University Hospitals of Morecambe Bay NHS Foundation Trust

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

'Fit for surgery' or 'fit for life'? Exploring the potential of using the perioperative encounter to promote regular exercise and physical activity: an expanded evidence synthesis

SHORT STUDY TITLE / ACRONYM

'Fit for surgery' or 'fit for life'?

PROTOCOL VERSION NUMBER AND DATE

v1.3 DATE 29.10.2020

RESEARCH REFERENCE NUMBERS

IRAS Number: 268841

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:  Date: 29/10/20

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Name (please print): Margaret Cooper

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Position: Associate Director of Research & Development

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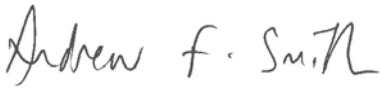
Chief Investigator:

Date:29/10/2020

Signature: 

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Name: (please print): Andrew Smith

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KEY STUDY CONTACTS

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Study Co-ordinator	Ms Suse Gibson, Research Coordinator

STUDY SUMMARY

Study Title	'Fit for surgery' or 'fit for life'? Exploring the potential of using the perioperative encounter to promote regular exercise and physical activity: an expanded evidence synthesis
Internal ref. no. (or short title)	'Fit for Surgery' or 'fit for life'
Study Design	Evidence synthesis: comprehensive literature search; case study surveys and focus group discussions; data synthesis; contextual analysis
Study Participants	Service users and staff within NHS hospitals/community groups, yet to be determined in number and location.
Planned Size of Sample (if applicable)	Not known at outset.
Follow up duration (if applicable)	n/a
Planned Study Period	01.09.2019 – 28.02.2021 (18 months)
Research Question/Aim(s)	Our aim is to examine a broad range of evidence and knowledge to identify, and set in context, interventions applied during the perioperative period to promote physical activity and exercise in the medium to longer term. We will do this through comprehensive literature searching and synthesis supplemented by analysis of relevant practical case studies.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton 023 8059 5586	£161,554.27 +£15,397.72 (agreed as a 3-month funding extension)

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor will be responsible for the regulatory management of the study and will not play any role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

The Funder will not play any role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Advisory Group

The project Advisory Group will complement our methodological expertise and clinical content, ensuring that we keep consideration of the patient and public agenda to the fore, and maintain links with the public health community and representatives from relevant professions and disciplines. They will also be able to advise us on 'target-specific' engagement and dissemination activities. We expect them to receive formal progress reports during the project and provide project oversight.

The Group will meet three times during the project. Additional plenary teleconferences will be arranged during the project if necessary, but we expect that most work will be done remotely by electronic mail and telephone.

Study Steering Committee

As there is an element of primary research within this project we have established a Study Steering Group to provide overall supervision for the study and to ensure we are operating within the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

All permanent members of The Study Steering Committee are independent from the Sponsor, the Investigators and our study, achieving the 75% independence required by the National Institute for Health Research (NIHR).

Positions including Chair will be designated by the NIHR Health Services & Delivery Research Programme Director. The Study Steering Committee will meet at least annually; it is predicted that it will meet no more than three times for the duration of the study. A minimum of two-thirds attendance is required to be quorate. Attendance by non-members will be at the Study Steering Committee's discretion though it is anticipated that the Chief Investigator or a member of the Project Team, and a representative of the Sponsor, as appropriate, will attend.

Project Team

Andrew Smith will be responsible for leadership, coordination and operationalisation of the review stages, meeting deadlines, ensuring maintenance of scientific quality and rigour, especially in the qualitative synthesis, and adherence to NIHR principles. He will lead monthly meetings with the whole project team, and weekly meetings with the researchers. He will provide line-management responsibilities to Sharon Lewis. He will also engage and disseminate to hospital clinicians.

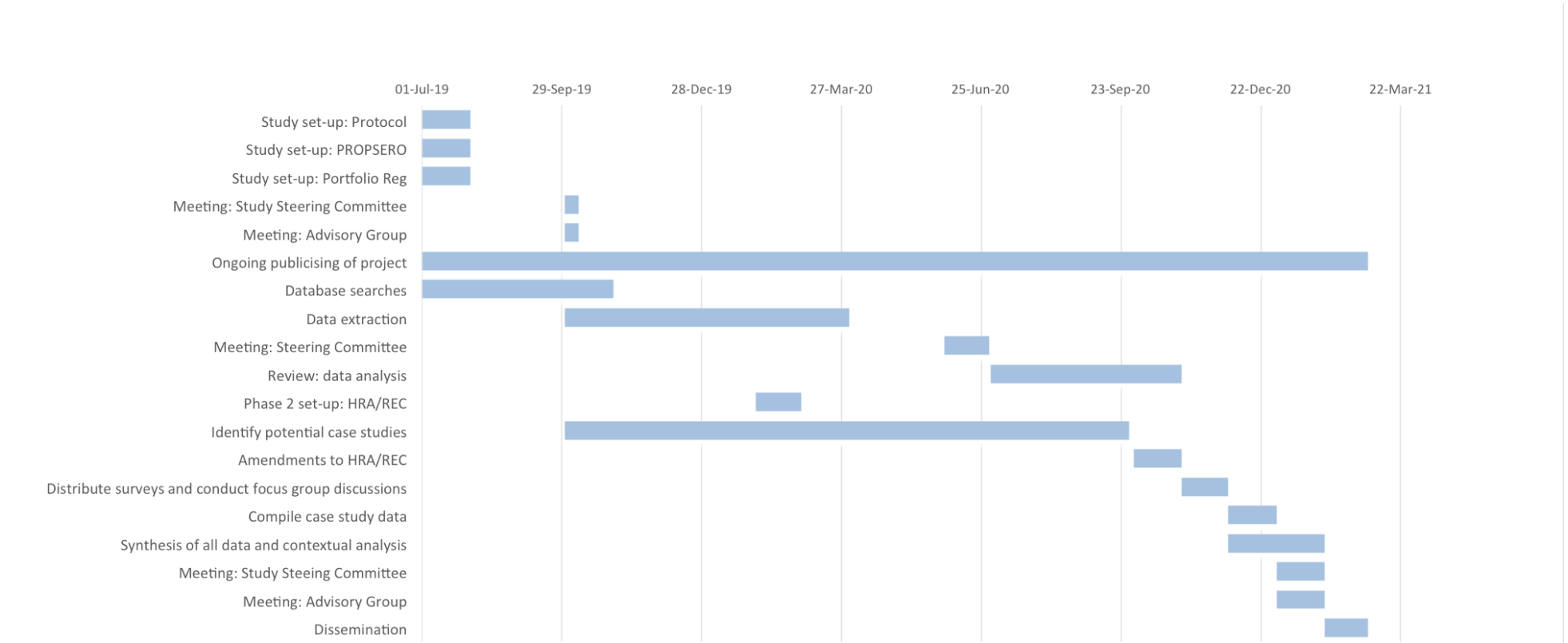
Sharon Lewis will lead and conduct the primary research tasks for this review to include database searches, identifying studies and case studies, data collection, quality assessment, contextual analysis and writing a narrative synthesis of the findings. She will line-manage Amy Robinson to assist in review production, and manage day-to-day work streams as appropriate.

Amy Robinson will assist with database searches, identifying studies and case studies, data collection, quality assessment, contextual analysis, and writing a narrative synthesis of the findings.

Euan Lawson, as well as involvement in the primary research tasks, will take a lead role in disseminating the results. He will put a strong emphasis on accessing and informing patients in addition to the scholarly research publication outlets by making good use of social media platforms as well as podcasts and a study-specific website.

Suse Gibson will provide administrative support to the project by completing the start-up tasks and the submission for approvals in good time; and throughout the project ensuring all documentation is prepared and updated. She will assist with research tasks as above.

The project team will be assisted at all times by the expert members of the Advisory Group. Though Euan Lawson will lead on the dissemination of our results, all members of the project team will play their part in this throughout the project.



Project Management Plan (V6.0 30.09.20)

STUDY PROTOCOL

1 BACKGROUND

It is estimated that around 20 million adults in the UK are physically inactive (that is, not active to the recommended levels) (1). Low levels of physical activity are associated with poorer physical and mental health (2). Encouraging exercise though physical activity is thus a key part of the UK's health promotion strategy (3), with levels of inactivity being an indicator within the current Public Health Outcomes Framework for England (4). There are over 4 million hospital admissions leading to surgery each year in England alone (5). This presents an opportunity which has hitherto not been fully exploited. Aside from the benefit which judiciously applied and successfully delivered surgical interventions can bring in their own right, the perioperative healthcare encounter offers the potential for substantial health gains in the wider sense and over the longer term. The perioperative period is typically defined as starting when the patient is first referred from primary care and ending at the point at which postoperative return to function is complete. The journey thus spans primary and secondary care (Figure 1) (6). However, we will adopt a still wider view for the purposes of this evidence synthesis. The point at which surgery is first contemplated is a better place to start. A patient presenting in primary care with a potentially operable condition (for instance, a hernia or gallstone disease) may find that, if they are able to increase their physical activity levels, the problem improves such that surgery is no longer needed.

Likewise, a focus on discharge from hospital is insufficient to allow a proper appraisal of the benefits and drawbacks of physical activity in the medium to longer term (for instance, 12 months after surgery). It also argues for an extended and more intensive involvement with primary healthcare than is currently considered within the perioperative pathway and this will be a particular focus of our work.

This proposal aims to explore the potential to use the perioperative encounter to promote physical activity and exercise in the medium to long term.

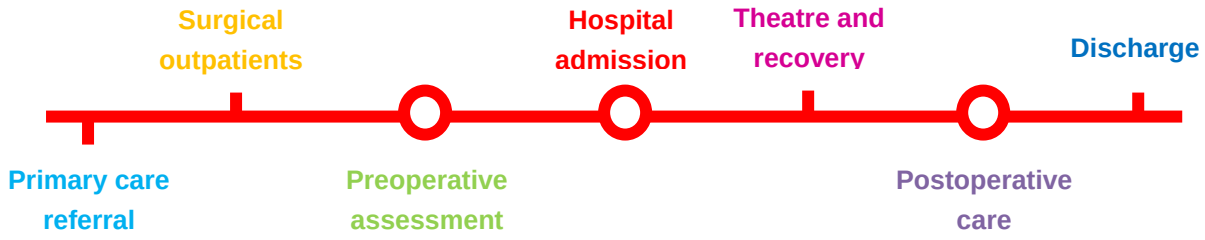


Figure1. The perioperative pathway.

There has been some work on promoting exercise pre-operatively, but this has focused on the use of physical exercise measurement to infer the risk of adverse outcome after major surgery, and how this risk might be modulated by exercise training in the weeks before surgery (7). Studies have focused on circumscribed groups of patients; for instance, the outcomes in the review by Loughney and colleagues (8) were physical fitness variables, but the participants were limited to people undergoing

neoadjuvant cancer treatments. This review's authors found that exercise interventions were safe and feasible in this patient groups and physical fitness was improved. To us, this demonstrates examples of how the incentive of impending surgery, with an appropriate intervention, can provide people with motivation to adopt healthier lifestyle behaviours.

The concept of 'perioperative medicine' has gained ground in recent years (9).This focuses on a wide package of measures to improve patients' fitness before surgery, attend more closely to patients' needs during procedures, and optimise recovery and rehabilitation to speed the return to work, home and family. This has been stimulated by two factors. First has come an understanding that earlier involvement of a wider team of healthcare professionals in the pre-operative management of surgical patients brings substantial benefits (10). For instance, 'pre-habilitation' through smoking and alcohol cessation and optimisation of pre-existing diseases has improved surgical outcomes (11, 12) and may in itself reduce the need for surgical intervention. Second, the recognition that early postoperative problems can affect long-term outcomes has helped clinicians and researchers think further than 30 days postoperatively (the usual length of follow up for many surgical outcome studies) to better promote longer-term health and well-being (13).

For any perioperative intervention to be effective, involvement of the necessary multi-professional team as soon as surgery is contemplated is vital (rather than immediately before surgery) (14). In terms of health promotion – in this case, exercise promotion - a multi-professional approach allows for repetition and reinforcement of behaviour change messages and addressing barriers to change. General practitioners, specialist nurses, anaesthetists, psychologists, surgeons and physiotherapists (15) would need to be included in a pathway which works between primary and secondary care, within an integrated care model (16, 17). Whilst there is some work on primary-secondary care co-ordination in general (18), and early interest in primary care intervention to improve postoperative outcomes (19), the potential for collaborative working to improve health in the longer term has not been studied in this context.

We urgently need to understand how to integrate models of care which optimise not only surgical outcomes, but also the longer-term health benefits of increased physical activity, into a perioperative pathway, and understand why the successful models work. The current interest in a broader, cross-cutting approach to the medical needs of the surgical patient implied by the perioperative medicine 'movement' suggests that the time is right to explore this area more fully.

Therefore, our proposal will not only explore the current evidence for using the perioperative encounter to promote exercise promotion. It will consider the context of this encounter and the model of care in which any interventions occur. We will focus on: settings in which such interventions might be delivered; timings of intervention; incentives; staff (20); and the types of interventions used (for instance, use of social media applications (21), web-based interventions (22), and motivational interviewing (23)). Exercise promotion is the focus of this work, but it may be that something can also be learned from, for instance, interventions to promote alcohol and smoking cessation (11, 12). Williams and Glasby have argued that, in attempting to evaluate 'what works' in health and social care, too narrow a definition of valid 'evidence' has been used (24). They called for a notion of 'knowledge-based practice' which draws not only on research, but also on 'the tacit knowledge of

front-line practitioners and the lived experience of people using services' (24). With this in mind, and drawing on our previous work on tacit knowledge in healthcare practice (25, 26), we propose to expand our evidence synthesis by supplementing our appraisal of the peer-reviewed and 'grey' literature with a series of case examples.

Drawing on a previous mapping exercise we undertook (27), we have a working model of the 'extended' perioperative period (see above) and will use this at the start of the project as a substrate for suggestion and development at the first Advisory Group meeting, and as the basis for a final overarching narrative synthesis of evidence against our contextual framework.

2 RATIONALE

Ageing populations and increased longevity, coupled with chronic health problems, have become a global challenge, putting new demands on medical and social services. Delivering continuously improving care in the presence of increasing demand is perhaps the main challenge faced by health systems throughout the world. Reconciling the three aims of improving the patient experience, enhancing population health and reducing the per capita cost of care is a global problem, which the UK's Sustainability and Transformation Plans broadly aim to embed into the NHS (28).

Enhancing public health through promotion of physical exercise, whether at a community (29) or, more commonly, individual level (30) is a key public health priority. Current guidance is summarised by the National Institute for Health and Care Excellence (NICE) (30) and centres around delivering brief interventions. Brief interventions can take many forms and indeed, there remains some uncertainty about exactly what constitutes a 'brief intervention'. There is evidence that they increase short-term self-reported physical activity, but there is still insufficient evidence about long-term impacts and factors influencing their effectiveness (31). Longer interventions may include elements of motivational interviewing techniques that can be used by any healthcare professional, and for which there is strong evidence of increased physical activity (23). There is also evidence that brief interventions to promote physical activity are likely to be cost-effective (32).

However, given that so many people are still not active to recommended levels, with the UK ranking poorly in a recent international study (33), new models of encouraging physical activity are needed. Consequently, it makes good sense to make the most of the public health potential of every healthcare encounter (34). The Chief Medical Officer's 'Moving Medicine' initiative (to be launched October 2018) is part of this strategy (Sunday Times, 2 September 2018) but is more targeted at specific physical conditions than the perioperative period.

This proposal also addresses, and indeed expands upon, one of the key research questions within the NICE physical activity promotion guidelines (30), namely 'What infrastructures and systems help increase the number of assessments of physical activity undertaken and the delivery of brief advice?'. In addition, it draws on the NIHR-supported work Priority Setting Partnerships of the James Lind Alliance (http://www.jla.nihr.ac.uk/about-the-james-lind-alliance/). Cogent questions already prioritised through this engagement process with patients, carers, and clinicians include: "How can pre-operative exercise of fitness training, including physiotherapy, improve outcomes after surgery?"

3 THEORETICAL FRAMEWORK

This project involves a mixed methods approach. We will conduct a comprehensive systematic review (35) in order to identify and appraise available peer-reviewed and 'grey' literature on exercise interventions that have been used during the perioperative encounter. We will seek evidence on outcomes reflecting continued engagement in physical activity (for instance, at 12 months after intervention) and also measures reflecting patients' experience of the interventions. Only when study designs and interventions are appropriately homogenous will we conduct quantitative analysis (35).

Taking a broad view of 'evidence' after Williams and Glasby (24), we will also identify practical examples of relevant interventions to promote physical activity. For these practical examples we will use case study methods to explore which aspects of the intervention, the individuals and teams, and the wider organisation (whether within primary or secondary care) influenced the adoption of the intervention.

By using the multiple data collection sources in this phase of the project (to include document collection, surveys and focus group discussions) we intend to improve the accuracy and completeness of the current landscape in exercise innovations (26). This will also compensate for 'lag time' to publication which is an inevitable consequence within a systematic review approach.

We will use Bate, Mendel and Roberts' 'challenge' framework (36) to structure our examination of the contextual factors within the evaluation of exercise promotion interventions and models of care, both for the literature and practical case studies. A final integrative, interpretive synthesis will explore relationships in the data between context, mechanisms and outcomes.

4 RESEARCH QUESTION/AIM(S)

What is the potential for promoting physical activity and exercise in the medium to long term in people undergoing elective surgery?

Our aim is to examine a broad range of evidence and knowledge to identify, and set in context, interventions applied during the perioperative period to promote physical activity and exercise in the medium to longer term. We will do this through comprehensive literature searching and synthesis supplemented by analysis of relevant practical case studies.

4.1 Objectives

The research plan incorporates the following objectives:

1. A systematic search for, quality appraisal of, and data extraction from, published peer-reviewed and 'grey' literature.
2. Identification of, and the collection of data from, existing practical examples (i.e. case studies)
3. Analysis of context, using the 'challenge' framework (36), and its role in the effectiveness of interventions.
4. Overarching narrative synthesis of existing and possible models of perioperative care which offer the greatest potential benefit for the promotion of physical activity and, in conjunction with our

expert Advisory Group, the drawing-up of a practical toolkit and proposal for future study, as appropriate.

4.2 Outcome

The principal output of this research project will be a report presented as a narrative synthesis of existing and possible models of exercise interventions given during the perioperative period as part of an integrative care model. There will also be presentations, academic publications and 'feeds' into policymaking and relevant professional groups, such as the Royal College of General Practitioners, Royal College of Anaesthetists, the Pre-operative Association and the Royal College of Nursing. In addition, the project will generate content for a web-based 'toolkit' of possible interventions and success factors for their implementation to promote physical activity during the perioperative encounter.

The impact we would be most pleased with would be demonstrably higher levels of physical activity in the longer term as a result of the help and advice people receive during the perioperative period.

We hope that our outputs will enter the health system at multiple, mutually complementary levels, this knowledge mobilisation being facilitated by our Advisory Group.

By influencing or strengthening existing health policy; for instance, our project is highly relevant to the Chief Medical Officer's 'Moving Medicine' initiative, launched in October 2018. Sir Muir Gray, with his national connections, will be able to advise us. We also have Dr Phil Alderson on our project Advisory Group; as Consultant Clinical Advisor at the National Institute for Health and Care Excellence, he is well-placed to advise on relevant national guidance that our work could feed into.

By drawing on the findings of our research, we will collect intelligence to inform the development of a practical 'toolkit' with a menu of options and strategies for using the perioperative period to promote physical activity in the longer term. We will explore options and practicalities around a pilot of such a toolkit within the University Hospitals of Morecambe Bay NHS Trust, drawing as a minimum on the opinions of the local members of our Advisory Group about feasibility, towards the end of the project. The Clinical Lead for Surgery (Mr Deepak Herlekar) and the Trust Manager for Preoperative Assessment (Mrs Nicola Swindlehurst) have indicated their support for a practical pilot if this is possible at that stage. We would hope in due course, after the project is completed, and in conjunction with local patients and integrated service providers, to be in a position to consider developing an exemplar site within the local health economy for others to visit and learn from.
If this research is successful, we anticipate two main types of follow-on activity:

- Further research. We intend to use our findings to design an evaluative study of the most promising interventions; this would need further research funding in due course.
- Service development. Specific unanswered questions notwithstanding, we plan to establish a local exemplar service, as above. This will be funded by continuing involvement of, and negotiation with, local commissioners.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study design for our mixed-methods approach has four phases:

1. Comprehensive literature search
2. Case studies
3. Analysis of context
4. Narrative synthesis and the development of a practical toolkit

We will use the first project Advisory Group meeting to harness the experience and knowledge of the Group's members to fully understand the potential of extending the concept of the perioperative pathway as described above. This will allow us to identify points at which interventions have, or could be, applied and will act as a working model to guide the researchers throughout the project.

5.1 *Comprehensive literature search*

5.1.1 Criteria for considering studies for inclusion in the literature search

Types of studies: we propose to include a wide-range of studies: randomised controlled trials (RCTs) and cluster randomised trials; non-randomised trials (NRS) to include controlled before-after studies and interrupted time-series studies; and observational study designs, including cohort studies or longitudinal studies. We will also include reports of interventions such as before-and after case studies within the literature.

Types of participants: we will include adult participants (> 18 years of age) who are scheduled to undergo surgery in a hospital setting. We will include participants undergoing any type of surgery, with any baseline level of physical fitness.

Types of interventions: we will include interventions that are designed to promote exercise through physical fitness interventions or that are designed to require participants to engage in exercise activities during the perioperative pathway.
These may be specified as follows:

- designed to promote exercise through physical fitness interventions or designed to require participants to engage in exercise activities during the perioperative pathway
- given at any stage of the 'extended' perioperative pathway (from the initial point that the patient presents to primary care with a potentially operable condition, at least to the point after surgery where the patient has returned to expected function)
- given by any healthcare professional
- not part of a 'package' of measures aimed at promoting a healthier lifestyle
- have a follow-up period of no shorter than six months
- designed to measure clinical outcomes related to physical fitness for surgery or clinical recovery from surgery
- not rehabilitation to strengthen a specific set of muscles

Examples of such interventions that *promote* exercise may be information leaflets, face-to-face advice, or other motivational tools. Exercise is defined as a planned and structured activity, which takes place regularly to improve physical fitness (examples include: running, walking, swimming, fitness classes, aerobics, yoga). The intervention may be given at any stage of the 'extended' perioperative pathway (from the initial point that the patient presents to primary care with a potentially operable condition, at least to the point after surgery where the patient has returned to expected function) and by any healthcare professional. Interventions may be delivered on one occasion or more, and may extend beyond surgery to the immediate or later postoperative period. We will take particular note of interventions applied in primary care.

Types of outcomes: we will assess whether an exercise intervention may have improved physical health such that surgery is no longer required, and we will look at the medium to longer-term gains from an exercise intervention presented during the perioperative period. These medium to long-term outcomes will be measured up to the longest times point after surgery reported by study authors, and will include measures of HRQoL, physical fitness (measured using assessment tools such has cardiopulmonary exercise testing (CPET), continued engagement in regular exercise. We will also seek outcomes relating to patients' experience of participation. Whilst we hope to gain evidence of data beyond 12 months, we anticipate that study reports may have earlier follow-up time points.

5.1.2 Search methods

We will search MEDLINE (OvidSP), Embase (OvidSP), the Cochrane Central Register of Controlled Clinical Trials (CENTRAL), CINAHL, PsycINFO, the NIHR Journals Library, and KSR Evidence. In addition, we will search a subject specific database related to exercise literature: SPORTDiscus. We will search databases from inception and pose no restriction on language of publication. A draft search strategy is included in Figure 2.

We will conduct searches of clinical trials registers (www.ClinicalTrials.gov and www.int/ictrp/en/) to identify ongoing studies, or completed studies awaiting publication.

We will conduct forward citation of studies which meet our inclusion criteria, and backward citation searching of key articles and reviews using Web of Science citation index. We will also contact authors and experts in the clinical and organisational area of interest. We will examine grey literature, as defined by McGrath and colleagues (37), using 'opengrey' (http://www.opengrey.eu/) for valuable contextual perspectives and up-to-date intelligence not yet available within peer-reviewed sources.

Figure 2 Draft search strategy: Medline

1. exp exercise/ or running/ or walking/ or physical fitness/ or swimming/ or exp "physical education and training"/ or exp sports/ or exp yoga/ or exp fitness centers/ or recreation/ or exp motor activity/
2. ((fitness adj (regime* or program* or class*)) or (cardiorespiratory fitness) or ((moderate or vigorous*) adj activ*) or (led walk* or health walk*) or (physical adj5 (fit* or train* or activ* or endur*)) or (exercis* adj5 (fit* or train* or activ* or endur*))).ti,ab.
3. 1 or 2
4. general surgery/ or perioperative period/ or perioperative care/ or preoperative period/ or preoperative care/ or postoperative period/ or postoperative care/

5. (surgery.ti.ab.) or (prehabilitation.mp.)
6. 4 or 5
7. (promot* or uptak* or encourag* or increas* or start* or adher* or sustain* or maintain*).ti,ab
8. 3 and 7
9. 6 and 8

Identification of studies*:* we will use reference management software (Endnote) to manage and remove duplicates from search results. We will use software designed to manage systematic review organisation (Covidence, https://www.covidence.org/) to screen references, perform a full-text review of possible studies, and identify a final selection of studies that meet our review criteria (using criteria above for type of: studies, participants, and interventions). Two review authors will carry out screening and selection of studies for the review.

5.1.3 Data collection

We will extract data from studies using electronic data collection forms in Covidence (https://www.covidence.org/), which we will adapt and then pilot to meet the needs of the review. We will collect information on: study design; participants (sample size, type of surgery, baseline characteristics to include baseline level of fitness or involvement in existing physical exercise, body mass index (BMI), potential restrictions to activity for example existing co-morbidities or surgical problems); intervention (timing of intervention, type of intervention and whether the intervention is designed to adapt to the individual user, model of care in which intervention is given, number of times intervention is given); outcomes (type of measurement, unit of measurement, and scale); and event data. For this review, we will also consider fidelity (i.e. whether participants adhere to an exercise intervention); this is particularly problematic for studies that require a change to individuals' behaviour (38).
Data for this collection process will be taken from published reports. We will attempt contact with study authors if important data appears to be missing or unclearly reported.

5.1.4 Assessment of study quality

We anticipate identification of a variety of study designs. We will assess quality with reference to an existing hierarchy of evidence (39), with RCTs being considered the most robust design. We will use validated tools to assess quality accordingly to study design. For RCTs, we will conduct risk of bias assessment using the Cochrane risk of bias tool (35). We will assess whether each study has high, low, or unclear risk of bias for: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective outcome reporting; other sources of bias (for example differences in participant baseline characteristics).
For other study designs we will use guidance from the Cochrane Effective Practice and Organisation of Care Group, which provides resources to assess quality of non-randomised studies. For grey literature, we will follow recommendations from the US National Library of Medicine (40).

5.1.5 Synthesis of the findings from the literature search

Relevant published studies will be reported individually, with a summary of each study, its methodological quality and numerical results. It is likely (gauged from the scoping search above) that there will be heterogeneity between studies, and that there will thus not be enough studies of any particular study design, intervention or outcome to make quantitative synthesis either meaningful or sensible. Instead, we will make the most of each publication by extracting, by qualitative means, intelligence on contextual factors which helped or hindered the adoption of the reported intervention. If necessary or feasible, we will contact study authors directly for more information.

5.2 Case Studies

As Baker has noted, creating more effective evidence-based care relies on building knowledge of the ways in which interventions can be embedded into ongoing practice (41). Our case studies will complement the literature review by allowing us to capture this knowledge and set it into context. We will identify published initiatives reported as case studies during the comprehensive literature search, detailed in 5.1. We will identify unpublished initiatives through our network of professional contacts in primary and secondary care, as below.

5.2.1 Identification of case studies and services

We will identify case studies and services through a number of means:

- Personal contact and knowledge of the co-applicants, who are senior in their fields and have knowledge of primary and secondary care and PPI networks.
- Personal knowledge and contacts of members of the Expert Advisory Group
- Through NHS Improvement, Public Health England and relevant activities within the 'Getting It Right First Time' initiative
- A directed Internet search
- Searching proceedings of relevant conferences e.g. BMJ International Forum on Quality and Safety in Healthcare
- Relevant professional organisations e.g. the Preoperative Association
- Relevant Royal Colleges e.g. Nursing, General Practitioners, Surgeons and Anaesthetists
- Articles written in professional newsletters and bulletins as part of the early engagement and dissemination activities of the project can also contain requests for information.

We are especially keen to explore any initiatives where primary care has been closely involved, as our 'extended' perioperative period implies that much of the work related to the promotion of physical activity would take place in primary care. Should we discover attempted but unsuccessful innovations, we will consider including them, as valuable lessons could still be learned. In the absence of relevant interventions during the perioperative period, we will look to relevant interventions in other settings that may be transferrable to the setting of interest in this review.

5.2.2 Data collection

We will negotiate access to services, staff and patients through key 'gatekeeper' personnel within each service.

We aim to collect qualitative data through remote focus group discussions. We will use these discussions to explore the essential components that have made it possible for a service to establish themselves within, or with, NHS Trusts, across teams, and with communities. We will be interested in what services and service users see as the key elements of success (or otherwise) within services. We will also explore how services, in the current Covid-19 context, have been able to adapt and respond (through remote and digitally-delivered provision or otherwise), providing additional insight into the role of remote support for patients and the acceptability of these types of interventions. These focus groups will take the form of web-based (video) group discussions. There will be up to 10 participants in each group discussion and we aim to hold two or three discussions. Participants will include patient 'champions' (who have used, are currently using or who have been identified as someone who would benefit from a service promoting physical activity in the longer term) as well as service 'champions' (including frontline practitioners, service managers, commissioners or others seen as key gatekeepers to the delivery of interventions). We aim to audio record but will not video record these discussions. We are not collecting any personal data that can identify individuals so care needs to be taken in the recording and transcription of audio. Any recordings will be destroyed after transcription as per our confidentiality statement.

Prior to focus group discussions, we will compile information (basic summary quantitative data, examination of documents such as operating procedures, archival records such as outcome and patient experience data), and brief details about the physical setting, and other institutional and organisational factors (43) relating to the services involved. We will do these using an online survey provided to participating services via email. We will also ask patient participants to complete a short survey to help us understand their experiences relating to physical activity promotion. This will be conducted anonymously, using Survey Monkey. We will also consider how closely data in case studies align with the main objectives of our research proposal and we will make an assessment of the innovation's impact on effectiveness, efficiency, and acceptability. The multiple data collection sources used for case studies will allow triangulation, improving the accuracy and completeness of the account built up of the intervention studied (26).

The draft preliminary guide questions for the focus group discussions and draft survey questions are in the Appendix.

5.2.3 Data analysis

For the case studies, we will also start with a simple descriptive summary including type of location (exact details may be kept confidential), number and type of staff/patients, nature of intervention, outcome data available etc. However, the data generated through focus group discussions with staff and participants, will be analysed qualitatively for recurrent themes and categories relating to our outcomes of interest (contextual factors which helped or hindered the success, or otherwise, of the intervention, and intelligence relating to the experience of participants, as well as intelligence relating to the capacity and experiences of services and patients in adapting to the current Covid-19 context.

5.3 Analysis of context

We will subject the emerging themes and categories from the comprehensive literature search and the case studies to a final, overarching qualitative analysis of contextual factors based on Bate, Mendel and Roberts' 'challenge' framework (36), to unify the material gathered and further explore the relationships in the data between context, mechanisms and outcomes.

We will return to the annotated, extended perioperative pathway created at the first Advisory Group meeting to structure an integrative, interpretive synthesis (44, 45) of models of exercise interventions delivered during the perioperative period. For this narrative synthesis, we will be guided by a previous evidence synthesis publication conducted by Andrew Smith; this research project also included a systematic review and exploration of case studies (46). We will explore different types of exercise interventions and their effectiveness relative to context (47, 48), and we will establish how context leads to successful (or indeed, unsuccessful) outcomes (45).

5.4 Narrative synthesis

We will, again in conjunction with our Advisory Group, identify the specific points in the extended perioperative period at which physical activity and exercise might be promoted, and how it might be integrated across different disciplines, and across primary and secondary care, for the greatest effectiveness.

This annotated, context-enhanced pathway will be presented as a graphical summary of findings statement supported by the more expansive interpretive qualitative commentary. As well as assessing the quality of individual studies, we will include an assessment of the robustness of our overall evidence, using decision-making tools to report the confidence in our findings (49). For transparency, we will also explore and report any limitations to our research (50). We will note ongoing studies, and gaps in evidence coverage for the promotion of physical activity in the perioperative period that we identify in published and in ongoing studies. This will also be used to inform further research.

We will liaise with the Clinical Lead for Surgery, Mr Deepak Herlekar, and the Trust Manager for Preoperative Assessment, Mrs Nicola Swindlehurst, at University Hospitals of Morecambe Bay NHS Trust to explore the possibilities of piloting lessons learned from the evidence synthesis locally.

In addition, we will be able to provide an annotated compendium of current practice of all the sites we identified as part of the preliminary work for the case study element of the original project.

6 STUDY SETTING

The project team will be based within the Lancaster Patient Safety Research Unit situated at the Royal Lancaster Infirmary, part of University Hospitals of Morecambe Bay NHS Trust.

We will identify sites within the UK which we will use as case studies. We will identify these sites using the means described above and we will liaise with these sites directly to assist with the identification

and recruitment of personnel and patients who will act as participants in focus group discussions and who will complete short surveys.

7 SAMPLE AND RECRUITMENT

The eligibility criteria below refer to recruitment of participants who are users of an exercise intervention service for the case study phase of the project.

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

We will include adults participants who are 18 years of age or older; we will not specify an upper age limit. We require participants to be attending, have attended, or be considering, an intervention to improve exercise or physical activity, whether in a perioperative context or other relevant healthcare or community based setting.

We will include participants with any baseline level of fitness.

We will include participants who provide consent to participate in an interview with one of our researchers.

7.1.2 Exclusion criteria

Participants will be excluded if they are under the age of 18 years.

7.2 Sampling

7.2.1 Size of sample

It is not possible to say at the outset how many participants will be recruited during the collection of information from the case study sites. We anticipate contact with four to six sites; the number of people we engage with during the collection of information at these sites will be subject to the nature and organisation of the intervention.

7.2.2 Sampling technique

Due to the qualitative data collection methods to be used during the case study phase of our project, we will use purposive sampling technique. As well as being led by the nature and organisation of the specific interventions identified as case studies, the sampling in this phase will also be led by the quantity and quality of the data collected during the comprehensive literature search.

7.3 Recruitment

7.3.1 Sample identification

When the potential sites have been identified, we will approach a key 'gatekeeper' to assist in the identification of participants suitable for the study (see 7.1).

It is not anticipated that we will require participants by other methods such as through Patient Identification Centres or by publicity posters or leaflets etc. We will not require access to patients' records.

As focus group discussions will take place from participants' home or place of work, there should be no payments required to participants for travel etc.

7.3.2 Consent

We will obtain informed consent prior to conducting focus group discussions. To guide the consent process, we will use a Participant Information Sheet (PIS), which we will explain and discuss thoroughly with the patient.

We will ensure that any prospective participant is given the opportunity to ask the researcher any questions they may have about the study including its purposes, how their information will be stored, and what it will be used for. We will make available, on request, copies of our HRA Approval, ethical approval, this protocol, and copies of the researchers' CVs and training records as well as evidence of funding for the study for examination by potential participants to allow for transparency.

We will seek informed consent from patient participants through three steps. The named contact or 'gatekeeper' at the service will provide the PIS and consent form and explain the study to participants. Prospective participants will then be invited to a remote group meeting with other prospective participants. As well as aiming to familiarise patient participants with the process, the project and the discussion group facilitators this will be an opportunity to go over the PIS and consent form to explain to the potential participant any risk associated with participation, and answer any questions that potential participants might have. We will seek verbal consent during this meeting, following which the researcher will sign a copy of the consent form and send this to the relevant recruiting member of staff at a service, who will forward this to patients. We will accept attendance at the subsequent recorded focus group as a patient's formal consent. Consent with service participants will be managed directly between the service participant and /or key service gatekeeper and the researcher, via email. The capacity of the potential participant to understand, and therefore consent to involvement, will be assessed prior to researcher contact with participants by the named contact or service gatekeeper.

Participants will be encouraged to retain a copy of the PIS and consent form for their information.

It is commonplace for the period of time between sight of the PIS and requesting/receiving consent to be a minimum of 24 hours. Our three-stage process which will take place across the course of at least one week will ensure that this is the case.

We will ensure that the consent form is marked with the date of participant's verbal agreement and signed by the researcher and returned as a copy for participants via named contacts or gatekeepers within services. .

A draft copy of the Participant Information Sheet and Consent Form is in the Appendix.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The literature review does not include participants and is not subject to management of risk.

During our focus group discussions, we will have some contact with participants and personnel in the context of remote group discussions regarding physical activity interventions. We do not anticipate a risk to participants and at no time will we engage in one-to-one contact. However, in the unlikely event that we encounter the disclosure of any sensitive information or issues of harm to self or others, we will bring these to the attention of local staff for referral to the appropriate safeguarding mechanisms within the host organisation.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study will be submitted to the Research Ethics Committee for ethical review, which will examine this protocol, informed consent forms, Participant Information Sheets and other relevant documents and a favourable opinion will be sought before any research activity with patients be commenced. The outcome of the REC will be retained in the site file along with any other decisions, detailing any changes that need to be made before clearance is granted; and the favourable opinion once received that will allow the study to start.

The Chief Investigator will produce the annual reports as required and will notify the REC at the end of the study; if the study ends prematurely; or if the study is halted for any reason.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. We have a prepared Organisation Information Agreement which we will share with the host organisation.

For any amendment to the study, the Chief Investigator, in agreement with the Sponsor will submit information to the appropriate body in order for them to issue approval for the amendment.

We have prepared blank documents in the site file and we will retain a copy of all project related documents in the site file.

Amendments

If we understand an amendment to the study to be required we will be bring it to the Advisory Group in the first instance. This will allow for discussion regarding the necessity of amendment, whether the amendment is substantial or non-substantial; and to set in action the process for submitting the amendment. We will make the Study Steering Committee aware if an amendment is deemed necessary and they will agree the proposal of amendment and advise the Sponsor and Funder to their actions.

We will use the Integrated Research Application System (IRAS), which will instruct us to whether we need to notify any specific review bodies and in what capacity; and to receive further information regarding the submission of amendments.

Ultimately, the Sponsor will determine if an amendment is substantial or non-substantial. If an amendment is deemed to be substantial, the Sponsor will submit a Notice of Substantial Amendment form to the REC for consideration; and we will receive a response within 35 days of receipt of the notice.

At this stage, we will also notify of the amendment, whether substantial or non-substantial, to the study sites; the research team; the local Research & Development office; and the local Clinical Research Network. This will be undertaken by the Chief Inspector/Research Coordinator. Any amendment history will be recorded and will be accessible if required.

8.3 Peer review

The project proposal has been extensively peer reviewed during the application process by appropriate reviewers from the NIHR's pool of experts.

8.4 Patient & Public Involvement

Our Patient and Public Involvement strategy sees patient representation and contribution in four areas of the project:

1. Topic selection and prioritisation
2. Choice and ranking of outcomes within the evidence synthesis
3. Intelligence on feasibility and acceptability of interventions designed to promote physical activity and exercise and their application in the perioperative period
4. Assistance with dissemination materials towards the end of the project

We have an experienced patient representative as a named, funded co-applicant. Mr Antony Chuter is experienced in supporting people who live with chronic pain and acting as an ambassador for patient and public involvement. He has extensive experience of incorporating the patient's perspective in research, having been a lay co-applicant on a number of research projects, including an NIHR HS&DR-funded investigation into patient safety incidents in primary care (12/64/118). He has advised on relevance during the preparation of the bid; how to involve patients throughout the project and also advised on the preparation of the Plain English Summary.

In preparation of this proposal, we have also worked with the Patient, Carer and Public Involvement & Engagement (PCPIE) team, Health Services Research Centre (National Institute of Academic Anaesthesia). Feedback from these members has been incorporated throughout.

We have also drawn on the NIHR-supported work of the Anaesthesia and Perioperative Care Priority Setting Partnerships of the James Lind Alliance (2014) (49), which prioritised the issue of pre-

operative exercise and fitness training. The concept of the project thus responds to patient and public priorities.

As the project progresses, we will continue to involve patients and the public. We will involve our lay members in an initial consultation with all Advisory Group members to clarify all aspects of the project, including commenting on the perioperative journey, and to seek advice as required. We propose that this initial consultation is made in person and have costed in travel for the patient representatives to attend this meeting. Further consultation will take place during the early stages of the project, and some of these meetings may take place by email, telephone, Skype or Webex. Lay members will be included in any decisions that are made, particularly decisions that differ from the original plan. As the project progresses, we intend further face-to-face meetings; we will update the Advisory Group on progress, but also work together to make decisions regarding management and analysis of the data.

We will work with our patient representatives/lay members in preparation of engagement materials and dissemination, particularly when information is being prepared for a lay audience/readership. We will be mindful of lay members who may be unfamiliar with formal meetings. This will be done by clarifying any concerns or expectations before meetings; ensuring that lay members are given appropriate opportunity to contribute to meetings; and offering a 'de-brief' session with lay members to address any additional issues that may have arisen as part of this process.

We commit to meaningful PPI engagement throughout the project, and will ensure equality and equity with all members of the Advisory Group, and project team. Following a suggestion from our co-applicant patient representative, we will keep a log of all PPI activity and PPI comments. As well as providing transparency, this will allow us to evaluate the effectiveness of PPI activities throughout the project.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. We will document any such deviations on the relevant forms and report to the Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

We will bring all breaches of protocol compliance whether accidental, minor, significant or recurring to the attention of the Study Steering Committee and the Advisory Group in case further action is required and to decide on that action.

8.6 Data protection and patient confidentiality

We – our investigators and study site staff – will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

- The majority of data that we collect from the study sites will be qualitative, however some sites may provide us with patient outcome data. This will not be cross-referenced to personal

data or supplied with any personal identifying data and therefore there will be no need to code and depersonalise data; there are no means by which patient confidentiality can be breached.

- If we make audio recordings of the focus group discussion, we will have these transcribed omitting any identifying data, such as names, and the original recordings will be destroyed.
- We will need to maintain some personal contact details for the participating staff members at the study sites, with their consent, in a physical file in a locked filing cabinet and will be destroyed at the conclusion of the project. The purpose of keeping this information is to allow follow up/feedback with the participating sites as required.

8.7 Indemnity

For research within the NHS, NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. Clinical Negligence Scheme for Trusts (CNST) provides indemnity that covers clinical negligence and harm caused.

8.8 Access to the final study dataset

The Chief Investigator and the Research Team alone will have access to the final study dataset.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Throughout the research project, we will develop and deploy a multi-faceted knowledge translation strategy, which will include:

Media: We will use the Lancaster Patient Safety Research Unit's website (https://www.lpsru.org/), and our Twitter account (@LPSRU) to publicise the project before, during and after the funded period. In addition, Euan Lawson will develop a dedicated website to promote the project as it progresses and ensure the research programme resources, and toolkits are made available in a range of accessible media including audio and video. In particular, we will make use of podcasts, both to be posted on our own sites, but also in connection with articles published in journals, when they have the ability to do so. We will also make use of mainstream news media as much as possible, as we are aware that we are dealing with a topic of interest to the public at large.

Patients' and carers' organisations: Drawing on Antony Chuter's expertise and national networks, we will develop suitable materials for a lay readership and make them available to relevant patients' and carers' organisations.

Healthcare policy and guideline production: In the first instance, we plan to organise an online workshop event for public health policymakers. This will not only enable cost-efficient preliminary dissemination of our findings to this important target group, but it will also give us the opportunity to ask participants to highlight critical findings and help with further policy implementation. We also plan

to link into the NHS commissioning process (see below) and would make our reviews available for guideline production by forwarding the links to our work to NICE and others.

Professional groups: We would like to present our work to healthcare professionals at national meetings of health care providers. We would also distribute our briefing sheets to relevant national organisations such as the Royal College of General Practitioners, Royal College of Anaesthetists, the Pre-operative Association and the Royal College of Nursing. As well as the peer-reviewed journals of these organisations, we will write more accessible pieces for their members' newsletters and similar publications.

Academic publication: We anticipate publications in peer-reviewed journals not only of the narrative synthesis but potentially also of the methodological developments and refinements we encounter during the work. We will also offer editorial/comment and educational articles relating to the project's subject matter.

Data arising from the study will be owned by the study Sponsor, the University Hospitals of Morecambe Bay NHS Trust. On completion of the study the data will be analysed and tabulated and a final study report will be prepared.

As per their guidelines, we will use the "Funded by NIHR" logo on all appropriate outputs. We will acknowledge NIHR as our funder, and a disclaimer regarding our findings/opinions will be on all written and oral output. The study protocol will be made available along with the abstract and plain English summary for the life of the study, on the NIHR website.

9.2 Authorship eligibility guidelines and any intended use of professional writers

We will adopt The International Committee of Medical Journal Editors' guidelines for authorship. These guidelines state that an author must meet four criteria:

• Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.

• Drafting the work or revising it critically for important intellectual content.

• Final approval of the version to be published.

• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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11. APPENDICES

11.1 Appendix 1 – Required documentation

Local documentation required prior to initiating a participating site:

- Participant Information Sheet (PIS) on headed paper, stating NIHR as funder, with detachable consent form (see 11.1.1 below)
- Regulatory applications and approvals: HRA/REC Approval; Organisation Information Document; NHS to NHS Confirmation of Pre-engagement Checks; Letters of Access, etc.
- Research team CVs and relevant training logs
- Data collection requirements (11.1.2: draft indicative focus group discussion guide and patient and service surveys)

11.1.1 Draft Participant Information Sheet (PIS) and Consent Form

'Fit for surgery' or 'fit for life'?

Exploring the use of the perioperative encounter to promote regular exercise and physical activity: an expanded evidence synthesis

Participant Information Sheet

We would like to invite you to take part in our research study Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the information below.

Sometimes it's helpful to talk to other people about what you're getting involved in. Please feel able to do this and please ask us if there is anything that is not clear or if you would like further information.

What does the study look like?

Every year, more than 4 million people need surgery in England. People visit several different health professionals (such as their GP, hospital staff and social care teams) before, during and after their planned surgery. The fitter people are before their operation, the faster they recover from it.

The aim of this study is to find out how people have been encouraged to be more physically active when surgery is planned or being considered. We want to know when this encouragement has been helpful and why it was helpful, as well as any difficulties people face. We particularly want to hear about these experiences from people having surgery and from their health care professionals. The study is interested

in the period of time from when you might first talk to your GP or health care professional about surgery, through to the time of operation and recovery, and ending with your discharge from all hospital care.

Why am I being asked to take part?

We are asking you to consider taking part in our research because you are using, have used, or are thinking of using, a service to help you become more physically active. You may be using this service because you need surgery or have had surgery. It is up to you if you wish to join the study.

A member of your clinical or support team will describe the study and encourage you to read this information sheet, they will also provide you with a copy of the participant consent form. If you decide you are interested in being involved in the study you will be invited to a meeting to give you more information about the focus group discussions and a survey that we would like you to be involved in.

This meeting will also be an opportunity to go over the information in this sheet and the consent form and for you to meet the people facilitating the focus group sessions. It will also be an opportunity to ask any questions that you may have. This meeting will take place online with one of our researchers and an experienced patient representative (someone who is experienced in acting as an ambassador for patient and public involvement in research). It will be a group meeting with other people using similar services to you. Towards the end of the meeting you will be asked if you agree to be involved. If you agree to take part, we will accept your verbal consent and then your subsequent attendance at a remote focus group discussion and your completion of the survey as your consent to participate in each part of the study. You can change your mind at any time, without giving a reason. Your care or access to services will not change or be affected. Your health care professionals will not be disappointed if you withdraw.

What will happen if I take part?

If you decide that you would like to take part, you will be provided with details of how to access the survey online (we expect this to take about 30 minutes of your time) and how to join a remote focus group discussion. The discussion will be through online video-based software, such as Zoom. If you do not have access to this software we will discuss how we can support you to still take part. There will be up to 12 people in the group discussion, including an experienced patient representative and researcher and a mix of patient 'champions' and service 'champions'. Patient 'champions' will include people who have used, are currently using or who have been identified as someone who might benefit from a service promoting physical activity in the longer term. Service 'champions' might include a health professional, a physical activity specialist and someone who manages or funds a service supporting physical activity for people thinking about or undergoing surgery.

Together, we will have conversations about patient and service 'champions' experiences of physical activity promotion, about the support that patients have received, the support they have been offered and who has been involved and what has happened in making this possible. This might include conversations about the sorts of words and language that have been used to convey messages, the relationships between colleagues and different services, and resources. We will also ask questions about any remote or digital service that you have received.

As an individual you hold a lot of the answers for the future development of programmes that may help people improve their physical fitness in the future. What you tell us may be positive or negative and whatever you choose to share will be really useful for us.

We will make audio recordings but not video recordings of the focus group discussions. We do this because it means the researcher can focus on what you and others are saying rather than taking notes. The researcher will later make a written report of your spoken words. For your confidentiality, we will not write down any names that are used in these recordings. The audio recordings will then be destroyed and the written report will be kept in a secure location for the duration of the study and will only be used for work by the research team. Audio recordings are a useful tool and we can't work without them. If you are not comfortable with this then you might feel that you do not wish to take part in the study.

What are the possible disadvantages and risks of taking part?

We aim to take up as little of your time as possible. If you agree to join a meeting to discuss the research this will take about 60 minutes.

If you complete the survey we expect this to take about 20 minutes.
If you take part in a focus group discussion this may take up to 2 hours. There will be an opportunity for a break part way through the discussion.

What are the possible benefits of taking part?

As with a lot of research within the NHS, the benefits will most likely be seen by people in the future. So, although there are no *direct* benefits to you taking part in a group discussion, it is hoped that we will be able to improve future care, by advising on what you and others have told us about what works when promoting the benefit of physical activity.

You may find that talking about your experiences does help you; sometimes it is helpful, and can motivate us when we reflect or share our thoughts about things.

How will we use information about you?

We will need to use information from you for this research project. This information will include what you tell us during a focus group discussion or by completing the survey but will not include any personal identifiable information. People will use this information to do the research and to make sure that the research is being done properly. We will keep all information from you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our policy available from https://www.uhmb.nhs.uk/privacy-policy
- By asking one of the research team, or

By sending an email to DataProtectionOfficer@mbht.nhs.uk

What if there is a problem?

If you have any concerns about the study please speak to one of the research team who will do their best to answer your questions. If you have further questions following your involvement please use the contact details at the beginning of this sheet. If you remain unhappy and wish to complain formally please contact our Trust's Patient Advice and Liaison Service (PALS) on 01539 795497 who will be able to listen to you and advise you further.

Like all research that takes place in the NHS this study is covered by the NHS indemnity scheme. If you are harmed due to someone's negligence then you may have grounds for legal action for compensation against the University Hospitals of Morecambe Bay NHS Trust but you may have to pay your legal costs. Regardless of this, if you wish to give feedback (good or bad) about any aspect of the way you have been treated during the course of this study then you should get in touch using the contact details on the front in the first instance.

What will happen if I change my mind and no longer want to be part of the study?

You are free to leave the study at any point, without giving a reason. Your care and treatment will not be affected and your doctors and clinicians will not be disappointed. GDPR provides you with rights so that you can ask us to stop using your information. You can do this at any point up until two weeks after focus group discussions. This is the point at which we will start to analyse the information we have collected. If you lose capacity to consent whilst taking part in the study, you and any data we have collected will also be withdrawn from the study, up until this point.

What will happen with the results of the research?

The results of the research will be collected and analysed. We will look for common themes to help us get a better view of how people feel about physical activity before or after they have had surgery. We will then share our findings with other healthcare organisations, including GPs, anaesthetists and nurses. We will write reports for the NHS, articles for academic journals and present our findings at conferences. We may also put together resources to help other healthcare professionals in the future and our research could help shape future health policy.

Throughout the research project we will use mainstream news media where possible, and social media to publicise and talk about our research. This can be found on Twitter @Fit_for_Surgery and via our website: https://www.lpsru.org/.

Though we cannot feedback to you directly, you should be able to see how your input has helped our research.

Who is organising and funding the research?

We are based at the Lancaster Patient Safety Research Unit at the Royal Lancaster Infirmary which is part of the University of Morecambe Bay Health Trust. Our Chief Investigator is Professor Andrew Smith who is a Consultant Anaesthetist at the hospital. We are being funded by the National Institute for Health Research.

Who has reviewed the research study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee.

What happens next?

The next step will be asking you to join a meeting to discuss the study and focus group discussion process further, and to ask you to consider and consent to be involved. We would like you to hold onto this information sheet in case you require any of the details at a later date.

Please contact:
Professor Andrew Smith
Royal Lancaster Infirmary
Ashton Road
Lancaster
LA1 4RP
andrew.f.smith@mbht.nhs.uk

01524 583517

Consent Form

Name of researcher: Professor Andrew Smith

	Please initial box
• I confirm that I have read the information sheet dated 30.09.2020 (version 1.5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
• I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
	☐

- I understand that the information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers. ☐
- I consent to audio recordings being made of focus group discussions and understand that any recordings will be destroyed once transcribed and no personal data will be recorded. ☐
- I agree to take part in the study. ☐

Name of participant:	Signature:	Date:
Name of researcher:	Signature:	Date:

11.1.2 Draft indicative surveys and focus group discussion topics

Survey and document list for services

Page 1 (online)

You are invited to participate in a research project titled "'Fit for surgery' or 'fit for life'? Exploring the potential of using the perioperative encounter to promote regular exercise and physical activity: an expanded evidence synthesis". The study is being conducted by the Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust, alongside colleagues at the University of Lancaster, Sheffield Hallam University and patient and public involvement representatives.

Our aim is to examine a broad range of evidence and knowledge to identify, and set in context, interventions applied during the perioperative period (the point at which surgery is first contemplated to the point at which patients are discharged from post-operative care) to promote physical activity in the medium to longer term. We will do this through comprehensive literature searching and synthesis and by analysis of relevant approaches in practice.

This survey you should take about 20 minutes.

Your participation in this survey is voluntary and you can withdraw at any time. You are free to omit any question. If you are interested in taking part, please ensure that you have read a copy of the participant information sheet provided to you with the link to this survey. If you have any questions, please email or call us using the details listed below.

The survey is managed by Survey Monkey and you may access their privacy policy here

If you have any questions regarding the project or the survey, please do not hesitate to get in touch with us. If you prefer a paper copy of the questionnaire, please let us know and we will mail this to you including a freepost return envelope.

Professor Andrew Smith
Royal Lancaster Infirmary
Ashton Road Lancaster

LA1 4RP andrew.f.smith@mbht.nhs.uk
01524 583517

Thank you for your support.

This project is funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research, reference NIHR127879. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Page 2 (online)

Please could you share, where possible, the following documents:

- Service specification
- Service pathway
- Job descriptions of staff
- Written guidance (local or national) that you share with patients/families
- Evaluations or reports about your service
- Patient reported outcomes, for example, pre and post-surveys
- Patient demographics
- Local Joint Strategic Needs Assessment if available
- If you have the above documents but are unable to share these, please briefly tell us why.

Please could you tell us a bit about your service (where this information can be found in supporting documents that you share you may leave these blank):

About your service

- What is it that your service aims to do?
- What is your offer to patients?
- What physical activity goals does your service have for patients?
- What sort of physical activities does it promote?
- Where is your service delivered?
    - Do you support people with access to this location, for example, with transport?
- Who commissions or funds your service?
- What sort of organisation is your service part of (NHS primary, secondary, specialist), community (charity/social enterprise sector, local authority), private corporation, partnership.
- In which local authority is your service located?
- What is the catchment area of your service?
- How long has your service been running?
- Have you received any letters of appreciation, feedback or complaints? Please provide details.
    - Please provide details of attrition / numbers not completing your programme.

Please tell us about the patients you work with

- How many patients do you work with each year?

- Who are the patients that you work with? Why are they referred to your service?
- What do you see as their primary focus or goal when they are using your service?
- What sorts of surgery are patients considering or have they had?
- Where are patients in their perioperative journey?
- How involved are you with patients' families or carers?
- How much time do you spend with patients?
    - Over what period of time?

Referral

- How does a patient end up in your service (the referral pathway)?
- What, if any methods do you use to recruit patients, for example, posters, leaflets, local publicity, word of mouth.
- Who is involved in referring or supporting access?
- How long does referral take?
    - Do you have a waiting list? If so how long is this?

Staffing

- Please tell us about the staff in your service. It would be helpful to know about their skills, responsibilities and the WTE hours that they work.
- Are there other people, in different teams, services or organisations that are essential to your provision?
- Please tell us about these people, services or care and how these relationships and services fit together?
- Have you received any feedback from other teams about your service or the impact on patients? Please provide examples.

Resources

- What resources do you rely on to deliver support to patients? For example, this might include equipment, patient information, and activity tracking devices.

Other

- Please tell us about any other services delivering similar care to patients that you are aware of.

Final webpage

By clicking the 'Submit' button below, you are consenting to participate in this study, as it is described in the participant information sheet, which you can download here [provide download link]. If you did not yet download and keep a copy of this document for your records, we recommend you do that now.

Many thanks for your support with our study

Survey for patients

Page 1 (online)

You are invited to participate in a research project titled "'Fit for surgery' or 'fit for life'? Exploring the potential of using the perioperative encounter to promote regular exercise and physical activity: an expanded evidence synthesis".

This means we are looking at the potential for using pre and post-operative support to promote physical activity and to improve patients' long-term health and wellbeing following an operation.

The study is being conducted by the Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust, alongside colleagues at the University of Lancaster, Sheffield Hallam University and patient and public involvement representatives.

We are searching for studies about physical activity for surgical patients. We are also talking to patients and staff, and collecting information about what methods are used to encourage people to be more physically active, who is involved in delivering and setting up these methods or services, and how people feel about them. This survey will help us to understand some of experiences you have had relating to physical activity promotion.

This survey you should take about 20 minutes.

Your participation in this survey is voluntary and you can withdraw at any time. You can choose not to answer any question. We will collect your answers and compare them with other survey responses in order to conduct analysis and produce a final report. Your survey responses are anonymous and your computer IP address will be excluded from the results. If you are interested in taking part, please refer to the participant information sheet provided to you and that was previously discussed with one of our researchers.

The survey is managed by Survey Monkey and you may access their privacy policy here. If you have any questions regarding the project or the survey, please do not hesitate to get in touch with us. If you prefer a paper copy of the questionnaire, please let us know and we will arrange for this to be mailed to you including a freepost return envelope.

Professor Andrew Smith
Royal Lancaster Infirmary
Ashton Road Lancaster
LA1 4RP andrew.f.smith@mbht.nhs.uk
01524 583517

Thank you for your support.

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Page 2 (online)

About you

1. Please could you tell us a bit about your current health situation?
2. What does the surgery for your current healthcare situation mean for you? Please tick all that apply
    a. To improve my quality of life
    b. To improve my physical function / help me conduct normal activities of daily living
    c. To improve my chance of survival
    d. Not sure
    e. Other, please specify

3. What does quality of life mean to you?
4. Do you feel in control of your general health?
    a. Yes, very much
    b. Yes, most of the time
    c. Sometimes
    d. Not usually
    e. Not at all

Physical activity promotion

5. During your current healthcare journey, have you been encouraged to use a service that promotes physical activity?
    a. Yes, I have used this service but have now finished using it
    b. Yes, I am currently using this service
    c. Yes, but I have not started using this service yet
6. Please tell us about the first time, in your current healthcare journey, that someone encouraged you to do more physical activity or to become more active?
7. Please tell us how this made you feel?
8. Which of these statements are important to you. Please tick all that apply:
   Being physical active will:
    a. Help me recover from my operation
    b. Help my operation go well
    c. Help me to be fitter
    d. Help me to loose weight
    e. Help me feel happier
    f. Improve my mental wellbeing
    g. Help me to be healthier
    h. Help me to socialise

About your experiences

9. If you have used a service during your current healthcare journey that encouraged you to be more physically active, please tell us what worked for you?
   If you have not yet used this service, please skip to Question 11.
10. Thinking about the service you have used, please tell us about something you feel could be improved or done differently?

11. Do you have any ideas that could help health services (and / or people who make decisions about health services) to support people to be more active? Please tell us about these below.

    Thank you very much for sharing some of your experiences. We look forward to talking with you during a focus group discussion

Final webpage

By clicking the 'Submit' button below, you are consenting to participate in this study, as it is described in the participant information sheet, which you can download here [provide download link]. If you did not yet download and keep a copy of this document for your records, we recommend you do that now.

Many thanks for your support with our study

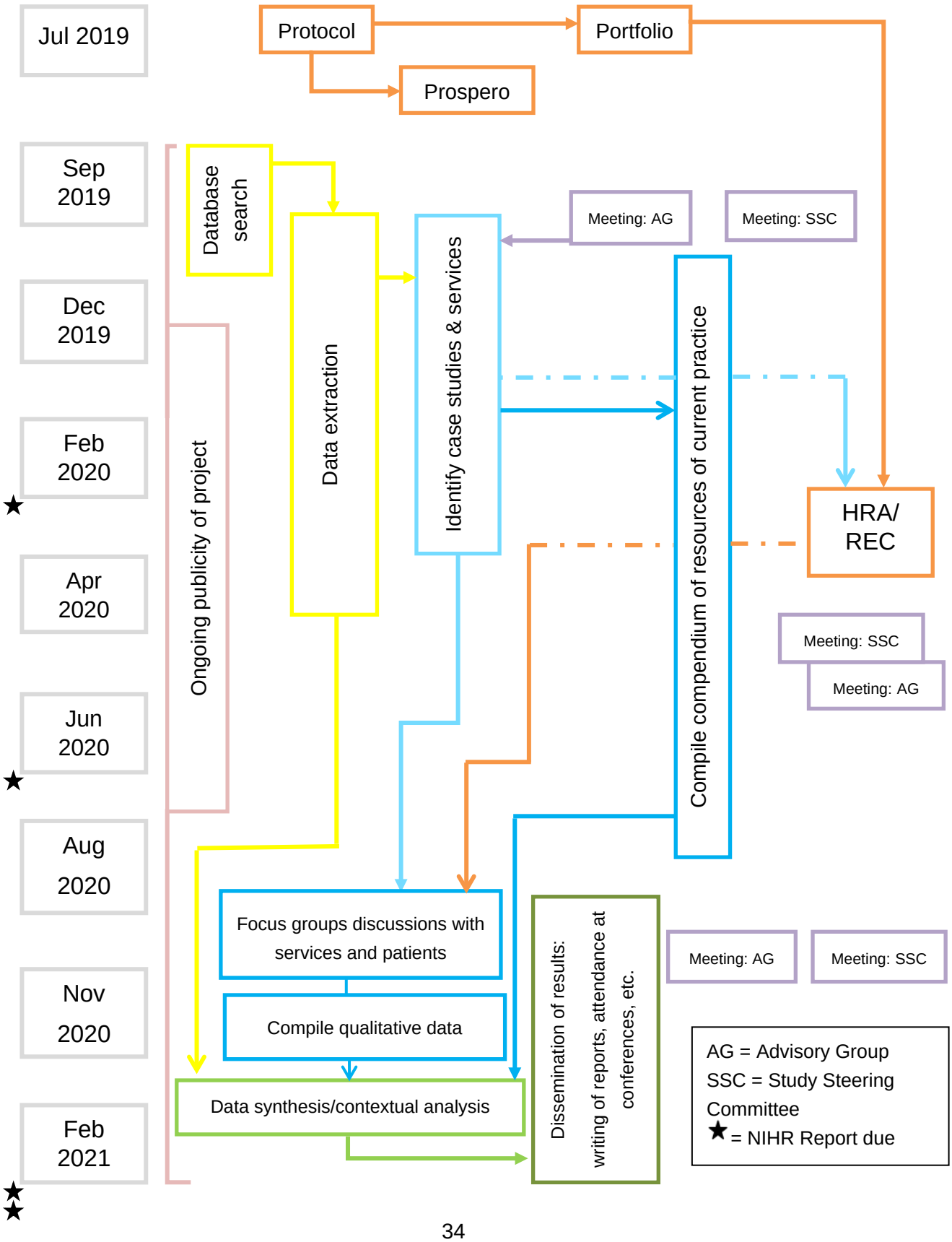
Focus group discussions: Discussion guide

Two - hour sessions with 10 minute break in the middle

Focus group topics

- What matters most to you
- Presenting physical activity
- What do we need across our services to support this work with patients and colleagues / partners
- Remote and digitally supported delivery

11.2 Appendix 2 – Project Management Flow Chart (V4.0 30.09.2020)



11.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	19.08.2019	SVG	Minor change: amendment of the project management plan and the flow chart to take account of the HRA/REC submission now taking place following identification of case study sites, yet still before any site visits take place; and removal of distinct PPI meeting as this will be incorporated in both SSC & AG meetings. Now includes history for Project Management Plan and Study Flow Chart, below.
2	1.2	22.01.2020	SVG	Minor change: to take into account revised timetable agreed with NIHR – ethics approval and protocol update March 2020, and to include progress report dates, bringing forward the second report date to the end of May 2020.
3	1.3	29/10/2020	AR	Extension of planned study period including financial support to 28 February 2021 Amendment of Project Management Plan in line with above extension Alteration of case study approach in respect of limitations placed on original project by Covid-19. Revised PIS, consent forms, survey (to replace interviews) and draft focus group discussion guide to account for above change to case study approach. Revised expectations in relation to the toolkit we plan to create; we think it unlikely that we will have capacity (time) to involve other sites through the North West Innovation Agency (as originally hoped) to validate the toolkit. We will however explore feasibility of the toolkit with our Advisory Group.

Project Management Plan History

V1.0	03.2019	SRL	
V2.0	09.2019	SRL/AFS	Changes related to resubmission of funding application
V3.0	26.06.2019	SVG	To include start-up tasks and update to most recent timescale
V4.0	19.08.2019	SVG	Change of timing of HRA/REC submission
V5.0	19.12.2019	SVG	Revised timeline – ethics and progress reports
V6.0	30/09/2020	AR	Revised timeline – accounting for extension of planned study period
Study Flow Chart History			
V1.0	15.07.2019	SVG	
V2.0	19.08.2019	SVG	Change of timing of HRA/REC submission
V3.0	19.12.2019	SVG	Revised timeline – ethics and progress reports
V4.0	30.09.2020	AR	Revised timeline – extended study period and focus group discussions