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 initiated prior to planned surgery for lower limb joint replacement (HTA call: 15/28/02)

SHORT 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
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 UK 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 at baseline (peri-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), 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 further stakeholder interviews. This will assess the acceptability, practicality and feasibility of the intervention 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.

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 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.

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).

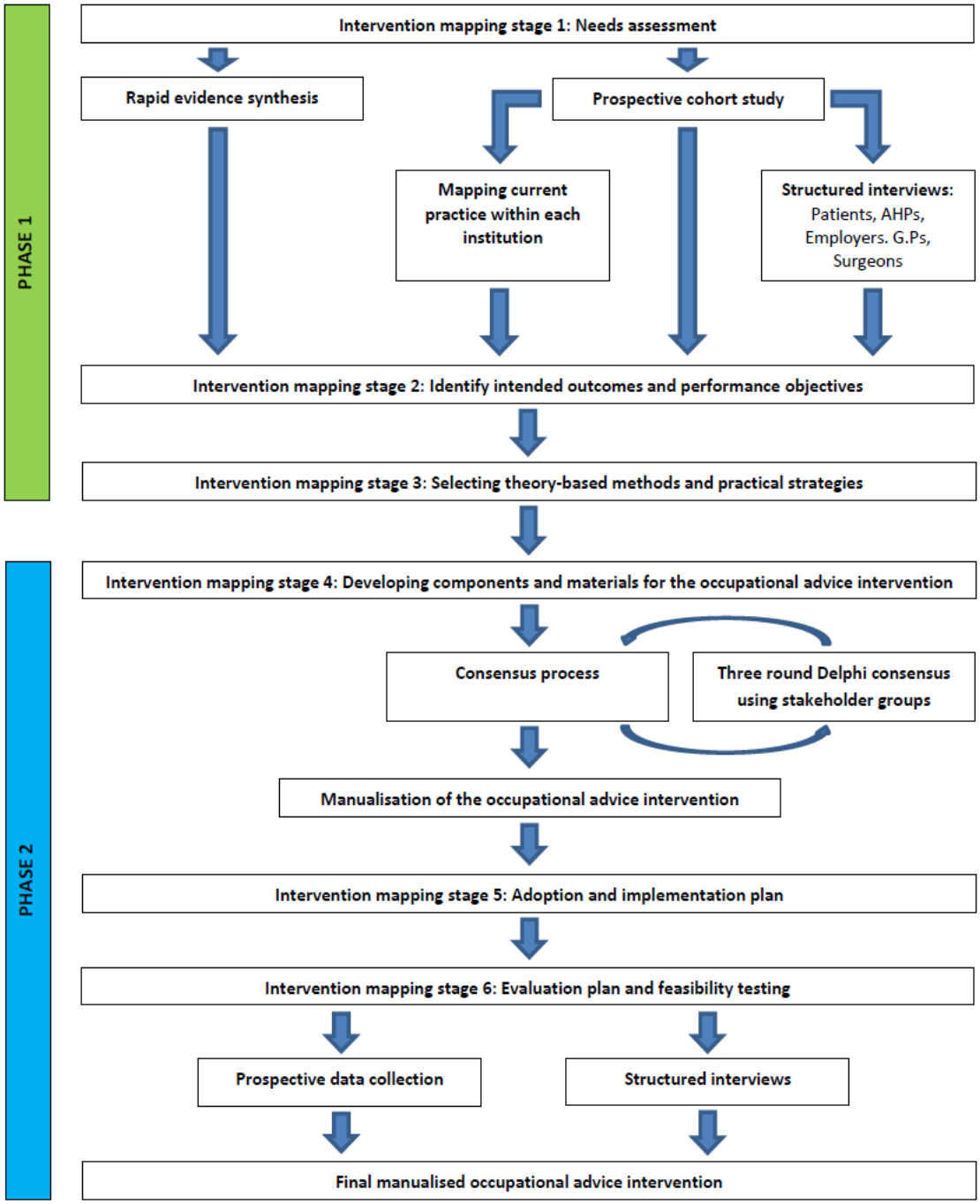


Figure 1: Diagrammatic overview of the proposed research project.

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 developed 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, GPs and employers). While specifically written for patients it will include information pertinent to all of these stakeholder groups. It will be delivered prior to surgery 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 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 a total of 150 patients. 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: Oxford hip / knee score
    - Health utility: 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, access to advice
    - 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 study 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 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 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 GP 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 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, 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

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.

The proposed consensus process will involve a three round email based Delphi survey to all recruited stakeholders. The aim of this process will be to reach a consensus on:

1. The content of the occupational advice intervention using the components developed as part of Phase 1 and invited additional content from stakeholders within the first round of the Delphi process.
2. The favoured format, timing and method of delivery of the occupational advice intervention.
3. The essential qualities of a 'return to work' outcome measure based on previous collected information from the rapid evidence synthesis and structured stakeholder interviews within Phase 1.

In the first round the recruited stakeholders will be invited to provide opinions on statements relating to these three elements based on their knowledge and experience. Statements will be developed by members of the

research team based on information gained from Phase 1 and subsequently reviewed and revised by the chief investigator alongside nominated members of the steering group. Participant responses will be grouped together under a limited number of headings and statements drafted for circulation to all participants in an email based questionnaire. Using the headings: Agree; Slightly agree; Slightly disagree; Disagree; participants will rank their agreement with each statement. They will also be provided with an additional opportunity for 'open' comment, specifically aimed at establishing whether there is additional intervention content that had not been identified with Phase 1 that may be important within the final intervention. The rankings of each statement are then summarised and included in a repeat version of the questionnaire.

During subsequent rounds a similarly structured survey will be circulated except that a) the modal round one rating for each intervention / outcome component will be presented b) participants will be reminded of their own round one ratings c) participants will be given the opportunity to change their ratings if they wish d) additional interventions / outcomes suggested during round one will be available for review e) response categories may be modified to help reach consensus. The re-rankings from the second round 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 >75% 'Strongly agree' or 'Agree' and a consensus for exclusion of >75% '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 measure 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 draft version 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 the 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.

Potential users will be defined using similar eligibility criteria to that used in Phase 1: a) on the waiting list for hip or knee replacement with a date for surgery in the subsequent 4 weeks b) in work prior to joint replacement and c) intending to return to work following surgery. Within the delivery frameworks assigned to each centre the methods and strategies to achieve the necessary change in behaviour given the institutional context will be formulated. 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 practicality and acceptability of the intervention to clinicians and patients who will be potential trial participants. The feasibility stage will include not only an assessment of the intervention but also an assessment of the feasibility of undertaking a trial using the intervention. However, it is not our intention to undertake a formal pilot study during these stages (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 the feasibility of delivery is crucial

In this 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 used to assess the intervention are similar to the methods used in Phase 1. At each site we will undertake a 10 patient cohort analysis using the same patient questionnaires, outcome measures and sampling time points (Baseline (peri-operative), 8 and 16 weeks) 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). These patients will also be given a very brief questionnaire asking 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.

This information will be supplemented by 5 patient and 4 stakeholder interviews (sampling from employers, health professionals, G.Ps, orthopaedic surgeons etc.) again performed at 16 weeks post-surgery. These interviews will collect information about the acceptability and utility of the final 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. We envisage that it will be possible to recruit the 10 patients required at each site within the first month of this period. Factoring in a maximum 4 weeks lag time to surgery and a 16 weeks follow up we expect that recruitment and data collection should be achievable within 6 months. Analysis of this data and revision of the final occupational advice intervention will then occur within the 5 month 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 (occupation therapists and physiotherapists); 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)	Dr D McDonald & Mrs C Coole	Association of Chartered Physiotherapists in Occupational Health and Ergonomics Chartered Society of Physiotherapy Occupational therapy networks e.g. College of Occupational Therapists Specialist Sections in Work and Trauma & Orthopaedics AHPs 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 undergoing primary hip or knee replacement
- In work within 6 months prior to joint replacement (including Full time, Part time, Paid & unpaid job roles)

11.2 Exclusion criteria (For patients recruited into the cohort / interview elements of Phase 1 & Phase 2 of the study)

- 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, 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 list 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 at each site (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 (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 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, 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 at the study sites from the waiting lists of surgeons performing hip and knee replacements. This cohort will test the feasibility, acceptability and practicality of the final occupational advice intervention with data collected using questionnaires (all patients) and further structured interviews (15 patients in total). These interviews will be supplemented by interviews with a combination of twelve other stakeholders (AHPs, GPs, surgeons, employers) identified from the study sites (an average of 4 interviews per site)

15 Data collection and Confidentiality

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 continue 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

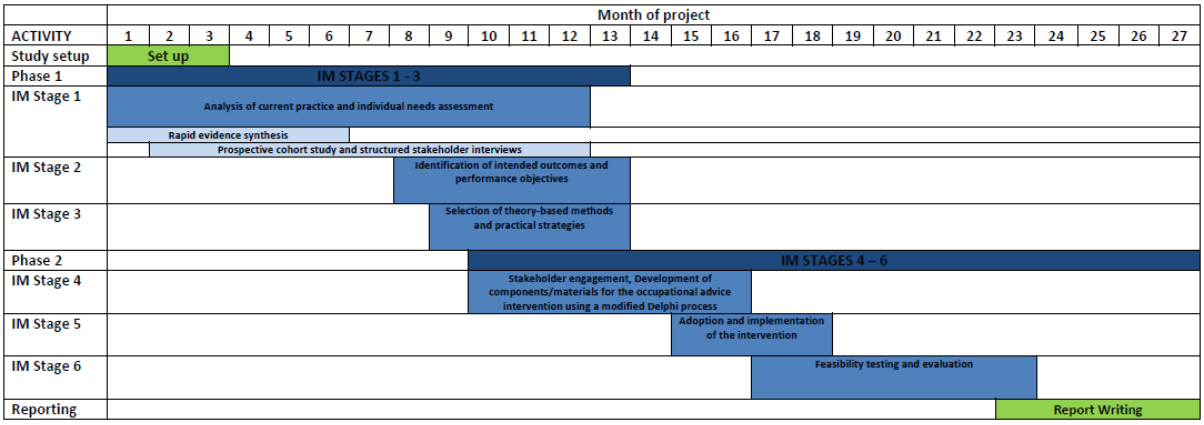
We will be mindful in all dissemination activities and production of outputs that we are reporting the results of a feasibility study and not a definitive trial determining the effectiveness of the occupational advice intervention. The key outcome of the study will be to lay the foundations for a definitive 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



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.

26 Change log / Version history

Protocol version	Notes
OPAL V1.0	• Approval by HTA 29.06.16
OPAL V2.0	• Amended prior to REC submission • REC review 04.08.16 – provisional approval • Further minor amendments in response to ethics committee • V2 finalised 10.08.16 • Resubmitted and approved by HTA 11.08.16 • Final OPAL V2.0 uploaded via MIS 12.08.16

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