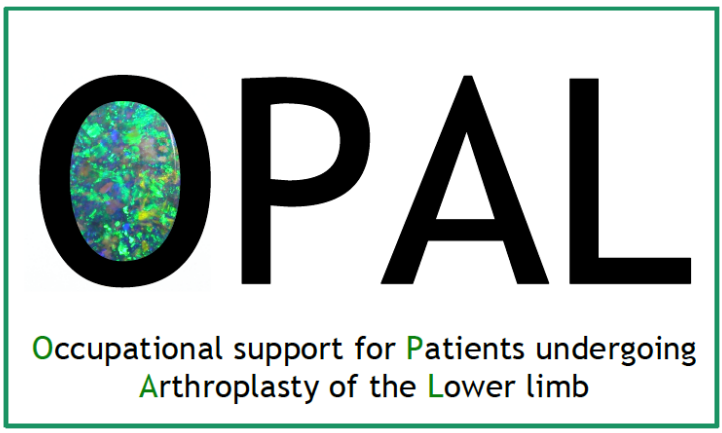

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Chief Investigator
Professor Paul Baker, South Tees Hospitals NHS Foundation Trust

Sponsor
South Tees Hospital NHS Foundation Trust, Marton Road, Middlesbrough, TS4 3BW

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The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care

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Work, Return to work, Occupational Advice, Workplace support, Employment, Hip replacement, Knee replacement.

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor. I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Date: 14/08/23

Signature:
Name: Jane Greenaway
Position: Associate Director, TVRA

Chief Investigator: Date: 25.11.22

Signature:
Name: Prof Paul Baker

Statistician:

Signature:

Date: 01/10/2023

Name: Ada Keding

Key Trial Contacts

Chief Investigator	Prof. Paul Baker 01624 854168 Paul.baker1@nhs.net
Trial Manager	Lesley Sinclair 01904 324158 lesley.sinclair@york.ac.uk
Trial Co-ordinator(s)	Lucy Sheehan Lucy.sheehan@york.ac.uk Maisie Martland Maisie.martland@york.ac.uk
Previous Trial Co-ordinator(s)	Amie Woodward Amie.woodward@york.ac.uk
Sponsor Representative	David Rollins david.rollins@nhs.net
Funder	National Institute of Health Research (NIHR) Health Technology Assessment funding scheme
Clinical Trials Unit	York Clinical Trials Unit https://www.york.ac.uk/healthsciences/research/trials/
Statisticians	Ada Keding 01904 321510 Ada.keding@york.ac.uk Gillian Parkinson 01904 321715 Gill.parkinson@york.ac.uk
Health Economist	Qi Wu Qi.wu@york.ac.uk
Committees	Trial Steering Committee (TSC) Committee chair: Prof. Gwenllian Wynne-Jones g.wynne-jones@keele.ac.uk
	Data Monitoring Committee (DMC) Committee chair: Dr. Jonathan Bishop j.bishop.1@bham.ac.uk
	Trial Management Group (TMG) Group Chair: Prof. Paul Baker paul.baker1@nhs.net
Associate PI Scheme contacts	CTU API champion: API ambassador:

List of Abbreviations

AE	Adverse Event
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials statement
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health and Care Research
OPAL	Occupational Advice For Patients Undergoing Arthroplasty of the Lower Limb
PAG	Patient Advisory Group
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PROM	Patient Reported Outcome Measure
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RTW	Return to Work
RTWC	Return to Work Coordinator
SAE	Serious Adverse Event
TMG	Trial Management Group
TSC	Trial Steering Committee
YTU	York Trials Unit

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

Plain English Summary

Background to the research:
Hip and knee joint replacements relieve pain and improve function in patients with arthritis. One in four patients are in work at the time of their hip or knee replacement surgery, equivalent to 50,000 people in the UK each year. Many patients get back to work after surgery, however, the time this takes varies considerably. A lengthy recovery time can affect patients' physical and mental wellbeing. Patients receive little or no return-to-work support from their hospital or GP specific to their individual needs and work situation. As part of an earlier research study we developed an 'occupational' (back-to- work) programme (known as OPAL) that supports return-to-work after surgery. We now need to assess whether this is effective in supporting a timely, safe and sustained return-to-work.

Aim(s) of the research:
We will evaluate the OPAL occupational support programme to find out whether it assists patients to make a timely, safe and sustained return-to-work and normal activities after hip or knee joint replacement surgery.

Research plan:
The OPAL occupational support programme provides personalised, targeted support for people in a range of jobs. As part of the programme, patients receive a variety of resources to help them plan their return-to-work. This includes access to a trained co-ordinator who helps and supports them before and after surgery. We will undertake a large study to compare the OPAL occupational support programme against standard care.

All adults listed for elective primary hip or knee replacement from a minimum of 14 UK hospitals, who are in paid or unpaid work, will be invited to take part. They will be approached before surgery to explain the study and seek consent, either at their pre-assessment appointment or via a phone call. Consenting participants will then be randomly assigned (using a computer) to receive either the OPAL programme or standard care. This will allow a fair comparison between the two. We aim to recruit 742 participants over 15 months. We will ask participants to complete questionnaires for 12 months following surgery in relation to when and how they return to work, and their normal activities. From these, we will understand if the OPAL programme helps to reduce the length of time until full, sustained return-to-work. We will find out if there is a difference between the groups in time to return to any work, the speed and quality of recovery, and if there is a need for additional workplace support. We will find out if the cost of care differs between the two groups, to determine whether one is better value for money for the NHS. We will also ask what those receiving and delivering the OPAL programme think about it, and if the programme is effective, determine how it could be incorporated into routine NHS care.

Patient and public involvement (PPI):
The study has been developed with patient advisors who have had hip or knee arthritis and joint replacement surgery. A patient advisory group, along with public members who worked with us securing funding for the study, will help us to develop patient facing documents, advise on any trial processes and suggest how best to report study findings to the public and patients.

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

Scientific Summary

Background: Currently patients undergoing hip and knee replacement receive little or no information or support relating to their return to work (RTW) from orthopaedic teams. There is a need for an occupational support intervention that encourages safe and sustained RTW which can be integrated into NHS practice. As part of earlier work (OPAL Feasibility Study HTA15/28/02) we developed an occupational support programme for this patient group that comprised two core components: 1) provision of multimedia information resources; and 2) access to, and support from, a designated RTW co-ordinator. The OPAL feasibility study demonstrated that delivery of the intervention was feasible and may help improve time to RTW after surgery. We are now seeking to assess the intervention in this trial (The OPAL trial).

Aims and Objectives: To assess whether an occupational support intervention (the OPAL intervention) for people undergoing elective primary hip and knee replacement, initiated prior to surgery, is effective in supporting a reduced time to full, sustained RTW compared to usual care and is a cost-effective use of NHS resources.

Methods: The study includes an a) effectiveness trial, b) health economic evaluation and c) assessment of implementation, fidelity and acceptability. We will undertake a multi-centre, individual level randomised superiority trial of the OPAL intervention versus 'standard care', with internal pilot (sample size = 742; 371 control group, 371 intervention group). The study will be delivered at a minimum of 14 UK study sites. It will include adults ($\geq$ 16 years) listed for elective primary hip or knee replacement, in paid or unpaid work, who intend to RTW after surgery. Participants will be followed up for 12 months after surgery. The primary outcome is time until 'full' sustained return to any work, defined as work resumption to the same hours as prior to joint replacement in any role, without any day of sick leave for a consecutive 4-week period. Secondary outcomes are: time to any RTW, measures of functional recovery to daily activities and social participation, number of 'sick days' between surgery and 'full' sustained RTW and the proportion of patients using workplace interventions, adaptions and modifications to facilitate their return. The health economic evaluation will assess the cost-effectiveness of the intervention versus usual care over a 12-month period. A mixed methods process evaluation will assess the implementation, fidelity and acceptability of the intervention, including participant adherence to the intervention and its component parts.

Timelines for delivery: Total duration 44 months. Study set up (9 months); recruitment (15 months, including 6-month internal pilot); follow-up (14 months); analysis and dissemination (6 months).

Anticipated impact and dissemination: If the intervention is found to be effective and cost-effective it has the potential to greatly improve patient care. Dissemination will focus on supporting the wider adoption and implementation of the intervention (if effective) and will target groups for whom the results (and implementation plan) will be relevant.

Contents

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

1. Background and Rationale

1.1. Problem being addressed

NICE clinical guidance (NG157) recommends that orthopaedic teams discuss and provide information on return to work (RTW) for patients undergoing primary hip and knee replacement (1). Despite this, there is substantial variation in provision of occupational advice and support (2) and the current 'standard of care' is for patients to receive little or no information about RTW or support to enable RTW from their hospital orthopaedic team or GP (3-6). Furthermore, fewer than 35% of patients have access to occupational health support at work (3-6). There is a need for an occupational support intervention that encourages safe and sustained RTW and can be integrated into NHS practice.

1.2. Why this research is important

Planned surgery to replace a hip or knee joint is a routine NHS procedure that is becoming more common in people of working age. A quarter of UK patients undergoing primary hip and knee replacement are in work at the time of surgery (approximately 50,000/year) (3, 7, 8). This proportion will rise over the next decade with an increasing incidence of hip and knee arthritis (9)and people working longer (10). Returning to work is seen as an important indicator of functional rehabilitation and quality of life. Working has physical and mental health benefits and aids recovery after joint replacement (11-13). Estimates for the mean time to RTW after hip or knee replacement range from 10 to 14 weeks (3, 14-17). This equates to approximately 4.2 million days of sickness absence related to recovery after surgery at a societal cost of approximately £400million/year (3).

1.3. Why this research is needed now

Advice from health care professionals about expected time to return to work can influence absence duration. Patients' expectations are a predictor of treatment outcome. It is therefore important to provide appropriate advice and support and help patients set realistic and achievable expectations about their RTW after surgery. Encouraging and supporting RTW through an occupational intervention initiated prior to surgery could help minimise some of the health and socioeconomic consequences of joint replacement surgery.

Determinants of RTW are rarely considered when advising patients about hip and knee replacement surgery and their subsequent RTW (2, 4, 5). In a UK survey only 19% of healthcare respondents routinely offered RTW advice to this patient group and <10% used written information or offered onward referral to occupational health services (2). There is therefore significant scope to improve current practice in line with NICE recommendations (NG157) (1).

1.4. Research completed to date to support the OPAL trial

In 2016, the HTA programme funded a feasibility study conducted by our group (HTA:15/28/02) (3). This study developed an occupational support intervention for working adults initiated prior to elective hip and knee replacement, to improve the speed of recovery to usual activities including work.

The OPAL feasibility study utilised a mixed-methods research design within an intervention mapping framework to develop an occupational intervention to support RTW after hip or knee replacement. The intervention had a strong theoretical background and was underpinned by biopsychosocial models that supported behaviour change in the target groups (patients, healthcare professionals and employers). It was manualised as a set of patient and healthcare professional performance objectives that defined its content, format, delivery and timing whilst maintaining pragmatism in the ability for participating sites to administer the intervention alongside standard care.

The OPAL occupational support intervention consists of a suite of multimedia resources that support the patient to develop an individualised RTW and rehabilitation plan tailored to their needs. It involves them in decisions about their care and RTW, and provides a framework for their healthcare team to provide support and advice. The intervention also includes a return to work co-ordinator (RTWC), to facilitate active delivery of each of the elements of the intervention. This aligns with previous studies that demonstrate provision of an RTWC is positively associated with time to RTW and the probability of returning to work across a variety of healthcare settings (18-23). Moreover, a systematic review recommended service coordination as a core component of RTW interventions (24).

The OPAL intervention has been designed to integrate with current care. Current care is extremely varied in its timing, content, format and mode of delivery. OPAL support has therefore been designed as a patient-led process that focusses on the needs of the individual but is supported by employers, GPs, orthopaedic surgeons and allied health professionals.

2. Aims and Objectives

To assess whether an occupational support intervention for people undergoing elective primary hip and knee replacement, initiated prior to surgery, is effective in supporting a reduced time to full, sustained RTW compared to usual care and is a cost-effective use of NHS resources.

The objectives are to:

1. Undertake a multicentre, two-arm parallel superiority RCT to determine whether a tailored occupational support intervention initiated prior to elective primary hip and knee replacement reduces time to 'full' sustained RTW
2. Undertake a 6-month internal pilot to confirm the feasibility of the trial in terms of site set-up, recruitment rate, and fidelity of intervention delivery
3. Undertake an analysis of secondary outcomes
4. Undertake a cost-utility and cost-effectiveness analysis of the occupational support intervention compared to usual care
5. Assess the fidelity of intervention delivery and its acceptability to patients, healthcare professionals and commissioners
6. Develop an implementation plan for delivery of the intervention post-trial (depending on findings).

3. Trial Design and Timeline

3.1. Trial design

The OPAL trial is a two-arm multi-centre, randomised, superiority trial with parallel groups. There will be a 6-month internal pilot, and embedded economic and process evaluations. The trial will assess the effect on time to full, sustained RTW of the OPAL occupational support intervention versus standard care in 742 people undergoing elective primary hip and knee replacement in the UK. An overview of the trial design is shown in Figure 1. The risk of group contamination is low due to the experimental intervention being tailored to participants and being delivered when patients are physically separated.

3.2. Trial timeline

44 months. Study set up, finalise intervention materials, training of co-ordinators (9 months); recruitment (15 months, including 6-month internal pilot); follow-up (14 months); analysis and dissemination (6 months).

Table 1 Project Timetable

Activity	Duration	Time period
Study set up including relevant approvals	9 months	June 2022 – Feb 2023
Recruitment for internal pilot phase	6 months	March 2023 - August 2023
Recruitment for main trial phase	9 months	Sept 2023 - May 2024
Final follow-up	14 month*	June 2024 - July 2025
Statistical/Economic analyses and write up of HTA report	6 months	August 2025 - January 2026

*12-month follow-up from surgery, a 2-month period is allowed between randomisation and surgery taking place to allow for variation and any delays between being listed for surgery and surgery taking place.

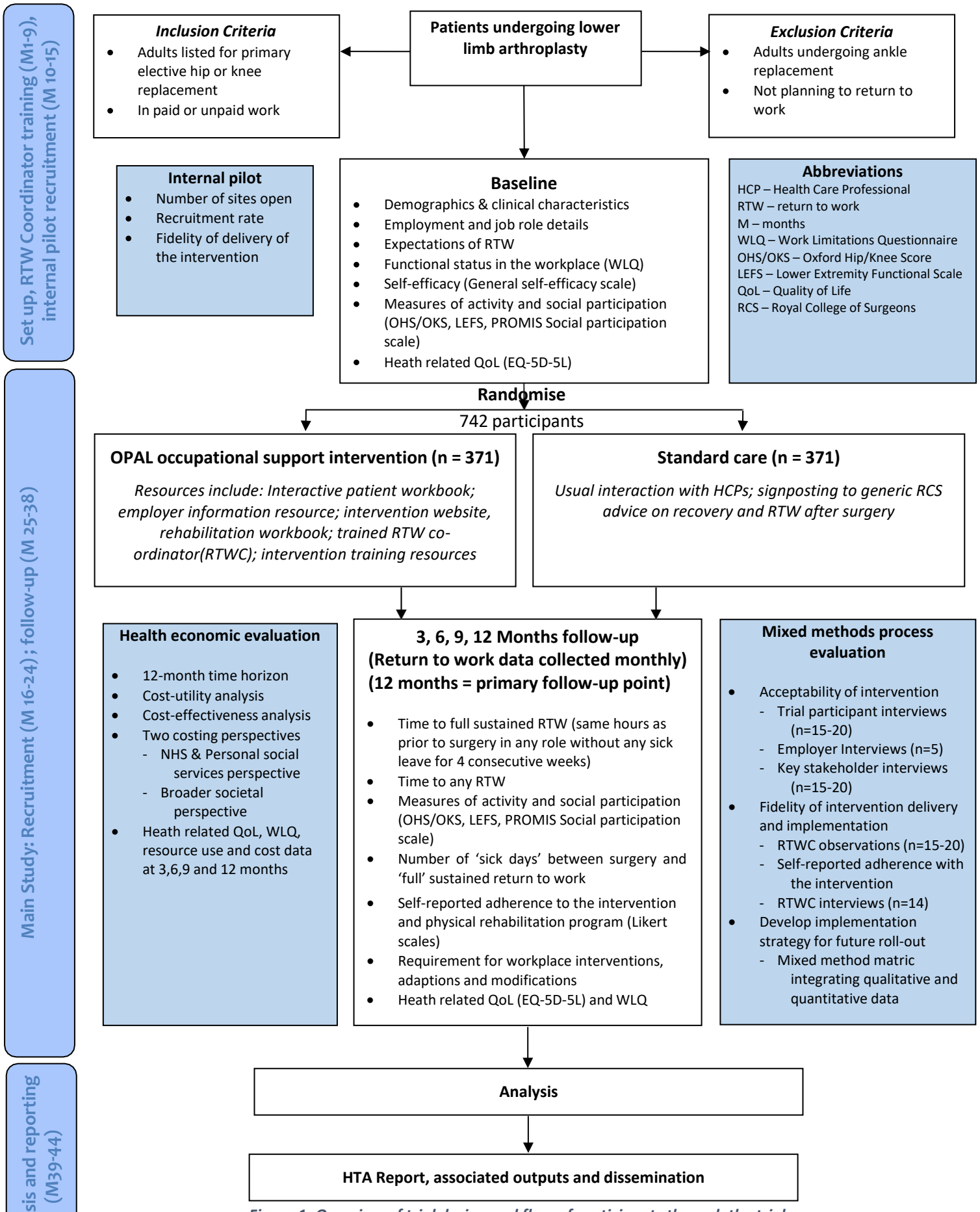

Figure 1: Overview of trial design and flow of participants through the trial

4. Methods: Participants, Interventions and Outcomes

4.1. Setting

The intervention will commence and be delivered in secondary care. There will be interaction with primary care (GP) and commercial (employers) stakeholders as part of the intervention.

We will use a minimum of 14 UK study sites drawing on a large national network of recruiting sites that we engaged with in previous trials in hip and knee replacement populations (25) (26). The sites are geographically spread and include a number of sites situated within the top decile for UK deprivation. Site selection will be targeted to ensure sampling is from a diverse range of demographic and occupational groups to optimise equality, diversity and inclusion (see section 4.4).

4.2. Eligibility

The study will include all patients, who are in both paid and unpaid work prior to hip and knee replacement surgery and who intend to return to work following surgery.

Inclusion criteria
Adults (≥ 16 years) listed for elective primary hip or knee replacement in paid or unpaid work who intend to RTW after surgery.
Any hip or knee procedure that is covered by the NICE NG157 guideline and would generate a K1 or H1 form on the NJR.

Exclusion criteria
Patients undergoing emergency arthroplasty (e.g. for trauma).
Adults listed for elective ankle replacement.
Adults planned to undergo further surgery within the six months after their joint replacement.
Patients listed for bilateral knee replacements.

4.3. Withdrawal criteria

Participants can withdraw from the trial at any point during the study by directly contacting the study team at YTU, or their clinical team. If a participant indicates that they wish to withdraw from the trial, they will be asked whether they wish to withdraw from the intervention only (i.e. withdrawal from engaging with the RTWC and workbooks) or withdraw fully from the trial. Where withdrawal is only from the intervention then follow-up data will continue to be collected. Participants will be informed that they do not have to give a reason for their decision to withdraw from the study. However, if the participant indicates the reason this will be recorded. Data provided by participants who withdraw will be retained for analysis.

4.4. Equality, diversity and inclusion

We aim to match our trial participants to the population the research will serve i.e. those in receipt of elective hip and knee replacement in paid or unpaid work (27, 28). In our

feasibility study, we achieved representativeness across broad socio-demographic characteristics, generally matching those receiving hip and knee replacements (3). To ensure this is mirrored in the full trial we will incorporate strategies to enhance recruitment and retention of underserved populations. These include targeted site selection, methods of approach and information provision to potential participants and use of a variety of data collection formats (e.g. electronic, paper and telephone) to maximise retention rates. A key issue for this trial is ensuring the intervention is accessible to the whole range of potential trial participants. We have optimised this through specifically designing intervention resources that allow patients to engage in a range of ways to suit their individual preferences and level of health literacy, hence optimising our ability to reach people who may not usually interact with written materials. We are confident our primary outcome is relevant to the broad range of patients we seek to serve and is unlikely to be affected by cultural bias.

4.5. Intervention and comparator

Intervention: The OPAL occupational support programme which was developed specifically for patients undergoing hip and knee replacement (3).

Comparator: Standard care (usual interaction with orthopaedic team) and signposting to generic RTW advice and support available via the Royal College of Surgeons (RCS) of England (29).

For information regarding intervention development, please see Appendix A.

4.5.1. Intervention content

The intervention contains two complementary elements that provide all the core components of a 'successful' occupational intervention for the target population, as demonstrated from the OPAL feasibility study (3). The two elements are a) provision of multimedia information resources which support key aspects of RTW and b) a return-to-work coordinator (RTWC) who provides 1:1 support and encourages engagement with and understanding of the provided information resources. The intervention is designed to accommodate the heterogeneity of paid and unpaid occupations undertaken by the target population. All the intervention components are required to enable the delivery of a sustainable occupational intervention for this diverse population across the variety of NHS settings that deliver orthopaedic services. Participants only complete the elements of the programme that are relevant/appropriate for them.

a) Information resources:

A collection of multimedia resources, aimed at patients, but which also act as resources for GPs, employers and hospital orthopaedic staff to facilitate wider stakeholder education. These resources are specifically designed to allow the patient to engage with the support programme in a range of ways to suit individual preferences and level of health literacy, thereby optimising the inclusivity of the intervention. Patients have a choice of which resource they use as the content is overlapping and presented in a variety of different formats to maintain engagement (e.g. written materials and web based digital resources). The design and breadth of the resources facilitates equity of access for the diverse

population of patients that need RTW support. These resources received positive feedback from our stakeholder groups, the OPAL feasibility study and in post-study PPI work (3) and include:

- **Patient workbook**: This provides tailored guidance, education and support to enable the development of a RTW plan using a novel 8-stage interactive process. It encourages patients to reflect on their health and recovery in the context of their work environment and set realistic expectations of return to usual activities and work.
- **Employer booklet:** This is provided to patients to share with their employer. It provides information for employers about the expected recovery after hip and knee replacement surgery and how to manage their employees RTW. It is a patient driven process that encourages interaction and discussion between the patient and their employer about RTW, job accommodation and workplace adaptions.
- **Rehabilitation workbook:** This prompts the patient, in collaboration with their hospital rehabilitation team and RTW coordinator (see below), to 'prescribe' a physical rehabilitation programme tailored to their individual recovery and specific RTW requirements. Through this process, exercises are selected to target specific occupational tasks patients are required to undertake in the workplace (work simulation). This approach follows the NICE guidance for self-directed rehabilitation (1), while allowing a personalised, targeted exercise prescription based on occupational requirements, co-morbidities and person-centred goals, to be delivered.
- **OPAL website:** This provides a web-based multimedia resource to include RTW information, exercises, occupational therapy and occupational health advice and support resources. This approach broadens our ability to reach certain groups who may not usually interact with written materials to further enhance inclusivity.
- **Return-to-Work Co-ordinator training resources:** These will support the RTWC role and wider education of the orthopaedic team around RTW issues.

b) The Return-To-Work coordinator (RTWC)

The RTWC role facilitates delivery of the OPAL programme. The co-ordinators support the provision of education and support, provide vocational counselling and guidance, signpost to relevant resources and support multidisciplinary team involvement in the RTW process. The 1:1 nature of the interaction between the patient and the co-ordinator allows for individualised support and helps to ensure RTW is managed sensitively and sympathetically without placing undue pressure on patients to return. This was felt to be important by our PPI co-applicants and patient advisory group.

The RTWC role aligns with previous research that demonstrates provision of a co-ordinator role is positively associated with time to RTW and the probability of return across a variety of healthcare settings (19, 20, 22, 23). Moreover, a recent systematic review recommended service coordination as a core component of RTW interventions (24).

The role will be adopted by a member of the hospital orthopaedic team who will be trained in delivering the intervention. A local hospital orthopaedic team member is best placed to adopt this role due to their knowledge of local treatment pathways, rehabilitation services and the specific needs of their local patient population. An occupational training specialist who will train and mentor the RTWCs at each study site using training resources adapted from the OPAL feasibility study. As part of the intervention, the RTWC will contact all

patients prior to surgery to review and support their engagement with the information resources and provide vocational advice to aid development of the RTW plan. They will encourage patients to share the employer booklet and their plan for returning to work with their employer. They remain a point of contact for advice and support post-surgery up to the point the patient returns to work.

4.5.2. Intervention delivery

Current care is extremely varied in its timing, content, format and mode of delivery (2) and this presents challenges for the implementation and adoption of a new intervention. In recognition of this, the OPAL intervention has been specifically designed to enable implementation across the NHS by allowing flexible delivery within the overarching framework of the intervention's patient and staff performance objectives that maintain its integrity. Delivery of the intervention will be initiated prior to surgery and continue until the patient has either returned to work or until 12 months after surgery (end of study follow-up).

4.5.3. Study comparator

Given the pragmatic nature of the trial, we will not make any changes to the usual care pathway. Determinants of RTW are rarely considered when advising patients about both the need for surgery and their subsequent RTW (2, 3). In a UK survey only 19% of healthcare respondents routinely offered RTW advice to this patient group and <10% used written information or offered onward referral to occupational health services (2, 3). When occupational advice is offered it is usually generic, ad-hoc advice using blanket timescales based on the limited experience of the treating surgeon (2, 3). However, generic written resources supporting recovery and RTW do exist via the RCS (29). To provide consistency of information for the comparator arm, we will signpost access to this information for all participants.

4.6. Outcome measures

4.6.1. Primary outcome measure

Time until 'full' sustained return to any work, defined as work resumption to the same hours as prior to joint replacement, in any role, without any day of sick leave for a consecutive 4-week period.

Two factors have driven our choice of outcome: 1) patient and stakeholder feedback and 2) the specific context of hip and knee joint replacement.

1) Patient and stakeholder perspective: A recurring theme from our PPI work for the OPAL feasibility study and the current OPAL trial has been a concern amongst the PPI group that the intervention could lead to people returning to work too soon, before they are fully ready, and that returning to work more quickly is not necessarily in a person's best interests. They suggested the emphasis should be both on sustained RTW as well as on the quality of the RTW. They, and we, recognise that returning to work more quickly is not necessarily positive, particularly if it is associated with a further period of sickness absence. Patients who have hip or knee replacement may have had to take sick leave before their

surgery and additional time for the surgery and recovery period. It is disruptive for them, their colleagues and managers, if they return too soon and subsequently require additional sick leave. The impact of this would be 'masked' by simply measuring any return to work. Furthermore, the OPAL feasibility study patient and wider stakeholder interviews and Delphi process specifically examined stakeholder perceptions about the measurement of RTW (3-6, 30). There was consensus that it is a complex outcome and not binary. Further sickness absence after initial return was viewed as an important outcome to measure and that incorporating a measure of safe and sustainable RTW was desirable (3, 30). In addition, and in line with our EDI strategy, we sought to select a primary outcome with high face validity which was unlikely to be impacted by cultural bias.

2) Joint and knee replacement context: Patients usually have an excellent outcome from primary hip and knee replacement with a reasonable expectation that they will be able to return to work: 85-90% of patients that intend to RTW have done so within 12 months of surgery (14, 16, 17, 31). There is also evidence that they may actually be able to perform work activities more easily: in the OPAL feasibility study the average productivity loss (based on the Work Limitations Questionnaire) was lower after surgery than at baseline (3). However more than 20% do not return to usual activities and have restrictions in their ability to work after joint replacement (32) and we believe it is therefore important to capture the impact of the intervention on both the nature of RTW and staying in work. A simple measure of time to RTW may be appropriate in some clinical contexts, for example in evaluating occupational support interventions for stroke survivors where RTW is achieved by fewer than half of working people (RETAKE trial NIHR 15/130/11). However, time to full sustained RTW more appropriately reflects the outcome expectations for patients having primary hip and knee replacement.

4.6.2. Secondary outcome measures

- Time to any RTW.
- Measures of functional recovery to daily activities and social participation:
    - Oxford hip/knee score (OKS/OHS) (33, 34) - Joint-specific, patient-reported outcome measures designed to assess disability in patients undergoing hip (OHS) or knee (OKS) replacement. Each score contains 12 questions scored on a 5-point scale (0-4 points) producing scores ranging from 0 (poor function) to 48 (good function).
    - Lower extremity functional scale (LEFS) (35) - A valid self-reported patient-rated outcome for the measurement of general lower extremity function. It contains 20 questions each scored on a 5-point scale (0-4 points) producing scores ranging from 0 (very low function) to 80 (very high function). It has been shown to have good measurement properties compared to the SF36 and WOMAC scores (36).
    - PROMIS social participation short form questionnaires (e.g. ability to participate questionnaire, satisfaction with social roles and activities questionnaire, satisfaction with participation in social roles questionnaires) (37, 38) - PROMIS (Patient-Reported Outcomes Measurement Information System) is a set of person-centred measures that evaluates and monitors physical, mental, and social health. We will use the social health tools developed by PROMIS to measure social participation and satisfaction with participation and social roles.
- Number of 'sick days' between surgery and 'full' sustained return to work

- Participant adherence to the intervention and the intervention's physical rehabilitation programme (including self-reported, five-point Likert scales [very helpful, helpful, neither helpful nor unhelpful, unhelpful, very unhelpful]).
- Proportion of participants using workplace interventions, adaptions and modifications to facilitate their RTW (e.g. changes in working hours or shift patterns, changes to work role or work environment, or use of additional equipment within the workplace)
- Health-related quality of life (EQ-5D-5L) (39) and Work Productivity (Work Limitations Questionnaire) (40, 41) (See section 8: Health Economic Evaluation).

Evidence suggests that, following hip and knee replacement, patients continue to RTW for up to 12 months after surgery (14, 17, 42). By 12 months the proportion of patients returning plateaus and 85-90% of patients that intended to RTW will have done so (14, 16). We will therefore follow-up patients for 12 months.

Table 2: Measurements and time points for study outcomes

	Baseline (Pre op)	**Monthly (Post op)**	**After patient has RTW (Post op)**	**Three months (Post op)**	**Six months (Post op)**	**Nine months (Post op)**	**Twelve months (Post op)**
Primary outcome (full RTW)		X					
Any RTW		X					
Workplace adaptations and modifications			X				
Demographics	X						
Oxford hip/knee score	X			X	X	X	X
Lower extremity functional scale	X			X	X	X	X
PROMIS Social participation	X			X	X	X	X
EQ-5D-5L	X			X	X	X	X
Work Productivity Questionnaire	X			X	X	X	X
Health resource use	X			X	X	X	X
Patient-reported adverse events					X		X
Participant adherence and satisfaction (intervention group only)			X				

5. Methods: Assignment of Interventions

5.1. Randomisation

Allocation will be on a 1:1 ratio (intervention:control). Randomisation will be carried out using a secure web-based randomisation system (REDCap) ensuring allocation concealment and stratified by surgical site (hip or knee joint) with randomly permuted blocks of randomly varying size.

The randomisation service will require the recording of information and a check of patient eligibility to avoid inappropriate entry of patients into the trial. The randomisation system will provide an immediate allocation and a confirmation email. The email confirming randomised allocation will be sent to the PI and all authorised users of the randomisation system at the recruiting site.

5.2. Allocation sequence generation

An independent statistician at YTU, who is not involved in the recruitment of participants, will generate the allocation sequence.

5.3. Blinding

This is an open study. Due to the nature of the treatment groups, it will not be possible to blind participants to their allocation, nor the trial team, Trial Management Group or Trial Steering Committee/Data Monitoring and Ethics Committee.

6. Methods: Trial Procedures and Assessments

6.1. Recruitment

The trial team will work closely with hospital research staff and multi-disciplinary surgical teams to optimise the identification, screening and recruitment processes to local circumstances. We will also encourage the appointment of a junior doctor, physiotherapist, nurse or other relevant healthcare professional as an Associate Principal Investigator (API) at each recruitment site to support recruitment. The APIs will be trained in study processes and will be supervised by the PI at site.
Participants will receive a £10 gift voucher for participating in the trial.

6.1.1. Identification and screening

Potential participants will be identified from the hip and knee replacement waiting lists at each centre. Eligibility screening for work status will take place either during the patient's pre-surgery assessment clinic appointment or via phone prior to surgery. The patient may be informed about the study in advance of their pre-surgery assessment clinic appointment where local practices relating to the provision of pre-appointment information allow this. Potential participants will be provided with information about the study including a patient information sheet; this will be available in a number of formats according to our EDI strategy. Patients will have the opportunity to ask questions of the clinical and local research team before consent for the study is obtained.

6.1.2. Eligibility assessment

Eligibility assessment will be undertaken locally during the pre-surgery assessment clinic appointment or via phone prior to surgery. The patient will be assessed against the eligibility criteria set out in section 4.2. If a patient is deemed to be ineligible for the study, the treating clinician will thank the patient for their interest in the study but inform them verbally that they are not able to take part. They will then continue with their usual care.

6.1.3. Consent

Written consent for participation may occur during the clinic appointment, remotely following the clinic if patients prefer further time for consideration, or remotely in the instance that the patient is identified and approached directly from the surgical waiting list. Consent for participation in the qualitative element of the study will be sought separately.

Participants will be able to provide consent electronically via REDCap, or they may request a paper form to give consent. For more information, see section 13.4. Local Principle Investigators will be required to have up-to-date Good Clinical Practice certification.

6.2. Internal pilot

We will undertake a 6-month internal pilot study to test our assumptions about site set-up, recruitment rate and intervention fidelity to confirm whether the trial is feasible (Table 2). The internal pilot will be reviewed by the TSC, DMC and the funder to determine whether the study can progress to the full trial.

Screening logs will be kept by participating centres throughout the trial. We will collect data on the number of eligible patients; eligible patients approached for consent; eligible patients not approached and reasons why; patients approached who provide consent; patients approached who do not provide consent and reasons why; patients providing consent who are randomised. We will also collect data on the number of patients randomised who do not receive the randomly allocated treatment and reasons why. With appropriate permissions and where feasible we will collect information on occupation so that we can monitor any variation across these metrics by occupational group.

We expect sites to list between 50 to 100 people for primary hip and knee replacement per month. Based on the OPAL study approximately 25% will be eligible (3). Assuming a smaller recruitment rate than the feasibility study (which was non-randomised) of 50%, we expect an average recruitment rate of 5 participants per month per site across a minimum of 14 sites (with a 50% reduction for the first 2 months of sites opening and staggered opening of sites). Recruitment will be over 15 months and the internal pilot will be assessed at 6 months at which point we will have recruited a fifth of the participants over approximately one third of the recruitment window.

6.2.1. Progression criteria

We have set targets using traffic light criteria (see Table 3). The green criteria for progression are seven sites set up and recruiting their first participant by the end of the pilot; an average of five participants recruited per site per month; and >90% of participants allocated to the intervention contacted by their return-to-work co-ordinator. We have not set progression criteria for completeness of follow-up as the primary outcome is time to event with 12-month follow-up.

Table 3: Proposed progression criteria to be assessed at end of 6-month internal pilot

Domain	Target at end of internal pilot	Green	Amber	Red
Site setup	7 sites set-up and recruiting first participant	100% (7)	60 to 99% (4 to 6)	<60% (<4)
Participant recruitment	Average of 5 participants recruited per site, per month	100% (5)	60 to 99% (3 to <5)	<60% (<3)
Intervention Fidelity	90% of patients contacted by RTWC	100% (130)	80-99% (104-129)	<80% (<104)
RTW data completeness	80% of patients submitting either 1, 2 or 3 month data	100% (116)	80-99% (93-115)	<80% (<93)

7. Methods: Data collection, management and analysis

7.1. Data collection methods

REDCap will be used to track participant recruitment and follow-up and electronic data collection. To minimise attrition, we will use multiple methods to keep in touch with participants. We will ask participants for full contact details (including mobile phone number and email address if available).

Data will be collected at baseline (pre-surgery) and 3, 6, 9 and 12 months after randomisation for the patient reported outcome measures (PROMs). Baseline data will include collection of the individual's work pattern pre-surgery.

We will collect the RTW data only on a monthly basis until participants have had a full sustained RTW as defined in the primary outcome. We will use monthly intervals to ensure we maximise recall: a follow-up period of greater than 2-months is associated with poorer recall (18). We will also monitor for balance in completeness of data across both groups. A recent UK feasibility trial successfully collected monthly employment activity data on work status (whether working or not, full-time, part-time, phased return, sick leave) and number of days worked by use of up to four monthly text messages. They reported that the method was acceptable to the majority of participants (43).

We will contact participants monthly by email with a link to an electronic data collection form (until they have achieved a full, sustained RTW). In order to optimise inclusivity this will be supplemented by telephone data collection where participants do not have an email address or are not comfortable using that method. The use of electronic data collection will allow us to have real-time information on data completion for the primary outcome, allowing prompt reminders by email and telephone to maximise data completion and accuracy. Two email reminders will be sent to non-responding participants, with a minimum of one attempt to obtain data by a telephone interview, and any further attempts will be to the sites discretion or as per local Trust policy. For participants not using the electronic method, three attempts will also be made to collect data. We will use the same method to collect the other outcomes at 3, 6, 9 and 12 months.

7.2. Data management

7.2.1. Source document identification

Source documents are original documents, data, and records from which participants' study-specific data are obtained. These include, but are not limited to, clinic records (from which medical history and previous and concurrent medication may be summarised where necessary into the study-specific documentation), clinical and office charts, correspondence, completed scales, quality of life questionnaires and interview recordings/transcripts. Study documentation entries will be considered source data if the form is the site of the original recording (e.g., there is no other written or electronic record of data). In this study the study documentation will be used as the source document.

7.2.2. Data handling and record keeping

Data collected as part of this research includes questionnaires and qualitative data from interviews. Questionnaire data will be collected via electronic data collection forms. These can be completed over the phone at the patient's preference. Every attempt will be made to ensure the data are accurate, complete and reliable.

- The staff involved in any data collection will be trained in the collection of it, including assisting participants with their questionnaires where required.
- Care will be taken to ensure participants are given clear instructions when completing the questionnaires and these will be checked for missing data by staff at YTU.
- Two email reminders will be sent to non-responding participants, with a minimum of one attempt to obtain data by a telephone interview, and any further attempts will be to the sites discretion or as per local Trust policy.
- All interviews will be transcribed verbatim by approved transcribers. A second researcher will check a sample of data transcripts against the audio recordings, for accuracy, and will interrogate the validity of the coding against the raw data. The first recordings of interviews will be checked against the interview topic guides to ensure consistency and the interviewer's approach refined if necessary.

7.2.3. Access to data and final trial dataset

Data will be held securely on the cloud-hosted REDCap server. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU.

All study files will be stored in accordance with GCP guidelines. Study documents (paper and electronic) held at YTU will be retained in a secure (kept locked when not in use) location for the duration of the trial. All work will be conducted following the University of York's data protection policy which is publicly available (www.york.ac.uk/records-management/dp/policy).

The final trial dataset held in Stata format (as a .dta file) will be accessible subject to a completed YTU Data Request form, and Chief Investigator confirmation.

7.3. Archiving

Data will be archived in accordance with current YTU's Standard Operating Procedures. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records. All electronic records will be stored on a password protected server within the York Trials Unit.

Data will be archived by the University of York for a minimum period of 5 years following the end of the study. Personal data will be processed under Article 6 (1) (e) (Processing necessary for the performance of a task carried out in the public interest) and Special Category data under Article 9 (2) (j) (Processing necessary for ... scientific ... research purposes) of the General Data Protection Regulation (May 2018).

7.4. Statistical considerations

7.4.1. Sample size

A previous meta-analysis of RCTs examining work co-ordination programmes for work disability found a hazard ratio (HR) for time to RTW of 1.34 (95% CI:1.14-1.56)(23). With 90% power, 5% alpha, to detect a HR=1.34, assuming a median time to RTW of 3.2 months (17) and an unequal group ratio of 1.3, the sample size required is 522 (295 in the control and 227 in the intervention). Accounting for 20% attrition, an average of 31 patients per RTWC, ICC=0.01 the sample size required is 742 with equal allocation. A minimum of 12 RTWC would be required to deliver the trial. The sample size was calculated for a log rank test using PS Power and Sample Size software.

7.4.2. Statistical analysis plan

Internal pilot: The recruitment rate and 95% confidence interval (CI) will be estimated from the data collected. A CONSORT diagram will be constructed to show the flow of participants through the study. Data will be summarised for: reasons why eligible patients were not approached, reasons for patients declining to participate in the study; reasons why randomised patients did not receive their allocated treatment and reasons for drop-out, if available. The number of participants contacted by the RTWC will be summarised. Results will be compared against the study's recruitment assumptions and progression targets using the traffic light system in Table 3.

Full trial: For the analysis of the full trial, a CONSORT flow diagram will be provided to display the flow of participants through the study. The number of participants withdrawing from the trial will be summarised with reasons where available. Baseline characteristics will be presented descriptively by group. All outcomes will be reported descriptively at all collected time points. Continuous data will be presented using means and standard deviations or medians and ranges as appropriate, and categorical data will be presented using frequencies and percentages. The analysis will follow the principles of 'intention-to-treat' with all events analysed according to the participants' original, randomised treatment allocation, irrespective of deviation based on non-compliance. Delays or cancellations of surgery are not anticipated to be an issue, but any delays would be distributing between arms equally. In addition, a sensitivity analysis accounting for waiting time will be conducted. This may be subject to change if delays or cancellations become a significant issue.

Primary outcome analysis: The primary analysis will be an assessment of treatment differences evaluated using the Cox Proportional Hazard (CPH) model with shared centre and RTWC frailty effects and adjusting for important baseline covariates (including stratification factors). The hazard ratio, confidence interval and p-value will be reported. Median time until full return to any work and Kaplan-Meier survival curves will be presented by the trial arms and a log-rank survival comparison will be made.

Secondary outcome analysis: Time to any RTW will be analysed using a similar model to the primary analysis. Other secondary outcomes will be analysed using linear mixed models (e.g. (OKS/OHS), LEFS, PROMIS) or logistic regression (workplace intervention) as appropriate.

For the number of sick days taken after surgery and before sustained RTW a Poisson regression will be completed. Differences between allocated groups will be reported for all available time points.

Subgroup analyses: A subgroup analysis by surgical site will be carried out by including an interaction term with treatment allocation in the primary analysis.

Missing data: Missing data will be dealt with, either as part of a time-to-event analysis or via application of imputation approaches.

Sensitivity analysis: A CACE analysis will be conducted based upon the adherence to the intervention.

The number of SAEs and AEs in each treatment arm will be summarised descriptively, with a full list of individual events in each arm.

7.5. Definition of end of trial

The end of the trial will be defined as the date at which the last participant has completed all the study processes. The trial will be stopped prematurely if:

- Funding for the trial ceases
- The Trial Steering Committee recommends it
- It is mandated by the Research Ethics Committee

8. Health economic evaluation

The economic evaluation will assess the cost-effectiveness of the intervention versus usual care over a 12-month period using patient level data, from an NHS and personal social services perspective in the base case. This will take the form of a cost-utility analysis (in terms of the incremental cost per quality-adjusted life year (QALY)) and also a cost-effectiveness analysis (in terms of the incremental cost per missed workday averted). The base case analysis will include the cost of the intervention and healthcare resources used by participants, with health-related quality of life data captured using the EQ-5D-5L (39) (at baseline, 3, 6, 9 and 12 months). A secondary analysis will explore the wider societal perspective.

Resource use questions via self-completed participant questionnaires (at 3, 6, 9 and 12 months) will capture participants' healthcare utilisation within primary care and the community (i.e. GP, nurse, occupational therapist, physiotherapist attendances) and secondary care (i.e. hospital outpatient attendances, inpatient stays, day cases and accident and emergency attendances) in relation to their hip/knee that has been replaced. Unit costs, sourced from established national costing sources (44, 45) will be applied to each resource use item to estimate a total cost per participant. Cost estimates of the intervention will incorporate the cost of all associated resources and materials, for development, training, and delivery of the intervention, including staff time. In addition to health-related costs, further indirect costs incurred by participants (e.g. travel costs for appointments) and information regarding lost productivity will be collected for the secondary analysis. Work productivity will be estimated, using the Work Limitations Questionnaire, a validated measure (40) that assesses the extent to which chronic health conditions affect the ability to perform job roles (41). Earnings information sourced from the Office for National Statistics will be applied to the time missed from work.

The cost-utility analysis will estimate the mean differences in costs and QALYs, using the EQ-5D-5L to generate utilities, with QALYs estimated for each participant using the area under the curve approach (46). A cost-effectiveness analysis will determine the cost per missed workday averted. Regression methods will be used to estimate mean within-trial costs and health effects, adjusting for baseline covariates and allowing for correlation between costs and effects. Missing data patterns will be analysed and dealt with using multiple imputation methods (47). Findings will be presented in terms of incremental cost-effectiveness ratios and net health benefit. Uncertainty will be described using confidence intervals and cost-effectiveness acceptability curves (48), to depict the probability of the intervention being cost-effective at different willingness-to-pay (for a QALY) thresholds. Sensitivity analyses will explore the robustness of the cost-effectiveness findings. Analyses will be conducted on an intention-to-treat basis, and in Stata v17 or later. The evaluation will follow up-to-date NICE guidance for the methods of cost-effectiveness (49) wherever possible and a pre-specified health economic analysis plan will be agreed with the TSC/DMC and signed off by the Chief Investigator.

9. Process evaluation

9.1. Design of process evaluation

A mixed methods process evaluation will be used to assess the intervention using a revised version of the Carroll et al. (50) conceptual framework for implementation fidelity. To inform how the trial findings could be incorporated into developments in service delivery/future implementation, we will draw on relevant data from across the qualitative components of the study, including how the intervention was implemented across the trial sites. This will be summarised using Normalisation Process Theory (NPT) (51) and, together with the main trial findings on effectiveness and cost-effectiveness data, will be discussed at the second stage interviews with service leaders. Data will be used to develop an implementation strategy for future roll out across the NHS, if appropriate.

9.2. Data collection for process evaluation

To address important issues of fidelity and acceptability of the intervention the following data will be collected:

a) Qualitative observations of the RTWC during an initial appointment with a sample of participants pre-surgery (n=15-20) to understand how the intervention is implemented in practice.
b) An intervention delivery checklist will be completed for all trial participants (by the RTWC) detailing exact elements of the intervention delivered.
c) Participant outcome questionnaires (3, 6, 9 and 12 months) will include self-report adherence with the intervention, physical rehabilitation and/or recommendations made by the RTWC.
d) Completion rates of the patient / rehabilitation workbooks (across different formats).
e) Qualitative interviews with trial participants from the intervention arm (n=15-20). Participants will be purposively sampled to ensure maximum variation (on the basis of age, gender, job role and site) to ascertain the acceptability of the interventions, ease of use and perceived impact of the intervention.
f) Interviews with a sample of trial participants' employers (n=5) will be conducted to understand key stakeholder perspectives.
g) Interviews with RTWCs (n=14) will be conducted on two occasions. At the start of the study brief interviews will be conducted regarding reasons for applying for the position, expectations for the post/intervention, anticipated barriers and facilitators to using the intervention. At the end of the intervention period, RTWCs will be asked about their experience of delivering the service, interfacing with other service providers and to highlight challenges/facilitators associated with service delivery.
h) Interviews with service leaders/key stakeholders (n=15-20) including clinicians, and commissioners will be conducted at two time points: during project set up to discuss current provision, how the new intervention will fit within existing services and how this will be funded; and at end of trial to discuss incorporating trial findings into service development.

9.3. Data analysis for process evaluation

We will use NVivo software to assist qualitative data organisation and coding. We will conduct Framework Analysis (using the broad categories as described in the implementation fidelity model and the key characteristics of NPT) in order to summarise findings according to key study outcomes: intervention fidelity, acceptability of intervention, engagement with/adherence to the intervention and implementation (52).

Descriptive statistics of the quantitative process evaluation data will be integrated with qualitative findings using a mixed method matrix. Where relevant these data will be integrated with appropriate quantitative data to provide a more complete picture.

Table 4: Fidelity assessment and proposed data sources

Fidelity component	Data utilised
Context Current service delivery relating to return to work Reasons for the introduction of OPAL intervention Integration of OPAL intervention with existing service provision	Initial interviews with service leaders/ clinicians/commissioners; Initial interviews with RTWCs
Coverage/Recruitment What proportion of the target group participated in the intervention? What recruitment procedures are used, potential barriers to participation/maintaining involvement?	Broad socio-demographic quantitative data on non-responders and decliners Interviews with service delivery staff Initial interviews with service leaders
Evaluation of adherence Was each intervention component implemented as planned, correct frequency/duration, appropriate quality?	Observations Intervention delivery inventory Interviews with RTWC
Participant responsiveness How engaged were participants with RTWC? Relevance of and satisfaction with OPAL Perception of outcomes associated with RTWC Response to the recommendations made	Interviews with participants Outcome questionnaires Interviews with RTWC RTWC engagement score
Intervention complexity/comprehensiveness How complex is the intervention? How specific is the description of the intervention?	Initial interviews with service leaders Assessment by study steering group
Strategies to facilitate implementation How was intervention supported? Perceptions of challenges to implementation	Final interviews with service leaders Interviews with RTWC

10. Trial Oversight and Monitoring

10.1. Trial Oversight

10.1.1. Site Monitoring

Participating sites may be asked to assist in trial related monitoring when required, for example audits, ethics committee review and regulatory inspections. The YTU will undertake central monitoring of sites. This may include: review of consent forms; review of screening forms to confirm eligibility; cross checking delegation logs; and annual audits completed by sites and returned to the YTU.

10.1.2. Sponsorship

The trial will be sponsored by South Tees NHS Foundation Trust.

10.1.3. Indemnity

As South Tees NHS Foundation Trust is acting as the research Sponsor for this study, NHS indemnity applies. NHS indemnity provides cover for legal liabilities where the NHS has a duty of care. Non-negligent harm is not covered by the NHS indemnity scheme. South Tees NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

10.2. Trial Management

The Trial Manager at York Trials Unit (YTU) will be responsible for all aspects of trial management and will be supported by other relevant staff members (e.g. trial co-ordinator(s) responsible for the day-to-day support of trial sites, trial statistician, data manager, trial health economist and administrative staff).

The YTU team will meet on a weekly basis and will work closely with the CI particularly at the start of the project and during the internal pilot of the study, including regular teleconferences to ensure that all aspects of preparation of study material, study site setup and the start of recruitment progress smoothly.

The Trial Coordinator, on behalf of the Chief Investigator, will submit and, where necessary, obtain approval from all relevant parties for all substantial amendments to the original approved documents. Regular progress reports will be submitted as required to the Funding Body.

10.2.1. Trial Management Group

A Trial Management Group (TMG) will monitor the day-to-day management (e.g. protocol and ethics approvals, set-up, recruitment, data collection, data management) of the study. Membership will include the CI, co-investigators and research staff on the project. Throughout the project there will be regular teleconference contact supplemented by face-to-face meetings where required. Frequency of meetings will vary depending on the stage of the trial but at least monthly during the early stages and pilot. We will keep in close contact via email and telephone throughout.

10.2.2. Trial Steering and Data Monitoring Committee

A Trial Steering Committee (TSC) will monitor progress of the study, provide independent advice and the independent chair will make recommendations to the funder. An independent Data Monitoring Committee (DMC) will monitor the data arising from the trial and make recommendations to the TSC about trial continuation based on ethical and safety considerations. The project will also be monitored by the Sponsor (South Tees NHS Foundation Trust) and a representative will be invited to attend the TMG, TSC and DMC meetings. Other study collaborators may also attend the meetings at the discretion of the Chair.

10.2.3. Roles and responsibilities: Chief investigator and co-investigators

We have widened the core team that successfully delivered the OPAL feasibility study to strengthen specific areas of expertise. The team includes experts in the care of people undergoing hip and knee joint replacement; patients with experience of returning to work following replacement surgery; and methodologists with expertise in the design delivery and analysis of multi-centre RCTs in the field of orthopaedics.

Joy Adamson – RCS Chair in Surgical Trials and Health Research. She is a mixed methods researcher who has extensive experience of the application of qualitative methods alongside trials and will be responsible for the process evaluation.

Paul Baker - Consultant Orthopaedic Surgeon specialising in hip and knee replacement surgery. He was Chief Investigator for the OPAL feasibility study and will lead the OPAL trial. He is the orthopaedic research lead for the Royal College of Surgeons surgical trials initiative and a member of the British Orthopaedic Association research committee and will use these networks to enable study delivery within orthopaedic services.

Avril Drummond - Occupational therapist and Professor of Healthcare Research with a long-standing interest in vocational rehabilitation: she was a member of the original OPAL feasibility study team. She is a mixed methods researcher and trialist with over twenty years of experience within the field. She will oversee the content of the OPAL intervention and roll out.

Catherine Hewitt - Professor of Medical Statistics and Co-Director of York Trials Unit. Her research portfolio is currently over £40 million, and she has a wealth of experience delivering and analysing large scale randomised controlled trials. Catherine will oversee the statistical design and analysis of the OPAL trial. She was a member of the OPAL feasibility study team.

Ira Madan - Consultant and Professor in Occupational Medicine. She has led or been co-applicant in several NIHR trials and feasibility studies. She developed and tested the feasibility of delivering an intervention to improve RTW in NHS staff with common mental health disorders and has helped develop and deliver a vocational support intervention to improve early RTW in people with chronic pain and for people with early sickness absence.

Catriona McDaid - Reader in trials and applied health researcher with several years' experience in the design, delivery and reporting of multi-centre trials of complex interventions in secondary care, particularly in the field of trauma and orthopaedics. She was a member of the OPAL feasibility study team and will be YTU lead for this trial.

David McDonald - Physiotherapist specialising in Orthopaedics/Arthroplasty Surgery. He has extensive knowledge and expertise in designing and developing clinical pathways for patients undergoing arthroplasty surgery and member of the OPAL feasibility study team. He works for the Scottish Government as a National Improvement Advisor and is responsible for standardisation of national clinical pathways across multiple specialities.

Mike Reed - Orthopaedic surgeon and clinical director for Northumbria Healthcare, and President of the British Orthopaedic Clinical Directors Society. He has led a number of multicentre improvement projects focussed on pre- and post-operative care and has run several RCTs with patients having elective joint replacement.

Sarah Ronaldson - Experienced Health Economist, with expertise in conducting economic evaluations within healthcare research. She has undertaken numerous analyses, including economic evaluations alongside clinical trials for NIHR funded trials, and worked on the OPAL feasibility study. Sarah will undertake the health economics component of the project.

Toby Smith - Professor in Physiotherapy and Senior Orthopaedic Physiotherapist. His clinical and research interests centre on the management of people with musculoskeletal disorders. He successfully leads/is co-applicant on a number of NIHR multi-centre RCTs investigating rehabilitation and recovery following hip and knee surgery. He will lead on the delivery of the physiotherapy/rehabilitation component of the intervention.

Louise Thomson - Associate Professor of Occupational Psychology and a HCPC-Registered Practitioner Psychologist. She is an expert in return-to-work, job retention and mental health at work and she has sat on recent NICE committees developing guidance on these topics.

Lucky Kottam – Orthopaedic research manager with experience of surgical trials coordination, management and leading PPI engagement. She has worked as PPI lead on several NIHR funded clinical trials including the OPAL feasibility study. She will act as the PPI lead for the OPAL trial working alongside the PPI co-apps and our wider patient advisory group.

Marion Archer and Carol Jordan - Patient co-applicants who are part of the wider Arthroplasty for Lower Limb (A4LL) patient advisory group (PAG) at the lead site and have lived with the experience of joint replacement surgeries. They will lead the patient advisory group.

10.2.4. Principle investigators/local site co-ordinators

Each site will have a Principal Investigator (PI) who will be responsible locally for the study. We will also encourage sites to adopt the NIHR Associate Principal Investigator (API) scheme.

11. Safety assessment and reporting

11.1. Definitions

For the purposes of the OPAL study, adverse events are defined as any untoward medical occurrence (i.e. any unfavourable and unintended sign, symptom or disease), experienced by a study participant and which is temporally associated with study treatment (intervention or control) and is related to the hip or knee replacement or to the study intervention or control treatments.

11.2. Adverse event management

For the purposes of the OPAL trial, AEs should only be considered as related to the hip or knee replacement or to the study intervention or control treatments if:

- They occur during the inpatient stay (after randomisation) for the primary joint replacement
- They occur in the same limb as the replaced joint.
- They are related to the anaesthetic, surgery, hospital admission, physiotherapy, or radiographic assessment.
- They are thought to be related to the trial interventions, trial processes or the condition being studied.

AEs will be collected from the point of randomisation onwards, up to the 12 month follow up point. Events occurring before randomisation will not be recorded.

11.2.1. Normal aspects of care

Some events that occur during treatment and recovery will be considered normal aspects of the anaesthetic and post-operative recovery process and will not be considered as AEs unless, in the opinion of the clinical team, they are untoward, excessive or outside of what might normally be expected for the procedure. These are not expected adverse events, they are normal events that occur frequently after surgery. These include:

- Nausea and vomiting after surgery
- Drowsiness or headache after surgery
- Temporary low blood pressure after surgery
- Sore throat after surgery
- Itching after surgery
- Post-operative pain
- Memory loss or confusion during the hospital stay only, or which the treating clinician believes is due to analgesics.
- Numbness adjacent to the surgical wound
- Early wound oozing which spontaneously resolves
- Swelling, within the confines of what is considered normal for low limb joint replacement by the treating clinical team
- Restriction of range of motion, within the confines of what is considered normal for lower limb joint replacement by the treating clinical team

- Bruising
- Mild discomfort during or immediately after physiotherapy (in-patient and out-patient).

11.3. Serious Adverse Events (SAEs)

Due to the low-risk nature of the occupational support intervention any related adverse events are likely to be uncommon and minor in nature. Adverse events (AE) are defined as any untoward medical occurrence in a clinical trial participant and which do not necessarily have a causal relationship with the treatment. All AEs will be listed on the appropriate Case Report Form for routine return to YTU. Serious adverse events (SAE) are defined as any untoward and unexpected medical occurrence that:

- Results in death
- Is life-threatening
- Require hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect
- Is an important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed.

All SAEs, occurring from the time of randomisation until completion of the 12 months follow up must be recorded on the SAE form in the participants CRF. The Sponsor, and YTU for this trial must be notified within 24 hours of the research staff becoming aware of the event. Once received, causality and expectedness will be confirmed by the Chief Investigator. SAEs that are deemed to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) and sponsor within 15 days. All such events will be reported to the Trial Steering Committee (TSC)/Data Monitoring Committee (DMC) at their next meetings.

SAEs that may be expected as part of the surgical interventions under investigation, and that do not need to be reported to the main REC include events which can be considered expected adverse events (or serious adverse events, if they meet the criteria) after lower limb joint replacement. These include, but are not limited to, the following:

Those related in general to surgery and anaesthetic:

- Post-operative medical complications (Chest infection, Myocardial infarction [Heart attack], Stroke)
- Death
- Nerve or vessel injury due to local anaesthetic (i.e. local blocks or spinal anaesthetic).
- Spinal Haematoma

Those related to the operation itself:

- Exacerbation/persistence of joint pain beyond what is considered normal by the treating clinical team. As this outcome will be captured in Patient Reported Outcome Measures (PROMs) throughout the study, only medical interventions for persistent joint pain need to be reported.

- Requirement for further surgery, for example manipulation under anaesthetic for a stiff knee or reduction of a dislocated hip replacement
- Infection
- Wound healing problems
- Injury to the bones, ligaments or muscles around the replaced joint
- Implant failure, dislocation, or loosening.
- Revision or other corrective surgery
- Thrombosis (deep vein thrombosis, pulmonary embolus, cerebral infarct).
- Damage to nerves or vessels in the surgical area.

Those related to physiotherapy after surgery:

- Persistent muscle soreness or muscle injury
- Bruising

For each SAE the following information will be collected:

- Full details of the event in medical terms and description of the case
- Event duration (start / end dates)
- Action taken
- Outcome
- Causality in relation to the trial interventions
- Whether the event would be considered expected or unexpected.

Relationship to trial intervention	**Description**
Unrelated	There is no evidence of any causal relationship
Unlikely to be related	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention or device). There is another reasonable explanation for the event.
Possible relationship	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial intervention or device). However, the influence of other factors may have contributed to the event.
Probable relationship	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

11.4. Audits and inspections

The Investigator(s) must ensure that source documents and other documentation for this study are made available to study monitors, the REC or regulatory authority inspectors. Authorised representatives of the Sponsor and YTU may visit the participating sites to conduct audits/ inspections as indicated in the Sponsor's risk assessment of the study.

Monitoring and source data verification will be conducted by YTU on behalf of the Sponsor according to the study monitoring plan. The extent and nature of monitoring will be determined by the study objectives, purpose, design, complexity, masking, number of patients and sites, and endpoints.

The Sponsor may suspend or prematurely terminate either the entire study, or the study at an individual site, for significant reasons that must be documented (e.g. an unacceptable risk to participants or serious repeated deviations from the protocol/ regulations). If this occurs the Sponsor shall justify its decision in writing and will promptly inform any relevant parties (i.e. participants, investigators, participating sites, REC, regulatory bodies).

A study specific monitoring plan will be developed to outline any monitoring or audit considerations.

11.5. Data quality assurance

See section 7.2. for more information on data handling and quality.

11.6. Data storage and confidentiality

The research teams at University of York and participating NHS Trusts will comply will all aspects of the current Data Protection Act (1998) and the forthcoming General Data Protection Regulation (May 2018). All documents will be stored safely in confidential conditions. Any paper forms containing participant identifiable information will be held in a location separate to the questionnaire data. Identifiable information held by YTU will be stored securely in a locked filing cabinet, in an office only accessible via registered swipe card access held by the YTU research team. On all study-specific documents, other than the signed consent form, the participant will be referred to by the study participant number/code, not by name.

Personal data held electronically, will be stored on the study specific participant management system which will record identifiable information and participant activity to enable study coordination (including personal addresses, postcodes and other contact details of consenting participants for the purposes of assisting in follow-ups during the study). The study specific participant management system will be developed by the YTU Data Management team for the purposes of this study. The system will be housed on YTU, University of York servers, which are secure and is subject to rigorous testing and continued backup. Sites will have access to the system, via individual password, to facilitate randomisation and permissions for access will also be detailed within the study delegation log. The study team based at York Trials Unit will have access to the system, via individual password, to facilitate study conduct including study coordination and the management of questionnaires. Permissions for access will also be detailed within the study delegation log.

Data from qualitative interviews will be transferred onto a secure server at the University of York as soon as possible and data removed from the portable recording device (e.g., audio recorder, laptop) as soon as possible. Transcribers will have a signed confidentiality agreement with the appropriate University including a section which acknowledges that any recordings downloaded or transcript files will be deleted after being sent to the researcher.

12. Patient and public involvement

Several meetings have been held with patient representatives and the 'Arthroplasty 4 Lower Limb' patient research group based at the lead site. The group of over 40 members, have been consulted about the proposed study design, the intervention, and associated resources. Suggestions from the PPI group have been incorporated into the study design, choice of primary outcome, method and timing of follow up, and the lay summary. Two patient representatives are co-applicants on this study, and they have worked with the study team to refine study design, trial processes, and provide feedback on comments from the panel. The study team will work with the two patient co-applicants and a study specific patient advisory group (PAG) who have lived experience of hip or knee joint replacements to ensure patient and public input on matters relating to study recruitment, content of patient-facing materials, participant follow-up and retention, and dissemination. This activity will be supported by the PPI lead (LK). The PPI co-applicants will be a link between the Trial Management Group and the PAG and will present views from the PAG at the TMG meeting where PPI will be a standing item.

13. Ethical and regulatory considerations

13.1. Ethics and research governance review and compliance

All required Health Research Authority and Research and Development (R&D) approvals will be obtained. The study will be performed subject to Research Ethics Committee favourable opinion and local R&D capacity and capability assessments.

We will adhere to the Research Governance Framework and MRC Good Clinical Practice Guidance. The participant information sheet for the study will be developed with the involvement of the PPI group and will give a balanced account of the interventions. It will state explicitly that quality of care will not be compromised if the participant decides to a) not enter the trial or b) withdraw their consent. Written informed consent will be obtained from all trial participants after they have had sufficient time to read the study materials and ask any questions. An application for NHS ethical approval will be made in the set-up phase, which will include all documentation that is to be given to participants. We do not anticipate major ethical concerns with this study. The YTU trial team/Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

The OPAL trial will be subject to approval from the REC and the Health Research Authority prior to study activity commencing. The study will be conducted in accordance with the UK

Policy Framework for Health and Social Care Research and Medical Research Council (MRC) Good Clinical Practice (GCP) Guidance.

Before NHS sites can enrol a participant into the study, confirmation of capacity must be sought from the site's research and development (R&D) department. In addition, for any amendment that will potentially affect the site's permission, the research team must confirm with the site's R&D department that permission is ongoing.

13.2. Peer review

This study has been peer reviewed as part of the NIHR HTA application process.

13.3. Potential risks and benefits

Informed consent will be obtained by the clinic staff authorised by the Chief Investigator to do so, using a detailed PIS developed with the help of service users, which will explain the risks and benefits clearly. It states explicitly that quality of care will not be compromised if the patient decides not to enter the trial or withdraw their consent. In the unlikely event that new information arises during the trial that may affect participants' willingness to take part, this will be reviewed by the Trial Steering Committee for addition to the PIS. A revised consent form(s) will also be completed if necessary.

13.4. Informed consent

Before being enrolled in the OPAL study, written informed consent will be obtained from all participants. Any measures specifically required for the study will not be undertaken until valid consent has been obtained.

All prospective participants will be provided with a detailed PIS and provided the opportunity to ask any questions regarding the study. The PIS will explain the nature and objectives of the study and give a balanced account of the possible benefits and known risks of the interventions. It will state explicitly that quality of care will not be compromised if the participant decides to a) not enter the trial or b) withdraw their consent. We will make it clear that there is no obligation to participate.

Participants may give consent electronically via REDCap. They will also have the option to complete a paper consent form. The original signed consent form will then be retained in the investigator site file held at each NHS site. Other copies of the consent form are required:

- One copy of the informed consent form will be sent securely to YTU (by secure fax or encrypted email) and filed in the Trial Master File.
- One copy of the informed consent form will be kept in the patient's clinical notes where applicable. If a patient does not have clinical notes at the trial site, the informed consent document will be filed in a separate folder and a note made in the Electronic Patient Records System.
- One copy will be given to the patient.

At the time of consent, written informed consent must be confirmed by the personally dated signature of the participant and the person conducting the informed consent discussions.

Written consent for participation may occur during the clinic appointment, remotely following the clinic if patients prefer further time for consideration, or remotely in the instance that the patient is identified and approached directly from the surgical waiting list. Consent for participation in the qualitative element of the study will be sought separately.

13.5. Protocol amendments

Changes to the protocol will be documented in written protocol amendments; the Sponsor is responsible for deciding if an amendment should be deemed substantial or non-substantial. Substantial amendments will be submitted to the relevant regulatory bodies (REC, HRA) for review and approval. The amendments will only be implemented after approval and a favourable opinion has been obtained. Non-substantial amendments will be submitted to the HRA for their approval/ acknowledgment. Amendments will not be implemented until all relevant approvals are in place.

13.6. Protocol Compliance

The Chief Investigator is responsible for ensuring that the study is conducted in accordance with the procedures described in this protocol. Prospective, planned deviations and/or waivers to the protocol are not acceptable. Accidental protocol deviations may happen and as such these must be reported according to the York Trials Unit SOP. Deviations from the protocol which are found to frequently recur are not acceptable and will require immediate action. Where events are repeated this may constitute a serious breach.

13.6.1. Notification of Serious Breaches to GCP and/or the Protocol

A “serious breach” is a departure from the protocol, agreed procedures (i.e. SOPs), or regulatory requirements which is likely to effect to a significant degree –

- The safety or physical or mental integrity of the subjects of the study; or
- The scientific value of the study.

If a serious breach is identified the Investigator should notify York Trials Unit immediately (i.e. within 1 working day) using the ‘Non-CTIMP Notification of a Serious Breach’ form. The report will then be reviewed by the Sponsor and CI, and where appropriate, the Sponsor will notify the REC within 7 calendar days of being made aware of the breach.

13.7. Retention of trial documentation

In line with the principles of Good Clinical Practice/UK Clinical Trials Regulations, essential trial documentation will be kept with the Trial Master File and Investigator Site Files. This documentation will be retained for 5 years after the conclusion of the trial to comply with standards of Good Clinical Practice, and Sponsor requirements.

Case Report Forms will be used to record all the information required from the protocol will be stored for 5 years after the conclusion of the trial (either as paper records stored in a secure storage facility either on or off-site, or electronically on a password protected server) in accordance with guidelines on Good Research Practice.

Data entered onto a database will be stored on a private network protected by a firewall at the YTU, University of York. Access to the database is restricted to trial staff. The trial database will be securely archived for at least 5 years on the YTU computer network with restricted access to YTU staff. Access to the archived data will be restricted to YTU staff and named individuals but will be retrievable at the request of the sponsor or investigators.

14. Dissemination, outputs and impact

If the intervention is found to be effective and cost-effective this research has the potential to greatly improve how patients undergoing hip and knee replacement are supported in their return to paid and unpaid work. Our feasibility study highlighted the importance of engaging a range of different healthcare professionals to allow flexibility in implementation of the intervention and we will develop a comprehensive list of relevant groups.

Dissemination will focus on supporting the wider adoption and implementation of the intervention (if effective); the dissemination plan, developed at the outset of the project, will be amended as results of the implementation sub-study become available. The study protocol will be published in a peer reviewed journal after the study commences. A HTA monograph of the findings will be produced as well as publications in other peer reviewed journals, regardless of the findings.

A range of methods will be used to target groups for whom the results (and implementation plan) will be relevant. In addition to academic journals, we will use lay summaries targeted at specific stakeholders, presentations at relevant professional society events and press releases through the collaborating NHS organisations, occupational health service organisations and universities. Clinical co-applicants' regular attendance at professional events and conferences will allow cost-effective dissemination of the findings. Occupational therapists, orthopaedic surgeons, physiotherapists, occupational medicine and employers will be targeted through a range of organisations/bodies such as; Royal College of Occupational Therapists, RCS, British Orthopaedic Association and affiliation specialist societies (British Hip and Knee Societies), Society of Occupational Medicine, Royal College of Nursing, Chartered Society of Physiotherapy, Royal College of General Practitioners, Federation of Small Businesses, Make UK the manufacturers organisation, Confederation of British Industry and the Department for Work and Pensions.

A plain English summary will be disseminated to trial participants who have expressed an interest in hearing about the findings. The results will also be disseminated more widely to patients, via key websites that patients undergoing surgery use, for example the Royal College of Surgeons of England information webpage https://www.rcseng.ac.uk/patient-care/recovering-from-surgery/total-hip-replacement/returning-to-work/. The findings will be relevant for the next update of NICE clinical guidance (NG157) and will be highlighted to the guideline team.

At the end of the trial the intervention content will be made available through the NIHR HTA Journals webpage for the project, with an implementation plan/toolkit. Even if the intervention is not proven to be effective there may be individual elements that would be useful to healthcare professionals or patients and these will be sign-posted, for example information about expected recovery or the home exercises booklet.

The SWAT findings will be disseminated in a relevant journal read by trialists such as BMC Trials or BMJ Open and disseminated at relevant conferences such as the International Clinical Trials Methodology Conference. Data will be made available to allow for inclusion in future meta-analyses with studies of the same intervention in other trials.

15. Protocol amendment history

Version	Date	Editor	Comments
1.0	25/11/2022	Amie Woodward	
1.1	25/08/2023	Lucy Sheehan	Sponsor contact updated in Key Trial Contacts
2.0	29/02/2024	Lucy Sheehan	Trial Coordinator and Health Economist contacts updated in Key Trial Contacts Participant voucher details added as stated in section A46 of the IRAS submission.
3.0	15/04/2024	Lucy Sheehan	Wording amended around phone call follow-ups by sites for data collection.

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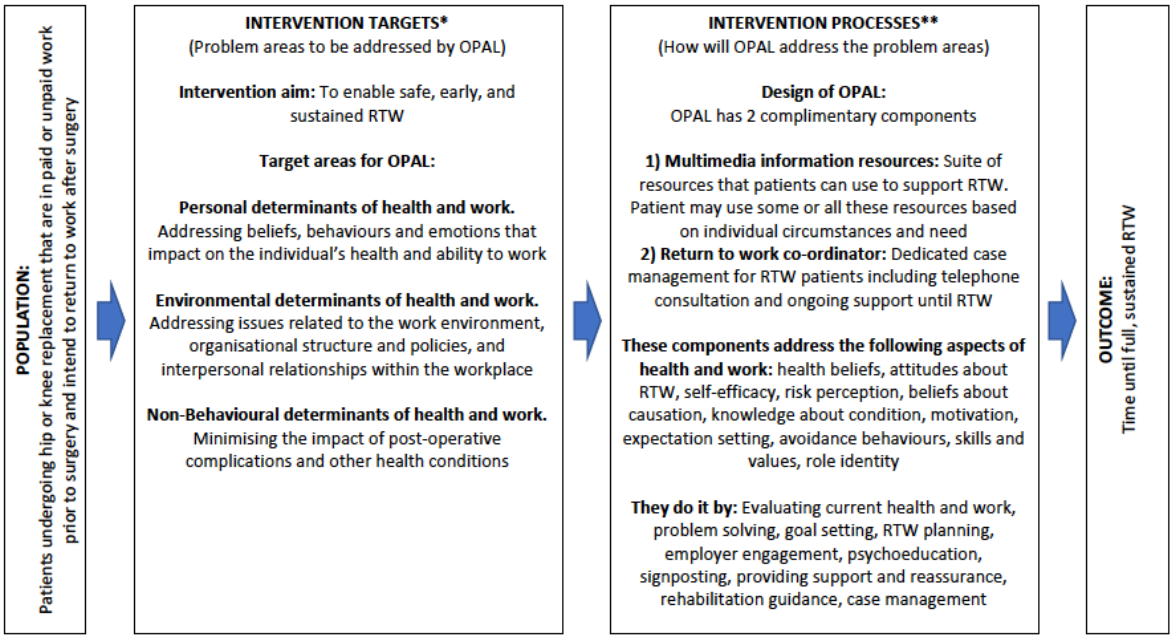
17. Appendices

Appendix A: Intervention development

The OPAL occupational support programme was developed using an intervention mapping process for the development of new interventions (53). A mixed-methods approach utilised data collected from evidence synthesis, quantitative cohort studies, qualitative patient and stakeholder interviews, Delphi consensus process and a feasibility assessment. From this data, we created logic models that allowed us to understand the problems associated with RTW after surgery and the changes that were required to enable successful return (3, 53) (Figure 2).



*see HTA report Figure 10 for logic model of the problem for patients intending to RTW after hip and knee replacement
** see HTA report Figure 11 for logic model of change for patients intending to RTW after hip and knee replacement

Figure 2: Summary of the logic models underpinning the development of the OPAL intervention.

This process identified six core components of a 'successful' occupational intervention for patients in the elective surgery/musculoskeletal health setting (1): 1) education and support; 2) vocational counselling and guidance; 3) physiotherapy and exercise; 4) work simulation and job accommodation; 5) contact with employer/workplace visits; 6) multidisciplinary team involvement. These components are the foundation of the OPAL occupational support programme.

The OPAL programme is designed to empower patients to take responsibility for their RTW as work self-efficacy is a strong predictor of successful RTW (54). The intervention provides a set of resources to enable patients to develop an individualised RTW plan. It encourages active engagement with employers and healthcare teams and provides structured rehabilitation tailored to individual personal circumstances, occupation and work demands.

The intervention was developed following extensive stakeholder engagement and consensus work (3-6, 30).The intervention therefore has a robust theoretical basis, underpinned by biopsychosocial models that supported behaviour change in the target groups (patients and stakeholders in the RTW process) (3, 53). As part of the original OPAL feasibility study the support programme was manualised as a set of patient and staff performance objectives that defined its content, format, delivery, and timing whilst maintaining pragmatism in the ability for NHS sites to deliver the intervention alongside standard care (3, 53).