary between patients and regions. Therefore if a tailored occupational advice intervention is to be developed an understanding of this variation and the factors that influence the outcome of interest is essential. Unfortunately these factors are poorly understood and, as a result, there is significant variation in current practice and with the advice currently delivered to patients returning to work following their surgery.

Review of the literature highlights a number of specific gaps that require attention before a clinical trial of a manualised occupational advice intervention can be developed. Important considerations include:

Population

- There is currently limited information about the population of patients that are in work and undergo hip and knee replacement. Further information is required to understand the individualised workplace needs of this group including an understanding of how job classifications (e.g. manual versus non-manual); employment status (e.g. employed versus self-employed); the type of employer (e.g. small and medium enterprises versus large companies; public versus private or third sector employer); and the presence of an occupational health service within the organisational structure influences the potential for early return to work.
  The target population for a clinical trial is therefore not currently defined

Intervention

- Current recommendations guiding return to work are limited and inconsistent. Information available (https://www.rcseng.ac.uk/patients/recovering-from-surgery/total-hip-replacement/returning-to-work) is often too generic and does not provide the patient, employers or health care teams with the advice required about return to specific activities.
- The majority of patients undergoing hip and knee replacement undertake an integrated multi-disciplinary team (MDT) programme of education and rehabilitation spanning the surgical episode. The provision and utility of occupational advice within these 'usual care' pathways is not currently clear and the unique role of this service to expedite return to work needs to be established.
- 'Fit notes' offer the patient and employer opportunities for early phased return to work. However, recent studies indicate that the vast majority of fit notes advise that patients are 'not fit' for work, with few doctors making use of the opportunity to advise on patient function and/or work modifications (Shiels 2013, Coole 2015)
- There is limited information on modifiable barriers preventing return to work. There is limited understanding of how modifiable psychosocial factors influence return to work behaviours and the specific needs of the patients regarding peri-operative care and advice (Clayton 2007, Malviya 2014)
  There is therefore no appropriate occupational advice intervention available that could be used as the intervention arm in a clinical trial.

Comparison

- There is little information about how, when and who is delivering occupational advice. The rapid and inconsistent adoption of enhanced recovery and early discharge pathways have led to variations in provision of perioperative care and advice.
  '**Standard care' is therefore not currently defined for use as a study comparator**

Outcome

- There is currently no standardised method of recording return to work. Dichotomous recording of work status (Yes/No) is blunt and does not address important aspects of workplace behaviour including absenteeism, presenteeism, return to usual activities and interference with activities. In the UK >20% of patients do not return to usual activities and have restrictions in their ability to work after hip replacement (Howie 2013). Measuring return to work should ideally consider specific elements of the job, the duties and the hours worked.
- Assessment of workplace disability and productivity is poor. Validated tools exist (e.g. Workplace Activity Limitations Scale (WALS), Work Limitations Questionnaire (WLQ)) but little is documented about their applicability to the UK workforce and their utility as outcome measures for clinical trials (Tang 2011).
  The suitability of individual return to work measures as primary outcome measures within a clinical trial setting is currently unknown

5. Aims and Objectives

5.1 What is the research question?

How feasible is a trial to evaluate whether an occupational advice intervention delivered to working adults, commencing prior to primary hip or knee joint replacement surgery, improves speed of recovery to usual activities including work?

5.2 Study Objectives

Based on the limitations of the current evidence highlighted previously this study has the following objectives:

1. To evaluate the specific needs of the population of patients who are in work and intend to return to work following hip and knee replacement.
2. To establish how individual patients return to work; the role of fit notes clinical and workplace-based interventions, and how specific job demands influence workplace disability and productivity.
3. To establish what evidence is currently available relating to return to work / occupational advice interventions following elective surgical procedures.
4. To understand the barriers preventing return to work that need to be addressed by an occupational advice intervention.
5. To construct a multi-stakeholder intervention development group to inform the design and establish the necessary components of an evidenced based occupational advice intervention initiated prior to planned lower limb joint replacement.
6. To develop and manualise a multidisciplinary occupational advice intervention tailored to the needs of this patient group.
7. To determine current models of delivering occupational advice; the nature and extent of the advice offered; and how tools to facilitate return to work are being currently used.
8. To define a suitable measure of 'return to work' through systematic review and evaluation of specific measures of activity, social participation and return to work including specific validated workplace questionnaires.
9. To test the acceptability, practicality and feasibility and potential cost of delivering the manualised intervention within current care frameworks and as a potential trial intervention.

6. Research Plan

6.1 Project Overview

The stated objectives will be achieved in **2 phases** and be delivered over **27 months**:

- **Phase 1** will take place in the first 13 months (Months 1-13) and will address aims 1-4, 7 and 8 by gathering information on current practice and barriers to change; it will also provide a theoretical framework for intervention development.
- **Phase 2** will use information from phase 1 and provide the context for intervention development and testing. It will address aims 5, 6 and 9 and will be delivered in the final 17 months (Months 11-27).

We will adopt an intervention mapping approach that has been used previously to successfully develop and assess occupational advice interventions within musculoskeletal medicine (Vermeulen 2009) and other surgical specialties (Vonk Noordegraaf 2012). Intervention Mapping (IM) is a stepwise approach to theory, evidence based development and implementation of interventions. IM consists of six stages: needs assessment, identification of intended outcomes and performance objectives, selection of theory-based methods and practical strategies, development of intervention components, development of an adoption and implementation plan and finally evaluation and feasibility testing. The first 3 stages will be undertaken in Phase 1 with the final 3 stages undertaken in Phase 2 (Figure 1).

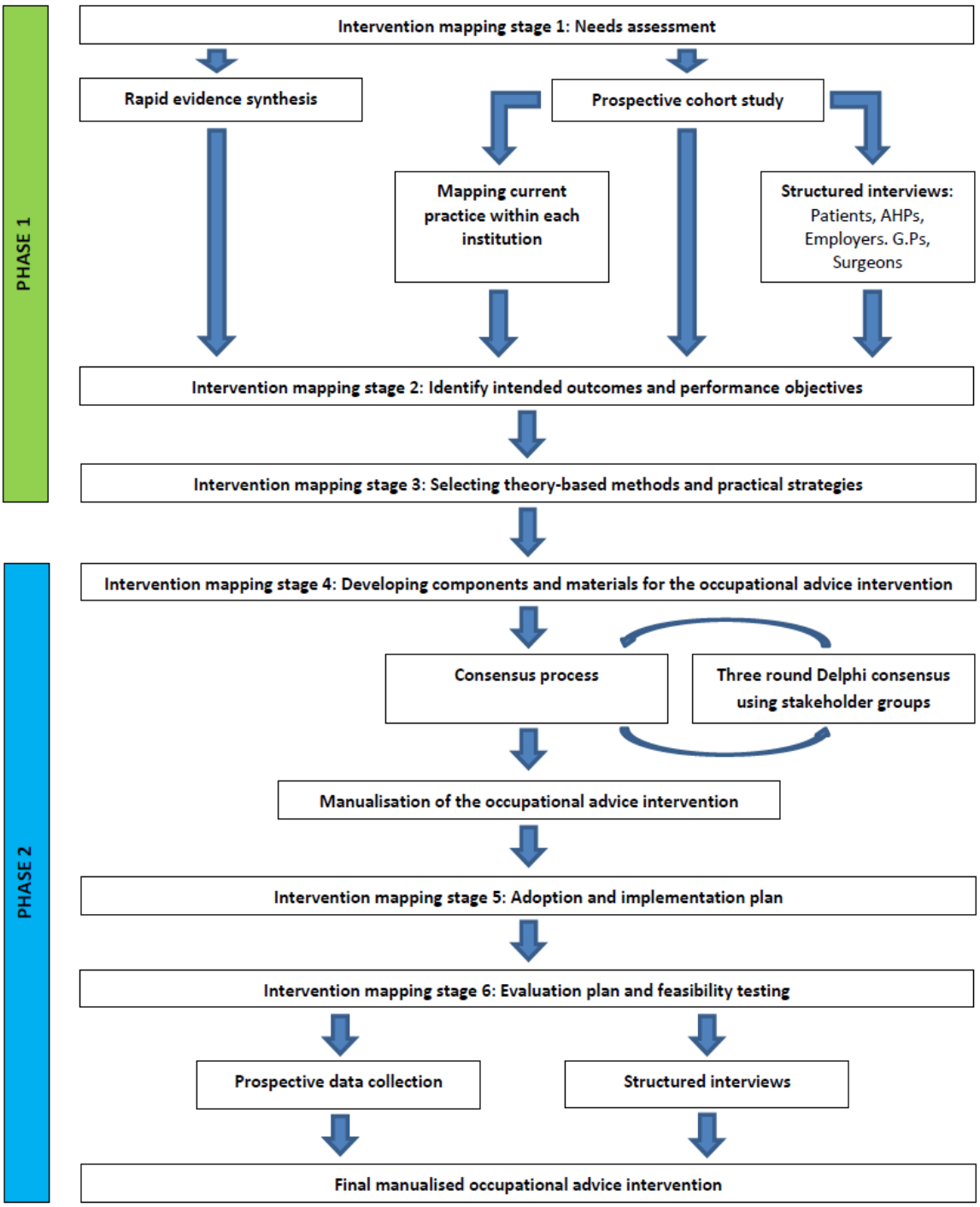


Figure 1: Diagrammatic overview of the proposed research project.

6.2 Likely content of the occupational advice intervention

While the intervention mapping process will determine the final content of the intervention it is likely that the occupational advice intervention will include one or more of the following elements:

Assessment of occupational requirements:

- Evaluation of patient's occupation, employment status, employer size and sector, work roles, associated responsibilities, work hours and duties and workplace contacts
- Individualised job analysis

Information about the surgical procedure and subsequent convalescence:

- A description of key people in the 'return to work' process: Who are they (e.g. patient, surgeon, nurses, therapists, GPs, work contact/manager, occupational health), their roles and responsibilities in the return to work process and their contact details.
- Information on the surgical procedure: The process in hospital from admission to discharge and possible complications of the procedure and contact information in case of problems.
- Convalescent recommendations:
    - Expected timescales/milestones for resumption of non-work roles, activities of daily living and recreational activities.
    - Expected timescales/milestones for resumption of specific work activities.
    - Rehabilitation recommendations with detailed recovery and exercise programmes.

Return to work information, leading to a 'return to work' plan

- Potential obstacles and enablers to recovery for both non-work and work related activities: e.g. expectations, fears, beliefs and attitudes of managers/colleagues/family/friends, potential for environmental alterations, workplace adjustments and temporary job re-grading.
- Information on return-to-work theories, models, guidance.
- Details on return to work planning:
    - Communication with other stakeholders
    - The return to work process: Return to work plans and interviews, job demands analysis, identifying and applying workplace modifications, the use of fit notes/AHP reports, financial matters (including sick pay, payment in phased return, annual leave etc.), redeployment, accessing support in seeking alternative employment, the roll of the Fit for Work and Access to Work services.
- Development of a 'return to work' plan: to include a suggested date, details of any requirements for modifications to hours, schedules, duties etc.

It is likely that the scope of the manual will be more focused and may not include all of the items listed above. However, we feel it is important not to rule out potential intervention elements that might later be found to be important for the population of patients aiming to return to work. Phase 1, with its patient and stakeholder interviews, is designed to assess what is important to patients and the findings from this section will help to define the necessary intervention components. This may or may not indicate a requirement to also include more 'general' information such as expected timescales on resumption of general activities of daily living (non-work) and obstacles/enablers to returning to usual activities: e.g. expectations, fears, attitudes of family/friends, potential for adjustments and grading. On an individual level it may also need to take into account patients' non-work roles (e.g. parent, child, friend, carer), associated responsibilities and activities e.g. hobbies, leisure, caring

We intend that the manualised intervention will be written for patients and their carers and will aim to empower them to take responsibility for their own recovery by working alongside the wider multidisciplinary team involved in their care (surgical team, AHPs and nurses, GPs and employers). While specifically written for patients it will include information pertinent to all of these stakeholder groups. It will be delivered in hospital by the multidisciplinary teams involved in the pre-operative education, assessment and subsequent follow-up of hip and knee replacement patients. They will, along with other stakeholders involved in their care, work through the manual with the patient identifying the aspects pertinent to their own circumstances. This will allow them to plan their own 'return to work' strategy and provide them with the information and support required to enact the developed strategy. While the intervention will be commenced prior to surgery we

anticipate that its delivery will span the surgical episode and include both pre- and post-operative content. It is expected that the developed intervention will be manualised and provided to patients as a paper version supplemented by an on-line PDF version. It may be supported by additional electronic resources (website, video clips etc).

6.3 Detailed project description

PHASE 1: (Delivered in Months 1-13)

During Phase 1 we will undertake the first 3 stages of the intervention mapping process:

IM Stage 1: Needs assessment

This will establish the rationale for an occupational advice intervention within this client group by evaluating the discrepancy between current and desired practice. It will be achieved by combining information gathered using the following mixed methods approach:

A. Rapid evidence synthesis
B. A cohort analysis mapping current practice
C. Patient and stakeholder interviews/focus groups

These complimentary approaches have been chosen to capture pertinent information about:

- Current practice
- Shortcomings and difficulties with current care and support
- Possible solutions and improvements to overcome these
- Content requirements of a manualised occupational advice intervention
- Views on potential primary outcome measures

A. Rapid evidence synthesis

To ensure that the occupational advice intervention is informed by the best available evidence, and that we are aware of relevant evidence that may be generalisable to lower limb joint replacement, we will undertake a rapid review of existing quantitative and qualitative evidence for all elective surgery populations. We will address the following questions:

- What evidence is available on interventions to support return to work following an elective surgical procedure?
- What is the content of interventions found to be effective (i.e. statistically significant and/or evidence of clinically meaningful benefit)?
- What components of the interventions are likely to be generic across conditions and therefore generalisable to an occupational advice intervention prior to planned surgery for lower limb joint replacement?
- What evidence is available on barriers and facilitators to delivery of the interventions and stakeholder perspectives (patients, healthcare professionals, employers)?
- What outcome measures are used in studies to assess return to work, return to normal activities and social participation?

We will use rapid review methodology as the call has already identified the evidence gap. The term rapid review covers a range of methods and there is no widely accepted definition, though generally the approach seeks to address a trade-off between time and methodological rigour and comprehensiveness of the end product (Featherstone 2015). To achieve efficiencies we will focus on the systematic review evidence in the first instance, include only English-language articles published in the last 20 years, restrict the range of databases searched, and double-check a proportion of the citations and data extraction. We will search for more recent primary studies (quantitative and qualitative study designs) to update systematic reviews or, if such reviews are not available, review the primary evidence.

A protocol will be developed prior to undertaking the rapid review, developing further the methods outlined below and registered on PROSPERO. An information specialist will undertake searches of MEDLINE, EMBASE,

CINAHL, CENTRAL, Cochrane Database of Systematic Reviews and Database of Reviews of Effectiveness for English-language studies. The following inclusion criteria will be applied.

- Population: People who have been on a period of sickness absence or where a prolonged absence is anticipated following an elective surgical procedure. The literature relating to elective surgical procedures is relevant to this review as it is likely that there is some generalisability across surgical procedures performed for different conditions. The literature outside elective surgery is likely to be vast and dominated by return to work following mental ill-health and musculoskeletal problems such and back and neck pain, where generalisability to hip and knee surgery is less certain. Inclusion of these groups would make the review element of the work larger and more expensive with uncertain benefit for the development of the intervention.
- Intervention: Any occupational advice intervention
- Outcome: Any outcomes related to return to work, return to normal activities and social participation. Condition specific measures will be excluded except where they are specifically related to people with lower limb functional limitations. We will also include any process measures related to the delivery of interventions such as barriers and facilitators and any data on stakeholder perspectives. The study is not designed to develop a new outcome measure. The rapid review will, however, identify what outcomes are currently being used in studies to assess return to work, return to normal activities and social participation.
- Study design: Systematic reviews, randomised and nonrandomised designs, qualitative studies.

Data will be extracted and studies quality assessed using tools appropriate for the study design. Details of studies will be tabulated and presented in a narrative synthesis in order to address the review questions. For evaluative study designs we will map the use of outcome tools measuring activity, social participation, workplace disability and return to work to establish what outcome measures are currently being used and identify possible tools for a future trial. With input from the project Steering Group potential outcome measures for a future trial will be identified.

B. Cohort analysis mapping current practice

The cohort study will collect important information about how patients undergoing hip and knee replacement return to work following surgery, what interventions are currently being used, and how specific job demands influence workplace disability and productivity prior to and following surgery. The prospective cohort study will be delivered in a minimum of 3 centres (Middlesbrough, Nottingham, Norwich). These centres have been chosen as they represent a mixture of semi-rural and urban populations across a range of socio-economic groups. The team also has established research and clinical links within these institutions.

Over a period of approximately three-months the research team in each centre will identify eligible patients who are a) undergoing hip and knee replacement during the recruitment and b) in work in the 6 months prior to joint replacement.

Information will be collected from 2 specific patient groups:
1) Patients that intend to return to work following surgery
2) Patients that do not intend to return to work following surgery

Screening of all hip and knee replacement procedures at each centre during the 3-month recruitment period will identify the proportion of patients working prior to surgery at each centre that could potentially benefit from a workplace occupational advice intervention. All eligible patients irrespective of which group they fall in to will be approached for enrolment within the cohort study.

Each centre undertakes >100 hip and knee replacements each month. Based on the NJR and ONS figures stated previously, a third of all patients undergoing surgery are likely to be in work prior to surgery. This should yield a minimum of 33 eligible patients at each site per month. Based on a conservative estimate of 50% recruitment, we would therefore expect to recruit a minimum of 50 patients during the recruitment period. Should our assumption prove wrong, we will extend the period of recruitment to the cohort until we have recruited 50 patients from each centre. Should recruitment exceed the expected target then we will continue

recruiting patients for a minimum of 3 months, maximising patient recruitment and data collection within this element of the study.

Once recruited each patient will complete prospective outcome measures at baseline (peri-operatively) and at 8 and 16 weeks post-surgery. In addition the first 15 patients recruited at each site will have an additional follow-up performed at 24 weeks after surgery. This will allow extended data collection for a subgroup of patients without extending the cohort element of the study. The 8 and 16 week time points have been chosen to strike a pragmatic balance between the proportion of patients returning to work (which we estimate at 70-80% at 16 weeks) and the cost of delivering this element of the study. It will also allow the characteristics and outcomes for those that have and have not returned to work to be compared.

The cohort study will collect information about each participant at 3 or 4 time points allowing us to map early functional recovery and return to work following surgery. Pertinent pre-operative information both from patients 'returning to work' and those not planning to return to work. Relevant post-operative information e.g. return to 'usual activities' and functional recovery will be collective postoperatively from both groups at the 8 and 16 week time-points and for a subgroup of patients at 24 weeks. Additional information about occupational advice, return to employment and recovery collected from the 'return to work' group. The following information will be collected:

Baseline:

- Patient demographic data (including co-morbidities, socio-demographic status, social support and living arrangements)
- Functional status:
    - Joint specific: e.g. Oxford hip / knee score
    - Health utility: e.g. EQ5D-5L
    - Functional status – Workplace disability and participation questionnaires including the, Workplace limitations Questionnaire (WLQ), Elements of the Workplace design questionnaire (WDQ), PHQ - 9 (Patient health questionnaire), Brief resilience scale (BRS) and GAD-2 (Generalised anxiety disorder scale - 2).
- Occupational information:
    - Type of employment e.g. manual versus non-manual; employed versus self-employed
    - Type of employer e.g. small and medium enterprises versus large companies; public versus private employer
    - Presence of an occupational health department within employment structure
    - Requirement to drive for work role and advice on return to driving post surgery

Post-operatively (8, 16, 24 weeks):

- Return to work (Yes/No), Return to same role / altered role and reasons behind this
    - In those that have returned to work the time and method of return to work (e.g. part time, phased return, workplace adaptions) will be recorded.
    - Requirement for workplace adaptions
- Use of fit notes
- Healthcare utilisation and adherence with rehabilitation programmes
- Details of interactions with occupational health practitioners / departments
- Details of any occupational advice received
- Return to driving following surgery
- Follow up functional status using the joint specific (Oxford hip / knee score) , health utility (EQ5D-5L) and functional status (WLQ) measures measured pre-operatively

This element of the study will provide information about how and when patients return to work following surgery, which groups (both patient and occupational) are at risk of 'delayed' return to work, what interventions are currently being used, and how specific job demands influence workplace disability and productivity prior to and following surgery. It will also provide useful information from patients who plan not to return to work following surgery and the reasons underpinning this decision. It will provide information about the discrepancy between current and desired practice and will identify specific sub-groups most likely to benefit from an occupational advice intervention.

In addition research associates based at each institution will collect information about the timing, content and delivery of current care pathways for hip and knee replacement patients and whether any additional interventions are provided for those intending to return to work following surgery. Information about the uptake and completion of current rehabilitation programmes will be collected. These data combined with information from the cohort study will allow the current 'standard care' pathway to be mapped and allow a basic health economic evaluation of current processes to be undertaken. It will also provide information about the variation inherent in this population of patients, rates of return to work (early within 8 weeks versus late within 16 and 24 weeks) and the factors that influence this.

C. Patient and Stakeholder interview/focus groups

The cohort analysis will be supplemented by qualitative data collected from patients and other stakeholders at each of the three centres The purpose is to obtain additional information about the shortcomings and difficulties with current care and support, how these might be overcome and how this might be translated in to a manualised intervention. This aspect will provide greater detail about the barriers preventing return to work that need to be addressed with an occupational advice intervention. We will also gather participants' views on potential primary outcome measures. Written or verbal consent will be taken from all participants prior to interview.

Interview sampling strategy
From within the cohort, a subset of patients will be approached and invited to participate in interviews. From the group of patients that intend to return to work following surgery a purposive sample of between 10-15 patients in each centre (or a maximum of 45 patients from all centres) will be interviewed. This number of interviews should provide sufficient diversity of views and experiences. Interviews will be conducted at 16 weeks post surgery to coincide with the final follow up time point of the cohort analysis. Patients will be sampled ensuring at least seven participants have had knee surgery, and seven have had hip surgery, and will represent a range of work roles and employing organisations. A further 3 patients at each centre (or a total of 9 patients from all centres) from the group of patients that do not intend to return to work will also be invited to interview to provide supplementary information from this group. Individual interviews will be conducted face-to-face at the patient's home or at the hospital, or by telephone, as preferred by the patient.

A sample of individuals from local employing organisations will also be invited to participate in individual face-to-face or telephone interviews. These individuals will be recruited from a variety of organisations of different sizes and sectors at each site. The sample will include human resources managers, line managers, occupational health and trades union representatives. Potential participants will be recruited through local employer organisations (e.g. Engineering Employers' Federation, the Institution of Occupational Safety and Health, Chartered Institute of Personnel and Development, Federation of Small Businesses, local Occupational Health networks and Chambers of Commerce) and contact networks developed by the research team. Employer participants will be eligible if they have experience of employees undergoing THR/TKR in the previous twelve months. Participants will be sampled from large organisations, small and medium-sized enterprises, the public, private and third sector, and manufacturing and service sectors. It is anticipated that a purposive sample of approximately eight individuals at each site (24 in total) will provide sufficient diversity of views and experiences.

We are aware that there may be potential issues with employer engagement. In our experience, for example in studying fit note use, recruitment of employers has not proved to be a problem as long as there is flexibility in dates, times and interview locations. Given the subject matter there will be a 'buy-in' for employers by increasing their ability to retain workers and to meet health, safety and wellbeing guidance and recommendations. By working flexibly with employers we have not found a need to compensate them for their time. To facilitate employer engagement we have included Prof Kahn as a co-applicant. As the current chief medical advisor for EEF, the manufacturers' organisation, he has strong links with a number of occupational health and employer organisations that will aid with both recruitment and dissemination of information.

Data will also be collected from orthopaedic surgeons, allied health professionals (AHPs: occupational therapists and physiotherapists) and nurses, and General Practitioners (GPs) involved in the pre- and/or post-operative care of patients undergoing hip or knee replacement. Orthopaedic consultants undertaking a

minimum of 20 THR/TKR operations per year will be eligible as this threshold will encompass surgeons with a specific interest in hip and knee replacements that are more likely to have experience of patients that return to work following surgery. AHPs and nurses involved in the current care pathways at each centre will be recruited. GPs with experience of treating patients undergoing either THR/TKR in the previous twelve months will be eligible. Potential participants will be recruited through local GP networks, LCRN primary care teams, and lists of GPs collated at each of the study centres. Where possible, focus groups will be arranged for each of these groups as this method can facilitate debate where there is potentially greater difference of opinion. However, if this is not practical then individual face-to-face or telephone interviews will be arranged. It is anticipated that a sample of twelve orthopaedic consultants, twelve AHPs / nurses and twelve GPs sampled from across all of the study sites will provide sufficient diversity of views and experiences.

Interview structure and theoretical framework

A semi-structured interview method will be used for both interviews and focus groups. Interview schedules and prompts will be developed by the research team and informed by service users and other study stakeholder representatives. Interviews will be digitally recorded and transcribed verbatim. Data will be analysed thematically using the Framework Method (Ritchie J 2003). This method is widely used in health research and particularly recommended for use in multi-disciplinary health research teams (Gale 2013).

The theoretical framework for the qualitative research reflects an essentialist/realist perspective, reporting on the experiences, meanings and reality of the participants, rather than examining the ways on which the broader social context impinges on those meanings. The biopsychosocial model will underpin the focus of the interviews. Findings from the interview study will be combined with evidence synthesis and mapping of current practice to identify intended outcomes and performance objectives by Dr Carol Coole together with the research assistants conducting the interviews. They will then map the objectives to appropriate theories or models to guide the strategies to be used in the intervention. We have provided an example of the theory of planned behaviour (See IM stage 3 on page 13). Others are likely to include social cognitive theory, cognitive behavioural theory, participatory ergonomic models. The initial results of this mapping process will be circulated to other members of the research team for comment and discussion by email and teleconference, and revised accordingly

IM Stage 2: Identify intended outcomes and performance objectives

Using the findings of Stage 1, the research team will specify who and/or what needs to change in order for workers to make a successful return to work following hip/knee replacement. A matrix of performance objectives for each stakeholder group will be constructed. The IM approach acknowledges that a number of factors might determine whether or not the objective is reached. For example, for the patient, one of the objectives might be to develop a return to work plan:

Performance objective	**Personal determinants**			**External determinants**	**Expected outcome**
	Attitudes /beliefs/ emotions	**Knowledge**	**Skills / Self-efficacy**	**Barriers/Support**	
1. Develop a return to work plan	Willingness to make effort to develop plan	Knowledge about the importance of phased RTW	Confidence in discussing plan with employer	Employer willingness to engage with RTW plan Healthcare encouragement in RTW	Return to work plan agreed between employee, employer and healthcare team

IM Stage 3: Selecting theory-based methods and practical strategies

During this stage we will generate a list of possible components matched to each performance objective/determinant, using theory, evidence, experience and consensus to identify the most practical ways to implement these interventions. Using the above example:

Objective/Determinant	**Theoretical model**	**Strategy**
Confidence to discuss RTW plan with employer	Theory of Planned Behaviour	Clinical team assess patient's relationship with employer, anxieties about contact, explain role of work modifications, explore possible options, liaise with employer if required.

PHASE 2: (Delivered in Months 10-27)

During Phase 2, the possible interventions with associated theory-based methods and practical strategies for the occupational health intervention identified in phase 1 will be developed in to a manualised intervention using a modified Delphi consensus process. An implementation and education plan will be then be developed to facilitate adoption of the intervention with a small cohort of patients in each of the study centres. Finally, the occupation advice intervention will be assessed using these cohorts to determine its feasibility, practicality and acceptability as a) an intervention for clinical practice and b) a potential trial intervention for any subsequent clinical trial. The final intervention will be revised and refined based on feedback from this process.

IM Stage 4: Developing components and materials for the manualised occupational advice intervention
The first stage of this phase will see the information and associated occupational advice strategies identified within Phase 1 translated into specific tailored tools and materials which will be considered as components for inclusion in the manualised intervention. A modified three-round Delphi process including all identified components from Phase 1 will be used to identify the strengths and weaknesses of these individual components and reach a final consensus on intervention content.

The modified Delphi process will engage with the key stakeholder groups identified previously (e.g. patients, employers, orthopaedic surgeons, AHPs and nurses, GPs). Specific members of the research team will be responsible for the identification, engagement and recruitment of each stakeholder group (see section 'stakeholder engagement strategy' on page 15) in attempt to ensure wider stakeholder participation.

A. Consensus process (A detailed version of the Delphi consensus protocol can be found in Appendix 1)

The modified Delphi process is an anonymous, multi-round, consensus-building technique used to generate, analyse and synthesise expert views to reach group consensus. Using this technique we intended to present information about potential components of the occupational advice intervention to a group of informed stakeholders in order to seek their opinion and judgement on the likely content of the final intervention. This process can be performed remotely, making it easier to gain a national sample, and anonymously, meaning that responses can be requested with the potential threat of peer pressure removed (Keeney 2011).

We wish to engage with all five of the listed stakeholder groups and we will be inclusive for any stakeholder member who wishes to participate. We intend to use both local and national stakeholders within the Delphi consensus process. We believe that some of the 'local' participants from the Phase 1 elements (cohort study and interviews) may express a wish to be involved in the consensus process but we will not recruit solely from this pool. It is our intention that 'local' stakeholders will be supplemented by 'national' stakeholders within the final Delphi panel. 'National' stakeholders will be recruited through the national groups outlined below under 'Stakeholder engagement strategy' (page 15).

To ensure wide participation and to ensure the validity of the consensus process we will recruit a minimum of 5 individuals from each stakeholder group. A maximum limit of 15 individuals from any given stakeholder group will be used to ensure one groups' opinions do not overwhelm the opinions of others within the consensus process. Before commencement all participants will be sent an introductory letter and/or email outlining the purpose of the process. Participants will be informed that they will not be identified to each other during the process and that they need not conform to the group view.

We will use a modified three-round Delphi process. We will follow the recommendations for reporting, developed by Sinha et al. (7) which focused on use of Delphi for development of core outcome sets, but which are applicable to the use of Delphi for other purposes. Before the Delphi process starts participants will be informed that the purpose of the process will be to reach a consensus on:

- The content of an occupational advice intervention to facilitate return to work and usual activities after hip and knee replacement
- The method, format and timing of delivery of an occupational advice intervention
- The essential qualities of an outcome measure for assessing return to work and usual activities after hip and knee replacement

The basis for the OPAL Delphi consensus process will be the information gathered during the intervention mapping stage 1 (Needs assessment) via the rapid evidence synthesis, cohort study and stakeholder interviews. Data from stage 1 will be analysed within intervention mapping stages 2 (Identification of intended outcomes and performance objectives) and 3 (Selection of theory-based methods and practical strategies) to create a list of specific themes and tailored tools / materials to be explored during the Delphi process. As the Delphi process progresses these will be refined and developed into specific components for inclusion in our occupational advice intervention.

Overview of the Delphi consensus process:

- **ROUND 1:** Within round one we will aim to define the content of the intervention. This will include passive ('written' advice and information) and active (actions or processes for patients, employers and healthcare members to undertake) content.
- **ROUND 2:** Round two will focus on the delivery and format of the intervention. Having developed an outline of the proposed content within Round 1, Round 2 will address how, when and who will deliver the intervention. Round 2 will also explore areas of residual uncertainty from Round 1 and address the measurement of outcome for the intervention and any subsequent trial.
- **ROUND 3:** In the final round participants will be asked to clarify any ongoing areas of uncertainty from Rounds 1 and 2. They will be presented with a draft framework for the proposed intervention and be invited to provide feedback and comment.

In each round participants will be sent and electronic survey via email. The participants will be presented with a number of statements relating to the proposed intervention. They will be asked to select a response for each statement within the survey. For each statement within the survey participants will be asked to rate individual statements with possible options being:

- Strongly agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Following each round the rankings for each statement will be summarised and circulated within the investigator team. Statements reaching consensus (>70% agreement or disagreement) will be listed for inclusion within the intervention. Specified criteria will be used to decide which statements that do not reach consensus should be taken forward for re-evaluation in the subsequent Delphi round.

During subsequent rounds a similarly structured survey will be circulated with the statements for that round. However, it will also include a summary of a) the modal round one rating for each intervention / outcome component for the previous round b) a reminder of each participants own round one ratings. Furthermore participants will be given the opportunity to change their ratings for statements for which there is residual uncertainty and rate any additional interventions / outcomes suggested during the previous round.. After each round the rankings will again be summarised and assessed for degree of consensus. If an acceptable degree of consensus is obtained the process may stop and final results fed back to the participants. However it is likely that a third round will be needed.

There is no complete agreement about when to terminate a Delphi survey and what constitutes an acceptable level of consensus as this varies dependent on the survey's purpose. (Jones 1995, Strauss 1975). It has been argued that 'if no consensus emerges, at least a crystallizing of the disparate positions usually becomes apparent' (Gordon 1971). Keeney et al (2011) suggests the level of consensus should be decided before commencing the study, and recommends the level be set at a minimum of 70%. In the initial phase we will set a consensus for inclusion of >70% 'Strongly agree' or 'Agree' and a consensus for exclusion of >70% 'Strongly disagree' or 'Disagree'.

Once consensus has been reached the research team will:

a) Draft all of the 'included' components of the occupational advice intervention in to a document and circulate it to Delphi panel members for final open comment.

b) Develop three different strategies for the delivery the occupational advice intervention. These will be based on consensus information about the timing and mode of delivery (For example: paper based manual, electronic manual, supplementary online content). The three methods developed will then be used to deliver the occupational advice intervention at each study centre and compared during the feasibility assessment.
c) Define a suitable 'return to work' outcome measurement strategy for use within the feasibility assessment.

The process will conclude with a one-day meeting of the research team and steering group to review the feedback from the Delphi group and finalise intervention content. Using information from the Delphi survey this meeting will also determine the format and optimal method of delivery for the intervention at each of three study sites during the feasibility assessment. It will also define the preferred outcome measure for intervention assessment. The occupational advice intervention will then be re-drafted and finalised as the final part of this stage.

IM Stage 5: Adoption and implementation plan

Stage 5 focuses on the implementation and adoption of the intervention will run concurrently with the final stages of intervention development as the content, format and method of delivery becomes finalised. The implementation plan will initially focus on the three modes of intervention delivery developed as part of the consensus process within a small cohort of 5-10 patients in each of the study centres. It will be designed to address the gaps and/or barriers identified within these centres in Phase 1 and assess how the intervention can be delivered alongside 'standard' care at each of these sites.

The optimal time to offer patients an occupational advice intervention is within the initial outpatient consultation during which they are listed for surgery. This is based on the following factors:

a) Patients and other members of the hospital orthopaedic team (AHPs, nurses) take the lead from their surgeon. Surgeons are integral to the delivery of information to their patients. Patients are guided by their surgeons and in many cases will not contemplate or consider returning to work without the permission of their surgeon. At the same time Allied Health Professionals and General Practitioners involved in the care of these patients will often defer decisions relating to return to work to the surgeon.
b) In over two thirds of cases the only time the patient sees their surgeon prior to surgery is in the initial outpatient consultation. Surgeons do then do not see patients again until the morning of their operation limiting the opportunity for interaction between the surgeon and their patients.
c) Over 90% of surgeons do not offer routine advice to patients returning to work after surgery and when it is delivered it is ad-hoc verbal advice based on anecdote and personal experience. We therefore have a situation where patients, GP's and Allied Health Professionals within the hospital orthopaedic team are looking to the surgeons to lead the return to work process, however the surgeons are not routinely giving advice and if they do it is not based on specific guidance or best practice.
d) The pre-operative assessment process is extremely varied between trusts. The composition, timing (sometimes only a week before surgery) and staffing of these services make it difficult to embed an intervention that fulfils the individualised needs of this patient group.

Therefore the best time to start an intervention to assist return to work after surgery is within the patient's initial outpatient consultation with the input of the surgical team. This is a consistent pillar of the preoperative pathway in all institutions and allows adequate time for patients and employers to develop communicate and instigate a suitable plan to enable early and sustained return to work.

Potential users of the intervention will be defined using similar eligibility criteria to that used in Phase 1: a) placed on the waiting list for hip or knee replacement during their outpatient appointment with the surgical team b) in work in the 3 months prior to being added to the waiting list for joint replacement and c) intending to return to work following surgery. The intervention will be designed to allow 'flexible' delivery alongside current 'standard' care whilst stipulating the achievement of specified performance objectives against which the fidelity of the intervention will be assessed. An outline of the proposed intervention with associated patient and staff performance objectives is given in Appendix 2. The delivery frameworks used by each centre and the methods and strategies used to achieve the necessary change in behaviour given the institutional

context will be addressed as part of this stage of the IM process. This is likely to involve education and training of relevant staff at each site in the delivery of the intervention, but may involve other issues such as the design of the clinical pathway, alterations to length of hospital stay, clinical documentation, and staff skill mix and allocation etc. Appropriate support systems will be developed and an implementation plan constructed to assist adoption of the new occupational advice intervention within each of the study centres.

IM stage 6: Evaluation plan and 'feasibility' testing

This study aims to assess how feasible it is to undertake a trial to evaluate whether an occupational advice intervention delivered to working adults, prior to primary hip or knee joint replacement surgery, improves speed of recovery to usual activities including work. The final stage of the intervention mapping process will therefore focus on evaluating the fidelity of the intervention (its practicality, acceptability and feasibility of delivery) by assessing the intervention against defined performance objectives. The performance objectives will include specific objectives for hospital orthopaedic teams (staff objectives) and patients (patient objectives) both of whom will be potential participants in a future trial (See Appendix 2). The 'feasibility' stage will include not only an assessment of the intervention (intervention fidelity) but also an assessment of the feasibility of undertaking a trial using the intervention by assessing screening, recruitment, consent and follow up procedures and rates at each of the study sites. It is not our intention to undertake a formal pilot study during this stage (as per the commissioning brief). Delivery of the intervention is the key component in a future trial and as this is a newly developed intervention, testing its fidelity is crucial.

During the feasibility testing stage the cost of delivering the intervention will be also estimated; this will include type and grade of staff necessary to deliver the manual and the duration of these contacts. It will also assess the suitability of the intervention and selected 'return to work' measure as a future trial intervention and primary outcome measure respectively. The utility of the developed intervention as a tool for clinical practice will also be assessed alongside the evaluation of feasibility as a trial intervention.

The methods for the 'feasibility' testing stage will be similar to the methods used in Phase 1 (See flowchart in Appendix 3). All patients attending the outpatient clinics of participating surgical teams at each of the study sites will be screened using a screening occupational checklist. All patients will be asked to complete the first section of the checklist that asks about work status and details of any work undertaken. The surgical team will then complete the second section confirming the patient's eligibility based on the study inclusion / exclusion criteria (see section 11, page 19). Details of eligible patients will then be passed over to the research team who will approach the patients, explain the nature of the study and seek written consent. At each site we will aim to recruit an average of 10 patients (30 patients across the 3 sites) for a cohort assessment of the intervention. This will be performed using similar patient questionnaires, outcome measures and sampling time points (Baseline (pre-operative when listed for surgery) and at 8 and 16 weeks after surgery) as those used in Phase 1. This will be supplemented by the selected 'return to work' outcome measure defined during the consensus process (If not already collected). As part of these questionnaires patients will be asked for details of other resources they have used as part of their rehabilitation process and the frequency of this use. This will inform the design of an economic evaluation that may be required alongside the full trial.

The information from the cohort analysis will be supplemented by a maximum of 15 patient and 12 stakeholder interviews (sampling from employers, health professionals, nurses, G.Ps, orthopaedic surgeons etc.) across the 3 study sites. Patient interviews will be performed at 8 weeks post-surgery. Stakeholder interviews will be performed once all patients at the site have received surgery (i.e. once all patients are recruited and have as a minimum been through the pre-operative phase of the intervention). These interviews will collect information about the fidelity of the final intervention and will be structured to assess the specified patient and staff performance objectives linked to the intervention. Using the methods described we will also collect and monitor other key information such as a) patients' and surgeons' views on their willingness to participate in such a future trial b) potential rates of recruitment and proportion of eligible patients consenting c) information about the behaviour and distributional characteristics of the selected 'return to work' outcome measures that will help inform the power calculation for any subsequent trial. We will therefore capture the core components of feasibility with stages 5 and 6 which will allow us to make a recommendation about the feasibility of any subsequent trial.

A six month period has been allocated to undertake this feasibility element although this is currently under review given the need to commence the intervention during the patient's outpatient clinic appointment and

the current position with NHS waiting lists due to winter cancellations and on-going bed pressures. We envisage that it will be possible to recruit the 10 patients required at each site within the first month of this period.. Analysis of this data and revision of the final occupational advice intervention will then occur within the reporting period at the end of the study

7. Stakeholder engagement strategy

We have identified 5 key stakeholder groups that are central to the development of the intervention. These are: patients; employers and their associated occupational health departments; allied health professionals (occupational therapists and physiotherapists) and nurses; orthopaedic surgeons; and general practitioners. To maximise engagement with these stakeholder groups we have identified a nominated member of the research team to be responsible for the identification and engagement of stakeholders within their area of expertise. This approach is facilitated by the structure and expertise inherent in the research team that includes members from all of these stakeholder groups. We have identified a number of professional bodies and employment institutions that will be approached as part of this stakeholder recruitment process. We believe this will provide the breadth of opinion and insight required to ensure generalisability and acceptability of findings and assist with dissemination of findings at various stages of the study.

We have specifically targeted the employment sector in this regard. Co-applicant Prof Sayeed Kahn is the current Chief Medical Adviser of EEF, a manufacturers' organisation that influences workplace health practices in 6,000 organisations totalling about a million employees. He has active links with a number of healthcare and employment bodies including the Health, Work and Well-being Strategy National Stakeholders Council as well as entities such as the Federation of Small Businesses, Confederation of British Industry, Trade Union Congress, the Department for Work and Pensions, the Fit for Work Service and the Work Foundation. Using his expertise we are confident of engaging with employers covering a range of employment types, structures and size.

An overview of the stakeholder engagement and recruitment strategy is given the table below:

Stakeholder group	Nominated research team lead	Participants recruited via:
Patients	Mrs J Fitch	National Joint Registry patient network British Orthopaedic Association patient group Patients identified from the cohort / interviews in phase 1
Employers and occupation health services	Prof S Khan	Federation of Small Businesses EEF – The manufacturers organisation Confederation of British Industry Trade Union Congress Department for Work and Pensions The Fit for Work Service The Work Foundation The Society of Occupational Medicine Institution of Occupational Safety & Health Society of Occupational Health Nurses Employers identified from the interviews in phase 1
Orthopaedic Surgeons	Mr I McNamara	British Hip Society British Association for Surgeon of the Knee British Orthopaedic Association Surgeons identified from the interviews in phase 1
Allied Health Professionals (AHPs – Physiotherapists and Occupational therapists) and nurses	Dr D McDonald & Dr C Coole	Association of Chartered Physiotherapists in Occupational Health and Ergonomics Chartered Society of Physiotherapy Occupational therapy networks e.g. Royal College of Occupational Therapists Specialist Sections in Work and Trauma & Orthopaedics Royal College of Nursing

		AHPs and nurses identified from the interviews in phase 1
General Practitioners	Mr P Baker & Prof A Rangan	Local Medical Committees Royal College of General Practitioners Local Clinical Commissioning Groups G.Ps identified from the interviews in phase 1

8. Health technologies being assessed

The health technology being developed is a manualised occupational advice intervention intended to expedite return to work in patients undergoing elective hip and knee replacement

9. Design and theoretical/conceptual framework

The occupational advice intervention will be developed using an intervention mapping methodology. This process will utilise a mixed methods approach during the needs assessment and feasibility testing stages (rapid evidence synthesis, prospective cohort study, structured interviews with patients and stakeholder groups) and a consensus process using a three-round Delphi consensus during the intervention development stage.

10. Target population

Patients of any age who are in work prior to elective primary hip or knee replacement and intend to return to work following surgery.

11. Inclusion/ Exclusion criteria

11.1 Inclusion criteria for patients recruited into the cohort / interview elements of study during Phase 1:

- Age 16 years and above
- Patients on the waiting list for primary hip or knee replacement
  In work within 6 months prior to joint replacement (including Full time, Part time, Paid & unpaid job roles) – 3 months prior to listing for surgery for feasibility stage (equates to approximately 6 months prior to surgery)

11.2 Exclusion criteria

- Lack of mental capacity to understand and participate in the cohort study
- Patients who do not understand written and spoken English
- Emergency surgical procedure e.g. Surgery for an indication of trauma
- Surgery for cancer
- Surgery for infection

11.3 Inclusion criteria for patients recruited into the cohort / interview elements of the feasibility assessment during Phase 2

- Inclusion criteria as listed in 11.1
- Patients intending to return to work following surgery

12 Setting/context

Study will be performed in a minimum of three UK teaching hospitals (Middlesbrough, Nottingham, Norwich) chosen to represent a mixture of semi-rural and urban populations across a range of socio-economic groups and two UK Higher Education Institutions. The intended study design will deliver wide stakeholder

involvement from patients, surgeons, AHPs and nurses, GPs and employers during all elements of the study. This should help ensure results are generalisable and maximise acceptance to all service users.

13 Search strategy for evidence synthesis

Please refer to section 'Rapid Evidence Synthesis' on page 9.

14 Sampling

In Phase 1 patients will be sampled from the lists of patients undergoing hip and knee replacements in each of the study centres. The eligibility criteria listed in section 11 will be applied to patients recruited to the prospective cohort and structured interviews elements of Phase 1. In total we aim to recruit 150 patients across the study sites (including a minimum of 60 hip and 60 knee replacements) to the cohort study. From this cohort 15 patients (minimum 7 hip and 7 knee replacements) or a total of 45 across the study sites will also be recruited for interview. Further interviews will be conducted with stakeholders sampled from the study sites. These include orthopaedic surgeons (12), AHPs and nurses (12), GPs (12) and employers (24) involved directly in the care of patients undergoing hip and knee replacement procedures in the preceding 12 months.

The sample size for the cohort analysis was chosen to strike a balance between adequate sampling and cost. The cohort is an observation of current practice and the sample size assumes a conservative estimate of eligible and consenting patients. A sample of 150 patients will be sufficient for representative estimates within an 8% margin of error with associated 95% confidence level (Bartlett 2001). The margin of error under different assumptions (number of procedures per site and recruitment rate) is presented in the table below. In addition, based on the rule of thumb of ten events per variable in logistic and cox regression, a sample size of 150 will allow a maximum of seven predictor variables to be included in the regression analyses; depending on the number of patients with the outcomes of interest (e.g. early return to work). We also felt that, given the volume of procedures undertaken at the three study sites, the recruitment of 50 patients per site was achievable within the timeframe outlined within the proposal.

Procedures per site per month	% working and intend to return	Eligible patients per site per month	Consent rate	Consenting patients per site	Total	Margin of error
100	33%	33	50%	50	150	8%
100	33%	33	75%	75	225	7%
150	33%	50	50%	75	225	7%
150	33%	50	75%	113	339	6%

In Phase 2 relevant stakeholders groups (patients, employers, AHPs and nurses, orthopaedic surgeons, GPs) will be invited to participate in a three-round Delphi consensus process. From each of these stakeholder groups we will sample a minimum of 5 and a maximum of 15 participants for inclusion in the Delphi process. In the final, evaluation stage of Phase 2 a further cohort of 30 patients will be recruited (average of 10 at each site) from surgeons performing hip and knee replacements. This cohort will test the fidelity of the intervention against specified performance objectives using questionnaire data (all patients) and further structured interviews (maximum 15 patients). These interviews will be supplemented by interviews with twelve other stakeholders (AHPs / Nurses, GPs, surgeons, employers) identified across the study sites.

15 Data collection

The Case Report Forms and outcome questionnaires for each phase/stage will be designed and agreed by the Study group. Personal data collected during the trial will be handled and stored in accordance with the 1998 Data Protection Act. Original CRFs must be sent to the co-ordinating team lead for each phase/stage of the study and copies retained on site. All of the data collected in this study will be entered into a secure database. All electronic patient-identifiable information will be held on a secure, password-protected database

accessible only to essential study personnel. Paper forms with patient-identifiable information will be held in secure, locked filing cabinets within a restricted area of each hospital. Patients and other stakeholder participants will be identified by a study number only. Personal information, such as participant's name, address and telephone number will be stored, in a separate file from the questionnaires and interview recordings/transcripts for the cohort studies and interviews for the duration of the study.

Personal contact details (address, telephone number) will continued to be retained after the end of the study for up to three years. This information will be used in the event that we need to contact the patients about the findings of the study (unless they advise us that they do not wish to be contacted). Only members of the research team (University of York & University of Nottingham), the Sponsor (South Tees Hospitals NHS Foundation Trust) and the recruiting NHS Trust will have access to the personal data. Some of the questionnaires ask for the participant's age, gender, date of surgery, and the first part of their postcode, as this is required research data. As requested by the funder (the HTA) written consent will be taken for collected data to be linked to routinely collected health data stored in national databases (via NHS Number) although this activity does not form part of this research project. Any other information (study data) about the patients which leaves the hospital will have their name and address removed (anonymised) and a unique code will be used to help protect their identity.

Personal data will be disposed of securely after it is no longer necessary to contact the patients/participants. All other research data will be stored securely for seven years, and after this time will also be disposed of securely. During this time all precautions will be taken by all individuals involved to maintain the confidentiality. If a patient makes a disclosure to a member of the research staff, which makes them seriously concerned about the patient or someone else's safety or well-being, the researcher is obliged to break confidentiality in accordance with the Human Rights Act 1998.

16 Data analysis

Quantitative data, derived from the cohort study questionnaires, will be analysed by Catherine Hewitt at York Trials Unit. All participant and centre data will be entered into a database for analysis. All analyses will be undertaken in Stata and will mainly be descriptive: continuous measures using n, mean, standard deviation, median, 1st and 3rd quartiles, minimum and maximum and categorical data using counts and percentages. For each centre, current practice will be summarised including timing, content and delivery of current care pathways for hip and knee replacement patients and whether any additional interventions are provided for patients intending to return to work following surgery. Preoperative patient characteristics, operative and postoperative data will also be summarised. A logistic regression model will be undertaken to predict early return to work (within 6 weeks) including preoperative, operative and postoperative characteristics. In addition, a Cox proportional hazards model will be undertaken to predict time to return to work in days from the date of the operation using the same covariates as the logistic regression.

Qualitative data, derived from the structured interviews, will be analysed by Carol Coole at Nottingham University. All interviews will be digitally recorded and transcribed verbatim. Data will be analysed thematically using the Framework Method (Ritchie J 2003). Following familiarisation with the data, the first few transcripts in each group will be independently coded by the interviewers, who will then compare, revise and agree a set of codes and/or categories to form a working analytical framework. This framework will be used to code the remaining transcripts in each group, but will remain flexible should further codes be identified. Summarised data will then be charted into a framework matrix to facilitate comparison of data across cases and groups as well as codes and categories. Potential themes will initially be identified independently by the interviewers who will then meet to discuss, revise and agree the final themes.

17 Dissemination and projected outputs

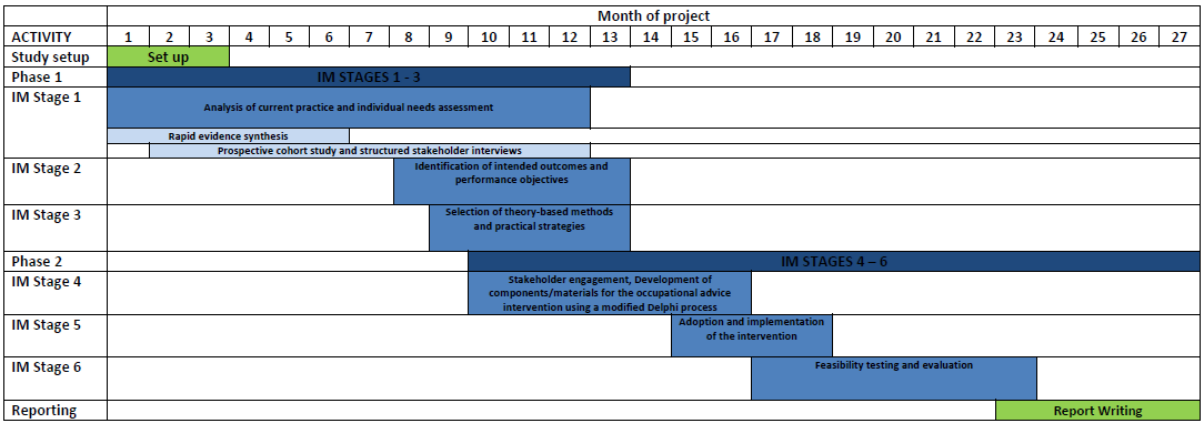
We will be mindful in all dissemination activities and production of outputs that we are reporting the results of a feasibility study and not a definitive trial determining the effectiveness of the occupational advice intervention. The key outcome of the study will be to lay the foundations for a definitive trial through establishing the relevant population and their needs, developing a manualised intervention that is acceptable

to stakeholders and suitable for routine delivery in the NHS, describing usual care (comparator for future trial) and identifying appropriate outcome measures. Dissemination activities will focus on reporting the research activities to inform the future trial (rather than the key focus of implementation in a definitive trial) and will cover the wide range of groups to which the findings will be of relevance to.

We intend to produce the following outputs, all of which will involve signposting those interested in further details to the full HTA report.

1. Given the wide range of healthcare professionals which the findings will be relevant to we will submit the main report of findings to the British Medical Journal. There will be other articles to publish such as the rapid review which we will submit to relevant academic journals to ensure maximum exposure to relevant groups.
2. We will present at relevant conferences of (e.g. British Orthopaedic Association (BOA) Annual Congress, Physiotherapy UK conference, College of Occupational Therapists' Annual Conference; Society for Research in Rehabilitation) and provide a summary report to be circulated through networks such as that provided by BOA, the National Physiotherapy Research Network and the College of Occupational Therapists. Wider dissemination to other health professionals such as general practitioners as well as employers through organisations such as EEF and CBI will also be facilitated.
3. We will work with the patient representatives to produce a short lay report which will be fed back directly to the study participants and wider patient community via the National Joint Registry and BOA patient groups
4. Publication of the findings will be press released through the collaborating NHS organisations, employers, occupational health service organisations and universities and the potential for short articles in the relevant lay media will be explored.

18 Plan of investigation and timescale



Project timescale is currently under review by the HTA.

19 Project Management

As the Chief Investigator (CI) Paul Baker will be responsible for overall management of the project. As a first time CI he will be mentored by Amar Rangan, an experienced CI from the same institution. Given the different elements of the study and expertise required, named individuals will be responsible for specific elements. The qualitative research and development of the occupational advice intervention and manual will be led by Carol Coole, supported by Avril Drummond at the University of Nottingham; the rapid review will be led by Catriona McDaid at University of York; the prospective cohort study led by Paul Baker based at South Tees NHS Foundation Trust; the Delphi consensus process led by Amar Rangan and Paul Baker based at South Tees NHS Foundation Trust, supported by Avril Drummond at the University of Nottingham; and data analysis of the quantitative elements will be led by Catherine Hewitt at University of York.

The complete research team (co-applicants and researchers employed for the project) from the participating institutions will convene for a start-up meeting followed by approximately quarterly project team meetings to coincide with key milestones of the project. In addition, there will be contact by teleconference and skype on at least a monthly basis. The research teams at the three institutions will meet on at least a fortnightly basis.

The South Tees Hospitals NHS Foundation Trust has agreed to be the lead sponsor for this project. This study will be fully compliant with the Research Governance Framework and MRC Good Clinical Practice Guidance.

Project oversight committee

The project will be overseen by the project oversight committee. This will comprise the CI of the research team alongside 4 or 5 independent lay members including at least 1 additional lay patient representative. The project oversight committee will meet at similar time points to the investigator meetings.

20 Approval by ethics committees

The study will adhere to the good clinical research practice guidelines (MRC and Research Governance Framework). The participant information sheet for the cohort study and small study testing the intervention, will be developed with the involvement of service users, and will give a balanced account of the possible benefits and known risks of participation. It will state explicitly that quality of care will not be compromised if the participant decides to a) not participate in the study or b) withdraw their consent. Written informed consent will be obtained from all patients participating in the study and written or verbal consent will be obtained from all stakeholders participating in the interviews. An application for ethical approval will be made through the Health Research Authority (HRA). We do not anticipate major ethical concerns with this study. We have excluded patients who lack mental capacity; however this is very rare in patients who are employed and under 70 years of age. Local R&D approval will be sought from each of the participating hospitals. Appropriate ethical approval will also be sought for the research activities outside the NHS and for participation of NHS staff.

21 Patient and Public involvement

During the development stage of this application we have had patient and public involvement and input from the National Joint Registry (NJR) patient network and British Orthopaedic Association (BOA) patient liaison group. Six patients who have had a joint replacement have commented on the proposal and plain English summary.

We are mindful of their feedback in addressing the commissioning brief; for example although the aim is to produce an occupational manual, a recurring concern was that a 'one size fits all' approach could be too generic. Other issues raised were variations across hospitals in the support provided; the needs of specific occupational groups such as self-employed; different expectations amongst people about return to work; the impact of the employer perspective, coupled with concerns about how early return to work interventions may result in pressure for people to return too early.

To address these concerns we will, in Phase 1, ensure we specifically assess individual patient's experiences. The interviews undertaken with the 45 patients (15 at each site) as part of this phase will highlight individual patient's needs, concerns and expectations related to the return to work process. This information, along with information from other stakeholders, will help shape the development of the intervention during the rest of the study. In Phase 2 we will include a minimum of 5 patients in our Delphi consensus process so that we will be better able to understand and address issues pertinent to them within our intervention.

As part of the study team we have included a patient representative as co-applicant (Mrs Judith Fitch). Mrs Fitch will be involved in the on-going management of the study through her involvement with the trial steering group, intervention development meetings and the dissemination of study findings. To supplement our lay co-applicant we will also invite a second lay person (to be confirmed) to sit on the trial steering committee. In addition we will continue to work with the National Joint Registry patient and public involvement group and the BOA patient network. We have worked closely with these groups already and will continue to work

alongside them to help develop the study documentation for the cohort analyses and qualitative interview elements of the study. This will include assistance developing lay summaries, patient information sheets and consent forms. The costing for all PPI activity has been calculated using the guidelines on the INVOLVE website.

22 Expertise and justification of support required

This is a mixed methods study which has a wide range of relevant stakeholders whose views will need to be sought when undertaking the research. A range of expertise is therefore required to ensure that the work is carried out to the highest standard and within the timescales proposed. In addition, several elements are carried out in parallel to each other which would be difficult to achieve by single researchers. We have therefore established a team that includes the research expertise, clinical expertise and topic knowledge to undertake the work as well as an expert panel of patients/public participants. The team includes researchers with expertise in undertaking qualitative research, Delphi exercises, systematic reviews, randomised controlled trials and cohort studies and clinicians involved in the care of people undergoing lower limb joint replacement including orthopaedic surgeons, general practitioners, physiotherapists, occupational therapists and occupational health physicians. The inclusion of a behavioural psychologist and health economist will benefit these elements of the study. The team also includes members involved with manufacturing and employment groups and with active links to a range of occupational health and employer organisations.

Mr Paul Baker (South Tees Hospitals NHS Trust): Paul Baker is an orthopaedic surgeon and honorary clinical lecturer with a particular interest in the treatment of patients requiring hip and knee replacement surgery. His previous research has focussed on clinical outcomes following hip and knee replacement procedures and he has published extensively in this area. Paul has expertise in the interrogation and analysis of large quantitative cohort data through his involvement with a number of large national datasets (National Joint Registry, Hospital Episode Statistics, Patient Reported Outcome Measures). He has previously been Principle investigator on NIHR studies (ISOS, WHITE3:HEMI). Paul will be chief investigator for the study and, in addition to study oversight, will have specific responsibility for leading the cohort element of Phase 1 and assisting with the Delphi consensus within Phase 2.

Professor Sayeed Khan (University of Nottingham): Sayeed Kahn is a general practitioner, occupation health consultant and Honorary Professor in Occupational Health at the University of Nottingham. He is the current Chief Medical Adviser of EEF, the manufacturers' organisation. This organisation influences workplace health in 6,000 organisations totalling about a million employees. He has active links with a number of healthcare and employment bodies including the Health, Work and Well-being Strategy National Stakeholders Council; NICE's Programme Development Group on long term sickness absence guidance; the Government's Fit Note Stakeholder Group, the RCGP's National Education Programme in Health and Work for GPs and the recent Department of Health's Responsibility Deal initiative. In 2011 he chaired a working group for the Government looking at the strategic direction of health, work and wellbeing for the next five years and was a board Member of Health and Safety Executive for six years. Sayeed will be responsible for employer engagement throughout the study and will facilitate dissemination of findings within this stakeholder group.

Professor Avril Drummond (University of Nottingham): Avril Drummond is Professor of Healthcare Research and Director of Research in the School of Health Sciences. She is an occupational therapist and rehabilitation researcher with an interest in trials and service evaluations. Avril has expertise in conducting feasibility studies, designing rehabilitation interventions, conducting mixed method studies and applying Delphi methodology. She is currently involved in several large trials examining rehabilitation in a number of healthcare settings including knee arthroplasty (CORKA, EXTRAS, CRAMMS). She will responsible for the co-ordination of the study elements led by the University of Nottingham (intervention mapping and structured interviews) and will assist with the development and co-ordination of the Delphi process in Phase 2.

Professor Amar Rangan (South Tees Hospitals NHS Trust): Professor Amar Rangan is an orthopaedic surgeon, researcher and clinical trialist. He has been CI for HTA funded trials including the ProFHER trial and UK-FROST, as well as acting as PI on a number of other studies. He is Chair of Trial steering committees (TSC) for HTA funded WOLLF and TARVA Trials and independent member of TSC for the ARUK funded CSAW Trial. Amar is Chairman of the BOA Research Committee and an Orthopaedic Specialty Lead at the RCS Clinical Research

Initiative, with responsibility to develop and support new surgical trials and trialists within orthopaedics. Amar will act as mentor to the CI for the duration of the study and will lead the Delphi consensus within Phase 2.

Mr David McDonald (Scottish Government Health & Social Care Directorates): David McDonald is Senior Physiotherapist and researcher with a particular interest in hip and knee replacement surgery and enhanced recovery rehabilitation programmes. He has extensive experience in service redesign and delivery after working with the Scottish Government to establish a National Programme for Enhanced Recovery in Orthopaedics. David is currently seconded full time to the Scottish Government within the Whole System Patient Flow Programme and leads on a wide variety of service improvement programmes. He is the National lead for Enhanced Recovery across all specialities in Scotland and works with a number of universities to further improve patient care and evaluate interventions to improve outcomes. David will be responsible for engagement with AHP groups throughout the study and will form part of the core team involved in drafting and revising the occupational advice intervention within Phase 2.

Dr Carol Coole (University of Nottingham): Carol Coole is an occupational therapist with a particular interest in treating musculoskeletal conditions. She has research expertise in qualitative methodology and has a specific interest in return to work issues; she has conducted research studies of return-to-work in musculoskeletal conditions including back pain. Her most recent study was a mixed methods study of 'fit notes' which included recruiting GP, patient and employer participants. She will be responsible for leading on the Intervention Mapping process and will supervise the structured interviews in Phases 1 and 2.

Professor Catherine Hewitt (York Trials Unit, University of York): Catherine Hewitt is Professor of Trials and Statistics and Deputy Director of York Trials Unit. She has over 13 years' experience of designing and analysing trials across a broad spectrum of topic areas with a particular interest in orthopaedic research. Her research has focused on developing, refining, and applying statistical methods in the conduct of randomised controlled trials. She has developed a programme of research in the analysis of trials, particularly in methodology work in the areas of selection bias, attrition and non-compliance. Catherine will provide statistical support throughout the project, oversee the statistical analysis of the cohort study, contribute to research design and interpretation and provide advice on future trial design

Mrs Judith Fitch (British Orthopaedic Association Patient Liaison Group (BOA PLG)): Judith has been a lay member of the BOA PLG since 2011. She is actively involved in providing plain English clinical content targeted to patients researching treatments and procedures on the internet. Judith is a moderator for a patient knee and hip replacement forum, coaching patients through the joint replacement journey. She is also a stakeholder in the NICE Low Back Commissioning Guidelines group and a Collaborator in the Better Outcomes for Older people with Spinal Trouble (BOOST) research project. Judith will act as patient advisor for the project and lead on patient engagement.

Dr Catriona McDaid (York Trials Unit, University of York): Catriona McDaid is a Senior Research Fellow in health services research including qualitative and quantitative methods. She has over 12 years' experience undertaking systematic reviews including reviews of complex interventions and recent experience of a mixed methods study including patients and healthcare professionals (HTA 13/30/02). She will contribute to the research design and interpretation and lead on the rapid review component of the project.

Mr Iain McNamara (Norfolk & Norwich NHS Trust): Iain McNamara is an Orthopaedic surgeon with a particular interest in hip and knee surgery. He has research expertise in functional recovery following joint replacement and quality of life outcome measures after a variety of lower limb surgical procedures. His most recent research involves patient outcomes and gait analysis after total knee replacement. Iain will be principle investigator for the Norwich site, will be responsible for engagement with Orthopaedic Surgeons throughout the study and will form part of the core team involved in drafting and revising the occupational advice intervention within Phase 2.

Dr Louise Thomson (University of Nottingham): Louise Thompson is Head of Research Support and Evaluation at the Institute of Mental Health, a partnership between the University of Nottingham and Nottinghamshire Healthcare NHS Foundation Trust. She is an HCPC-registered Occupational Psychologist with over 20 years' experience as a practitioner and researcher specialising in the design and management of work, return-to-work and job retention. She has led a number of funded projects in this area including the Implementation of

Employment Support for Mental Health Service users (IPS) (East Midlands AHSN), Best Practice in Rehabilitation following Work-related Stress (Health& Safety Executive), and The Impact of 12-hour Shifts on Health Care Assistants (NHS England). She will provide expertise in the psychological and behavioural factors affecting return-to-work.

Gerry Richardson (Centre for Health Economics, University of York): Gerry Richardson is a health economist with over 20 years' experience in economic evaluation. He has been the lead health economist on over 20 trials and also has experience in trial management, methodological development and data analysis. Gerry will evaluate the health economics of current care and the proposed intervention within the study.

23 Funding Acknowledgement

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24 Department of Health Disclaimer

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Health Technology Assessment (HTA), NIHR, NHS or the Department of Health.

25 Intellectual property

We believe there are no third party rights existing in terms of background intellectual property in relation to this project and as such there should be no requirement for schedule C within the contract. We are happy with the NIHR's standard arrangements and recognise that all arising foreground IP is held by the contractor. We do not wish to enter into any alternative ownership arrangements.

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APPENDIX 1: Delphi protocol (maps to IM stage 4)

1. Modified Delphi Consensus Process

1.1 Overview of Delphi methodology:

The Delphi consensus technique was developed by the Rand Corporation in the late 1940s as a means of reaching a consensus of expert opinion (1). It has subsequently been adopted in medical, nursing and health services research. In a Delphi study a questionnaire or interview schedule is presented to a panel of 'informed individuals' in order to seek their opinion or judgement on a particular issue (2). Due to its design individual responses can be solicited remotely, allowing broad representative sampling with the potential threat of peer pressure removed (3).

Several 'modifications' of the technique have been described but in essence the modified Delphi method is an anonymous, multi-round, consensus-building technique used to generate, analyse and synthesise expert views to reach a group consensus position. There is no universal agreement on an acceptable level of consensus, however Keeney (4) suggests this should be decided before commencing the study, and recommended at least 70%.

The process usually involves a minimum of three rounds, as described by Jones (5). In the first round either relevant individuals are invited to provide opinions on a specific matter, based on their knowledge and experience, or the team undertaking the Delphi expresses opinions on a specific matter and selects suitable experts to participate in subsequent questionnaire rounds. These opinions are grouped together under a limited number of headings and statements drafted for circulation to all participants on a questionnaire. Participants rank their agreement with each statement. The rankings are summarised and included in a repeat version of the questionnaire. In subsequent round participants re-rank their agreement with each statement in the questionnaire, with the opportunity to change their score in view of the group's response. The re-rankings are summarised and assessed for degree of consensus. If an acceptable degree of consensus is obtained the process may stop and final results fed back to the participants. If not, the third round is repeated. Participants are told that they need not conform to the group view. There is no complete agreement about when to terminate a Delphi survey, and it has been argued that 'if no consensus emerges, at least a crystallizing of the disparate positions usually becomes apparent' (6).

2. Delphi methodology for OPAL study

2.1 Overview

We will use a modified three-round Delphi process. We will follow the recommendations for reporting, developed by Sinha et al. (7) which focused on use of Delphi for development of core outcome sets, but which are applicable to the use of Delphi for other purposes. Before the Delphi process starts participants will be informed that the purpose of the process will be to reach a consensus on:

- The content of an occupational advice intervention to facilitate return to work and usual activities after hip and knee replacement
- The method, format and timing of delivery of an occupational advice intervention
- The essential qualities of an outcome measure for assessing return to work and usual activities after hip and knee replacement

Participants will be informed that the statements do not necessarily reflect the views of the research team.

The basis for the OPAL Delphi consensus process will be the information gathered during the intervention mapping stage 1 (Needs assessment) via the rapid evidence synthesis, cohort study and stakeholder interviews. Data from stage 1 will be analysed within intervention mapping stages 2 (Identification of intended outcomes and performance objectives) and 3 (Selection of theory-based methods and practical strategies) to create a list of specific themes and tailored tools / materials to be explored during the Delphi process. As the Delphi process progresses these will be refined and developed into specific components for inclusion in our occupational advice intervention.

Overview of the Delphi consensus process:

- **ROUND 1:** Within round one we will aim to define the content of the intervention. This will include passive ('written' advice and information) and active (actions or processes for patients, employers and healthcare members to undertake) content.
- **ROUND 2:** Round two will focus on the delivery and format of the intervention. Having developed an outline of the proposed content within Round 1, Round 2 will address how, when and who will deliver the intervention. Round 2 will also explore areas of residual uncertainty from Round 1 and address the measurement of outcome for the intervention and any subsequent trial.
- **ROUND 3:** In the final round participants will be asked to clarify any ongoing areas of uncertainty from Rounds 1 and 2. They will be presented with a draft framework for the proposed intervention and be invited to provide feedback and comment.

After the final round the investigators will report the results under the following headings in addition to presenting the draft framework for the intervention:

- Content of the occupational advice intervention
- Format of the occupational advice intervention
- Delivery of the occupational advice intervention
- Measurement of the occupational advice intervention

2.2 Delphi consensus process for OPAL

Round 1:

The aim of round 1 will be to define the content of the intervention

In round 1 each participants will be sent and electronic survey via email. The participants will be presented with a number of statements relating to the CONTENT of the proposed intervention. They will be asked to select a response options for each statement within the survey. For each statement within the survey participants will be asked to rate individual statements with possible options being:

- Strongly agree
- Agree
- Disagree
- Strongly Disagree
- Don't know

Within the survey participants will also have the opportunity to insert any comments regarding the statements presented in a free text box (either adjacent to an individual question or at the end of a section of questions) to solicit additional suggestions relating to the intervention.

Following completion of round 1 the research team will analyse the results and remove statements where participants had reached consensus (which was defined as $\geq$70% agreement / disagreement). Statements where consensus has not been reached will be further analysed based on the responses of the individual stakeholder groups. The level of consensus for each of the 5 stakeholder groups will be determined for each remaining statement:

- If no stakeholder group reached agreement / disagreement($\geq$70%) then the statement will be withdrawn (as 100% of stakeholder groups did not reach consensus)
- If 1 stakeholder group reached agreement/disagreement ($\geq$70%) then the statement will be withdrawn (as 80% of stakeholder groups did not reach consensus)
- If 2 or more stakeholder groups reached agreement / disagreement ($\geq$70%) then the statement will be reworded and represented in Round 2 (as $\leq$60% of stakeholder groups did not reach consensus)
- In the situation where 1 or more stakeholder groups reach 'agreement' and another group reach 'disagreement' the statement will be discussed by the investigator team and a decision on inclusion / exclusion of the statement will be made.

After round 1 the results will be discussed by the research team and a decision as to whether to include, revise or remove the statements from the next round will be made based on the criteria listed above.

Round 2:

The aim of round 2 will be to define the format and delivery of the intervention and to define how the intervention is to be measured

In round 2 participants will be sent a new series of statements via email. These statements will cover three areas:

1) Clarifying areas of residual uncertainty from round 1
2) Statements relating to the format and delivery of the intervention
3) Statements relating to the measurement of the intervention and the measurement of 'return to work'

The first set of statements will follow on from the statements and responses from round one to clarify areas of uncertainty. These statements may also include additional statements generated from the 'free text' comments in round 1. Additional statements relating to the format, delivery and measurement will be generated by members of the research team. These statements will be presented in the second half of the round 2 questionnaire. Statements will be rated using the same 5 categories used in round 1.

In addition, the round 2 questionnaires will include controlled feedback presenting modal round one rating for each item; the proportion of each response option selected by the other participants; and a reminder of the participants own previous ratings. This will allow each participant to compare their response with the anonymised responses from other participants and consider whether, for those elements for which consensus had not been reached, they might wish to change their initial response in the light of the responses of others. Following completion of round two the research team will analyse the results as per round 1 and categorise statements into those where participants had reached consensus (which was defined as $\geq$70% agreement) and those where consensus had not been reached.

Round 3:

The aim of round 3 will aim to clarify any areas of uncertainty from round 1 and 2 and present a draft framework for the intervention for comment and feedback.

In round 3 the participants will be asked clarify their position on any statements for which uncertainty remains. Patient may also be asked to rank the statements for which consensus had been reached. This will be completed under the following headings: Content, Delivery, Format, Outcome. Once the intervention components have been ranked the research team will draft all of the 'included' components of the occupational advice intervention into a document and circulate it to Delphi panel members for final open comment. Strategies for the delivery of the occupational advice intervention at each of the study sites will be developed alongside this process.

2.3 Definition of consensus

A consensus threshold of 70% will be pre-defined for analysis, similar to other previous studies (8,9). Consensus for this study will be defined as ≥70% 'agree' or 'strongly agree'; or ≥70% 'disagree' or 'strongly disagree'.

2.4 Delivery of the Surveys

The Delphi consensus process will be conducted electronically using email and an online survey platform. Access to the survey platform has been granted by the South Tees NHS Trust administrative team.

2.5 Piloting the Surveys

Before the Delphi surveys are disseminated they will first be piloted with a sample of stakeholders local to South Tees NHS Trust. A process termed 'think aloud' by cognitive psychologists, will be undertaken during

these meetings, whereby the stakeholders will be asked to complete the questionnaire and talk through their responses as they complete each item. By verbally voicing their thought processes and meanings attributed to each question as they complete the questionnaire, the validity of each question can be tested to see how well the questionnaire items address the study objectives. This stage of the questionnaire testing will also be used to explore the length of time taken to complete the questionnaire.

3. Composition of the Delphi consensus process

3.1 Delphi participants

For the Delphi process will intend to collaborate with the key stakeholder groups identified within Phase 1. This will include:

- Patients
- Employers
- Orthopaedic Surgeons
- Allied Health Professionals (Physiotherapists, Occupational Therapists, Nurses)
- General Practitioners

To ensure wide participation and the validity of the consensus process we will recruit a minimum of 5 individuals from each stakeholder group. A maximum limit of 15 individuals from any given stakeholder group will be used to ensure one group's opinions do not overwhelm the opinions of others within the consensus process. This will mean the Delphi process will include a minimum of 25 participants and a maximum of 75 participants. To ensure the majority of participants have direct experience with lower limb arthroplasty we would ideally aim to have >50% of each group's participants should fulfil the following criteria:

- Patients – Experience of returning to work after THR/TKR in the previous 12 months
- Employers – Experience of managing an employee returning to work after hip or knee replacement in the previous 12 months
- Orthopaedic Surgeon – Surgeons undertaking a minimum of 20 hip or knee replacements per year
- Allied Health Professionals – AHPs actively involved in the assessment and / or management of patients undergoing hip or knee replacement
- General Practioners - Experience of managing a patient returning to work after hip or knee replacement in the previous 12 months

The remaining participants from each stakeholder group will be identified from professional groups, specialist societies, employer bodies and patient networks to ensure wider involvement and acceptance. An overview of the groups to be approached as part of this process is given in the table below:

Stakeholder group	Nominated research team lead	Participants recruited via:
Patients	Mrs J Fitch	National Joint Registry patient network British Orthopaedic Association patient group
Employers and occupation health services	Prof S Khan	Federation of Small Businesses EEF – The manufacturers organisation Confederation of British Industry Trade Union Congress Department for Work and Pensions The Fit for Work Service The Work Foundation The Society of Occupational Medicine Institution of Occupational Safety & Health Society of Occupational Health Nurses
Orthopaedic Surgeons	Mr I McNamara & Mr P Baker	British Hip Society British Association for Surgeon of the Knee British Orthopaedic Association National Joint Registry
Allied Health Professionals (AHPs – Physiotherapists and Occupational therapists) and nurses	Dr D McDonald & Dr C Coole	Association of Chartered *Physiotherapists* in *Occupational* Health and Ergonomics Chartered Society of Physiotherapy Occupational therapy networks e.g. Royal College of Occupational Therapists Specialist Sections in Work and Trauma & Orthopaedics Royal College of Nursing
General Practitioners	Mr P Baker & Prof A Rangan	Local Medical Committees Royal College of General Practitioners Local Clinical Commissioning Groups

4. Administration of the Delphi consensus process

4.1 Delphi management

The Delphi consensus process will be led by Prof Amar Rangan supported by Mr Paul Baker, Prof Avril Drummond, Dr Carol Coole, Prof Sayeed Khan, Mr Iain McNamara, and Mr David McDonald. Administrative support will be provided by Reece Walker, Amanda Goodman and Lucksy Kottam based at South Tees NHS Trust.

4.2 Analysis and reaching consensus

Analysis of the Delphi responses will be undertaken at South Tees NHS Trust. Results will be shared with the wider OPAL research team before the questionnaires are redrafted for subsequent rounds.

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APPENDIX 2: Outline of the proposed occupational advice intervention with performance objectives (maps to IM stages 5&6)

In section 6.2 of the protocol the likely content of the intervention was described based on the investigator teams preliminary assessment of the literature and their combined expertise prior to commencing the OPAL study. Through IM stages 1-4 the intervention has evolved in to a complex intervention spanning the entire surgical pathway. It encompasses many of the elements previously described. An overview of the intervention at the end of IM stage 4 is described below. Specific patient and staff performance objectives for the intervention are given in the subsequent section. The intervention described below has been designed to all deliver these performance objectives. The feasibility testing stage will assess the fidelity of the intervention against these performance objectives

1. Outline of the proposed occupational advice intervention

The occupational advice intervention will include the following elements:

- PATIENT IDENTIFICATION:
    - All patients in work and intending to return to work after surgery will be identified as 'return to work patients' in their initial outpatient clinic appointment.
    - Identification of patients will be facilitated by the completion of an occupational checklist prior to the patients review with the surgical team.
    - The occupational checklist will record information about current work status, basic patient demographics, work type, work demands, driving in relation to work and access to occupational health services through work.
    - This information will be shared with the surgical team to facilitate surgical decision-making with respect to surgery and allow an individualised preliminary discussion of 'return to work' between patient and the surgical team.
    - Patients listed for surgery will be signposted to the OPAL intervention resources (OPAL patient workbook, employer information, website, return to work co-ordinator) by their surgical team and the wider hospital orthopaedic team within the outpatient department.
- DEVELOPMENT OF A RETURN TO WORK PLAN:
    - All patients in work and intending to return to work after surgery will be provided with a 'return to work' workbook. Completion of the workbook will help patients to list and understand their current job demands, set a provisional return to work date, identify potential barriers and solutions to safe and appropriate return to work, develop a provisional return to work plan that can be shared with their employer / work colleagues.
    - The completion of the workbook will be the responsibility of the patient but will be overseen by a designated 'return to work' co-ordinator who is a member of the orthopaedic team.
    - Completion of the 'return to work' workbook will commence after listing for surgery and will provide information and support spanning the surgical pathway (from listing for surgery to discharge back to GP)
- INFORMATION:
    - All patients will be provided with access to the OPAL intervention resources. This will include a variety of 'return to work' advice and information resources based on the statements reaching consensus with the Delphi process.
    - Available resources will include both written and online materials. Online materials will include resources for all stakeholders.
    - In addition to specific patient information patients will also be provided with Information to share with their employer.
- ASSESSMENT:
    - All patients in work and intending to return to work will be contacted by a return to work co-ordinator prior to surgery to ensure they have completed the 'return to work' workbook and discuss and review the plans they have developed. This contact will occur at a minimum of 4 weeks prior to surgery.
    - The 'return to work' co-ordinator will encourage patients to share their plans with their employer if they have not done so already.

  - **The 'return to work' co-ordinator is the only role within the intervention that requires additional time and resource. It is anticipated that all other elements of the intervention will be absorbed in to 'standard care' through the training and guidance developed and delivered to members of the hospital orthopaedic team as part of the OPAL intervention.**
- COMMUNICATION:
  - Patients will be encouraged to discuss their return to work plan (as documented in their 'return to work' workbook) with their employer.
- SUPPORT and REVIEW:
  - The return to work co-ordinator may offer additional support to patients based on need. This decision will be made on an individual patient basis having discussed and reviewed the information in their 'return to work' workbook.
  - The 'return to work' co-ordinator will facilitate a mechanism that allows patients to contact them following their surgery e.g. answerphone line or email. This could prompt further review and referral back in to local therapy services if required.
- DISCHARGE:
  - The OPAL intervention will provide guidance for hospital orthopaedics teams outlining how to:
    - Communicate issues relating to return to work between primary and secondary care within outpatient clinic correspondence and through discharge letters.
    - Prescribe and provide fit notes.

  This will support primary care at the point of discharge from secondary care to allow seamless continued management of their return to work process.
- TRAINING:
  - The OPAL intervention will provide training for members of the hospital orthopaedic care team who interact with 'return to work' patients to increase awareness and confidence about return to work issues.

2. Performance objective guidelines for patients

Performance objective (PO)		
What	When	Who
PO1: Patient completes occupational checklist prior to appointment with surgeon	At clinic prior to appointment	Patient
PO2: Patient makes informed decision about surgery with respect to work	At/following first clinic appt	Patient and hospital orthopaedic team
PO3: Patient acquaints themself with key information about recovery and RTW provided in the RTW workbook and associated online information resources	following first clinic appt/listing	Patient
PO4: Patient brings RTW workbook to each hospital appointment including hospital inpatient stay	Each hospital appointment	Patient
PO5: Patient completes sections of RTW workbook that will help them understand the demands of their work and set an approximate RTW date (With employer* as required)	Prior to surgery	Patient
PO6: Patient uses information resources provided to identify and prioritise potential barriers and solutions to a safe and appropriate RTW, and to develop a RTW plan (With employer* as required)	Prior to surgery	Patient
PO7: Patient discusses information within RTW workbook with RTW co-ordinator to help them further develop their RTW plan. This will include a minimum of 1 contact. The number and duration of further contacts will be governed by patient need based on progress and perceived level of 'risk' of prolonged sickness absence	Prior to surgery	Patient and 'return to work co-ordinator'
PO8: Patient provides employer* with written information provided by the HOT about their planned surgery and recovery/RTW advice	Prior to surgery	Patient and employer
PO9: Patient meets with their employer* to discuss their recovery and RTW plan	Prior to surgery	Patient and employer
PO10: Patient communicates with employer* regarding surgical outcome and progress/recovery	Following surgery	Patient and employer
PO11: Patient revises RTW plan following surgery as necessary with their employer* and hospital staff	Following surgery	Patient, employer and hospital orthopaedic team
PO12: Patient engages with RTWC via RTW helpline/answering service if having problems related to RTW for up to 16 weeks post- surgery	Following surgery and until RTW	Patient and hospital orthopaedic team
PO13: Patient adheres to postoperative rehabilitation plan and advice	Following surgery	Patient

* RTW = Return to work, RTWC = Return to work co-ordinator, HOT = Hospital Orthopaedic Team, 'Employer' = Within the OPAL study the term 'Employer' is used to represent a variety of people in the patients place of work that may be involved in facilitating and supporting their return to work. This includes: Managers, colleagues, occupational health teams, human resources (HR) teams.

3. Performance objective guidelines for staff

Performance objective		
What	When	Who
PO1: The *HOT*: o Identifies existing team members to act as *RTWC* and deputy o Identifies existing staff members to act as *OPALCs* for their team: - ward - Inpatient therapy team - outpatient clinic - pre-assessment and education o Develops a phone line / answerphone service for RTW patients to contact *RTWC* if they are having problems regarding RTW	Prior to delivery of intervention	Hospital orthopaedic team
PO2: *The outpatient clinic team* identifies RTW patients in clinic prior to consultation with surgical team	In clinic prior to first appt	Outpatient clinic team
PO3: *The outpatient clinic team:* o Requests RTW patients to complete occupational checklist prior to consultation with surgeon and explain its purpose to the patient o Gives completed occupational checklist to surgeon prior to patient's appointment	In clinic prior to first appt	Outpatient clinic team
PO4: *The Surgeon*: o Discusses pros and cons of surgery with patient including expected timescales of surgery and recovery – in relation to the patient's usual work and the patient's occupational checklist to enable patient to make informed decision about surgery; supports patient autonomy o Provides patient with personal risk feedback on potential RTW outcomes o Explores patients questions and concerns o Informs listed patients that they will be given a RTW workbook to read and why, complete where possible, bring to each subsequent appointment, presenting positive message o Informs listed patients that they will receive an Employer workbook and why, that the patient will be contacted by a RTWC at least 4 weeks prior to surgery and why. Names them. o Explains that RTW plan may need to be revised and that RTWC will help with this o Summarises and records patients RTW status/outcome in all clinic notes and following each appointment o Communicates with GP at point patient is discharged from orthopaedic surgical care outlining current RTW status and progress and on-going therapy received	At first clinic appt/listing	Surgeon
PO5: *The outpatient clinic team:* o Provides all RTW patients listed for surgery with written RTW workbook and gain contact details for RTWC to contact patient as completed in occupational checklist o Inform/encourage patient to bring RTW workbook to each hospital appointment, and draw attention to this instruction in the workbook o Discuss potential reasons why this might not happen, and	At first clinic appt/listing	Outpatient clinic team

formulate solutions with patient o Recommend patients read workbook and complete as much as they can (show relevant sections); present workbook positively and refer to coping model examples o Recommend patient asks employer to assist patient in completion if wishes and suggests who this might include, and discuss possible difficulties and solutions re communicating with employer o Explain to patient that the RTWC will contact them at least 4 weeks prior to surgery about their RTW plan		
PO6: The outpatient clinic team: o Provide all RTW patients listed for surgery with 'Employer RTW workbook' to share with their employer/colleagues* o Inform/encourage patient that giving the Employer RTW workbook to employer/ colleagues will help them understand surgery and prepare for patient's RTW o Suggests that patient might wish to meet with their employer to discuss RTW and who this might include o Suggest individuals in the workplace who might best receive the Employer RTW workbook	At first clinic appt/listing	Outpatient clinic team
PO7: The outpatient clinic team collects patient's completed occupational checklist from surgeon and forwards to RTWC	Following first clinic appt/listing	Outpatient clinic team
PO8: The pre-operative assessment and education teams: o Routinely include the topic of RTW in their clinics with examples of work demands, barriers and facilitators to RTW, RTW plans, importance of adhering to postop rehab plan o Ask if patients have brought their RTW workbook to appointment, praise patients, refer to the workbooks, and promote engagement with the RTWC	Pre-op	Pre-op assessment and education teams
PO9: RTWC contacts all RTW patients (phone/meet ups) at least 4 weeks prior to surgery to review: o Information provided in the occupational checklist o Information in the RTW workbook including o Current job demands o Provisional RTW date o Potential barriers and solutions to safe and appropriate RTW o The patient's provisional RTW plan o Encourages discussion about/coaches patient regarding communication with patients employer o Discusses the possibility of needing to revise RTW plan following surgery (All patients receive at least 1 contact with the RTW co-ordinator. This may be integrated within the pre-assessment / pre-admission process or done by phone. The number and duration of additional contacts will be governed by patient need based on progress and perceived level of 'risk') The RTWC will: o Refer positively to RTW workbook during discussions with patient o Praise patient for bringing workbook to appointments o Remind patient to bring workbook on admission	Pre-op at least 4 weeks prior to admission date	'Return to work' co-ordinator

○ Refer to other patient examples /models of job demands/RTW plans etc ○ Encourage discussion about/coaches patient regarding communication with patient's employer ○ Refer on/signposts where appropriate ○ Set goals/steps with patient ○ Discuss the possibility of needing to revise RTW plan following surgery ○ Document all consultations in RTWC workbook		
PO10: RTWC highlights RTW patients to ward teams managing *preoperative education and assessment* and records this action in RTWC workbook	At time of surgery	'Return to work' co-ordinator
PO11: RTWC highlights RTW patients to *the ward teams* when admitted for surgery and records this action in the RTWC workbook	Post-op prior to discharge	'Return to work' co-ordinator
PO12: The ward team (nurse and doctor): ○ *C*heck RTW patients have brought workbook into hospital and if not determine the reason for this. Give praise if workbook brought in. ○ Refer positively to RTW workbook.	With 24 hours of admission to ward	Ward staff
PO13: Ward therapists: ○ *A*sk RTW patients if they have brought workbook into hospital, and if not determines the reason for this. Give praise if workbook brought in. ○ Refer positively to RTW workbook, enter notes as appropriate. ○ Liaise with RTWC to update them on the patient's postop recovery prior to discharge.	After surgery prior to discharge	Inpatient therapy team
PO14: The RTWC: ○ Liaises with *inpatient teams* post-operatively to determine whether there are any issues with early recovery that may impact on the RTW plan. ○ Revises RTW plan with patient as required and ensures plan is documented in patients RTW workbook. ○ Supports post-operative rehab plans and problem-solves potential barriers to adherence with patient.	Post-op	'Return to work' co-ordinator / Ward staff (specialist nurse/doctor)/ inpatient therapy teams
PO15: The ward team (nurse/doctor/therapist): ○ Summarises patient's expected RTW outcome and RTW plan in ward electronic discharge letter. A copy/copies will be given to the patient to share with employer, therapists etc. ○ Praise/refer to the RTW workbook and remind the patient to use the RTW helpline following discharge if they are having problems. ○ Highlight the importance of adhering to the post op rehab plan.	Post-op prior to discharge	Ward staff (specialist nurse/doctor/in-patient therapy team)
PO16: The specialist ward nurse/doctor asks each patient whether they require a fit note on discharge and completes the fit note in accordance with best practice guidelines and the hospital contract, and with reference to the patient's RTW plan in their workbook.	Post-op prior to discharge	Ward staff (specialist nurse/doctor)
PO17: The RTWC checks the RTW helpline 3 x wk, and triages, advises (e.g. phone call) or refers back to therapy services (based on local service structure and availability) based on individual need.	After surgery until RTW/16 weeks post-discharge	'Return to work' co-ordinator
PO18: Surgeon, HOT and outpatient therapy teams summarise	Until RTW/16	Hospital

and record patient's RTW status / outcome in all outpatient clinic notes and following each appointment.	weeks post-discharge	orthopaedic team / outpatient therapy teams
PO19: Surgeon and HOT communicate with GP at point patient is discharged from orthopaedic surgical care, outlining current RTW status and progress and on-going therapy received and encourage engagement with RTWC until 16 weeks post-surgery.	At point of discharge from orthopaedic surgeon	Hospital orthopaedic team
PO20: RTWC continues to provide a point of access to RTW advice for patients following discharge from orthopaedic surgical care until 16 weeks post-surgery.	Until RTW/16 weeks post-discharge	'Return to work' co-ordinator

* RTW = Return to work, RTWC = Return to work co-ordinator, HOT = Hospital Orthopaedic Team, OPALC = OPAL Champion

Appendix 3: Flowchart for Feasibility testing element of the OPAL study