



National Institute for Health Research

Project title

'Function First' The role of primary care in reducing the decline in physical function and physical activity in people with long-term conditions; what works, for whom and in what circumstances? A realist synthesis of evidence (Stages 2-4 interviews and workshops)

Short title (IRAS): Physical function in primary care: Stages 2-4 interviews and workshops

Study 'acronym': 'Function First', with the strapline 'Be Active Stay Independent'

Protocol version: Approved protocol v 3.0, 12-09-2019

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Version control table

Version	Date	Authors	Details
1.0	26/04/19	Co-investigator team	Protocol for remaining phases of project, for to NHS REC submission
2.0	07/06/19	Co-investigator team	Revised protocol for remaining phases of project following provisional opinion
3.0	12/09/19	Co-investigator team	Revised protocol incorporating amendment to use a recruitment poster

HRA protocol compliance declaration:

This protocol has regard for the HRA guidance.

LAY SUMMARY

Aims: Your 'physical function' describes how well you can perform activities that are essential for daily living and staying independent, such as walking to the shops or standing up from a chair. People with long-term conditions, such as arthritis or diabetes, often become less able to do these tasks and are less physically active. The number of people living with long-term conditions is increasing. The purpose of this research is to work with patients and health professionals to work out how best to help people with long-term conditions maintain and improve their physical function and become more physically active.

Background: People with long-term conditions visit their GP surgery for regular check-ups and it is the first place they visit with their symptoms. However, physical function is not given as much priority as other measurements, such as body weight or blood pressure. If a person's physical function is poor, it means they are less able to look after themselves and do things they enjoy. Improving physical activity is an important way of improving physical function and is very helpful for many long-term conditions. Despite this, most people do not do enough physical activity. Therefore, it is important to pay attention to physical function and physical activity when a person visits their GP surgery. It is also important to consider psychological and social factors. However, we do not know the best way to address physical function and physical activity when people visit their GP surgery for regular check-ups.

Methods: We will examine previous studies that have looked at improving physical function and physical activity in primary care. Rather than only finding out whether or not something works, we will find out what works (or doesn't work), for whom and in what circumstances. This is especially helpful when investigating complex areas, such as improving physical function and physical activity. We will start by developing working theories about why some interventions have worked in primary care or others have not. We will talk to patients and health professionals involved in improving physical function and promoting physical activity to help us with this **(this part is now complete)**. This will help us refine our working theories. We will also describe these theories clearly and check that they make sense, including with patient and public representatives. We will end up with a final set of recommendations about how best to help people fulfil their functional potential when they visit their GP surgery. These recommendations will be taken forward to the 'co-design' stage. This stage will involve three creative workshops during which two to three ideas of new ways to improve physical function and physical activity will be developed. There will also be a workshop to develop ways of sharing the new findings from the study. A wide range of patients and people involved in the care of people with long-term conditions will be invited to participate in these workshops.

Dissemination: We will invite patient, public and professional representatives to be involved in our dissemination activities. Two research publications will be written. One will focus on how we completed the project and one will focus on the findings and recommendations. Reports will be written for the NIHR and we will write to everyone who took part. We will also present our findings at scientific meetings and share with professionals and with the public in a variety of ways, such as by making a video.

SCIENTIFIC SUMMARY

Aims: This proposal aims to conduct a realist evidence synthesis with embedded co-production and co-design, to provide evidence-based recommendations about how best to help people with long-term conditions, in the primary care setting, to maintain and improve their physical function and become more physically active.

Background: Long-term conditions comprise the biggest burden on the NHS and primary care services. 'Physical function' can be defined as an individual's capacity to undertake the physical tasks of everyday living. People with long-term conditions often have reduced physical functioning and become less able to live independently and, despite the clear benefits for health and functioning, are also less physically active. Long-term conditions are managed routinely in primary care, with assessment and treatment aligning closely to the medical model of illness. However, physical function and physical activity are often not given as much priority. Psychosocial factors influencing physical function and physical activity also need consideration. A new way is needed to address the decline in physical function and physical activity in people with long-term conditions as part of primary care service delivery.

Methods: This realist synthesis will use established methods and will embed the principles of co-production and co-design. Stage 1 will develop initial programme theory based on a scoping search of the scientific and grey literature, as well as two stakeholder workshops to generate initial ideas and theories. A stakeholder analysis will identify relevant stakeholders. These are likely to include patients, GPs, practice nurses, therapists and others involved in improving physical function and promoting physical activity (**this part is now complete**). Stage 2 involves more focussed literature searching, data extraction and synthesis to provide evidence to support the initial programme theories. We will focus our searching on physical activity interventions that are part of primary care service delivery and include assessment of physical function. However, we will iteratively broaden our searches to include relevant areas such as studies from secondary care, the voluntary sector and social care. We will tease out the complexities relating to whether or not something works, for whom and in what circumstances and develop (C)ontext, (M)echanism and (O)utcome (CMO) configurations. A taxonomy of physical activity interventions suitable for optimising physical function for people with long-term conditions will be produced. Stage 3 involves testing and refining the programme theories. We will seek additional input from stakeholders in order to refine the final programme theories. The resulting theories will feed into Stage 4. This stage involves three sequential co-design stakeholder workshops where ideas for service innovation will be developed. A final knowledge mobilisation event will take place in order to address issues relevant to wider implementation to ensure that the intervention is relevant, useable and accessible to stakeholders. It will provide the content for a suite of dissemination materials (such as short video), for development by the design team.

Dissemination: A protocol and overall findings paper will be written and published in a scientific journal. The materials from the knowledge mobilisation event will be used for targeted dissemination to relevant groups. PPI representatives will be invited to facilitate dissemination activities.

STUDY MANAGEMENT

Bangor University will assume overall responsibility for the initiation and management of the study including design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The project will be managed by Dr Rebecca-Jane Law (RL) who is co-Chief Investigator with Professor Nefyn Williams (NW).

A Study Management Group (SMG) consisting of individuals responsible for the day-to-day running of the study will be responsible for overseeing the progress of the study and will meet regularly every month. The SMG will include the co-Chief investigators, and the other co-applicants as required during the different stages of the study. The SMG will ensure that the protocol is adhered to, will take appropriate action to safeguard stakeholder participants and ensure the overall quality of the study. The SMG will report to the project advisory group (PAG).

A Project Advisory Group (PAG) meeting will be held at least once yearly and will fulfil an advisory role as well as overall supervision of the study in alignment with NIHR's requirements and guidance. It will consider study progress and adherence to the protocol and will provide advice to the study team. The PAG will make recommendations to the SMG and will report to the sponsor and the funder. The PAG will consist of an independent chair (Professor Adrian Edwards), the chief investigators (NHW, RL), two independent PPI representatives (TBC) and other members: Robert van Deursen (Professor of Rehabilitation Science, Cardiff University), Professor Julie Richardson (Professor in the School of Rehabilitation Science, McMaster University, Ontario), Dr Asan Akpan (Consultant Community Geriatrician, Aintree University Hospital, Liverpool), Dr Jeanette Thom (Associate Professor, Exercise Physiology Human Movement and Sports Science in the Faculty of Medicine, University of New South Wales), Malcolm Ward, who is working group lead for Physical Activity Promotion in Health Care Settings for the World Health Organisation Health Enhancing Physical Activity (Europe) Network and Chris Jones (Professor of Health Services Research and Deputy Chief Medical Officer for Wales/Medical Director NHS Wales), Dr Freya Davies (an academic GP with expertise within the area of realist synthesis) and Louise Williams from Public Health England.

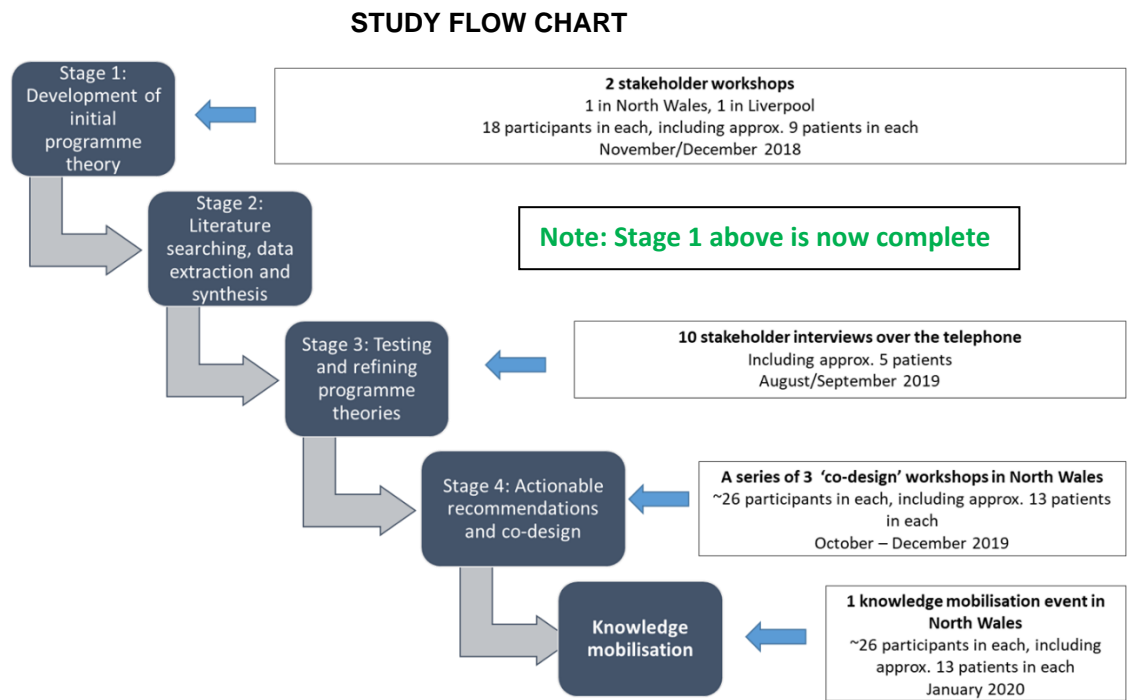


Figure 1. Flow diagram of study stages

STUDY GANTT CHART

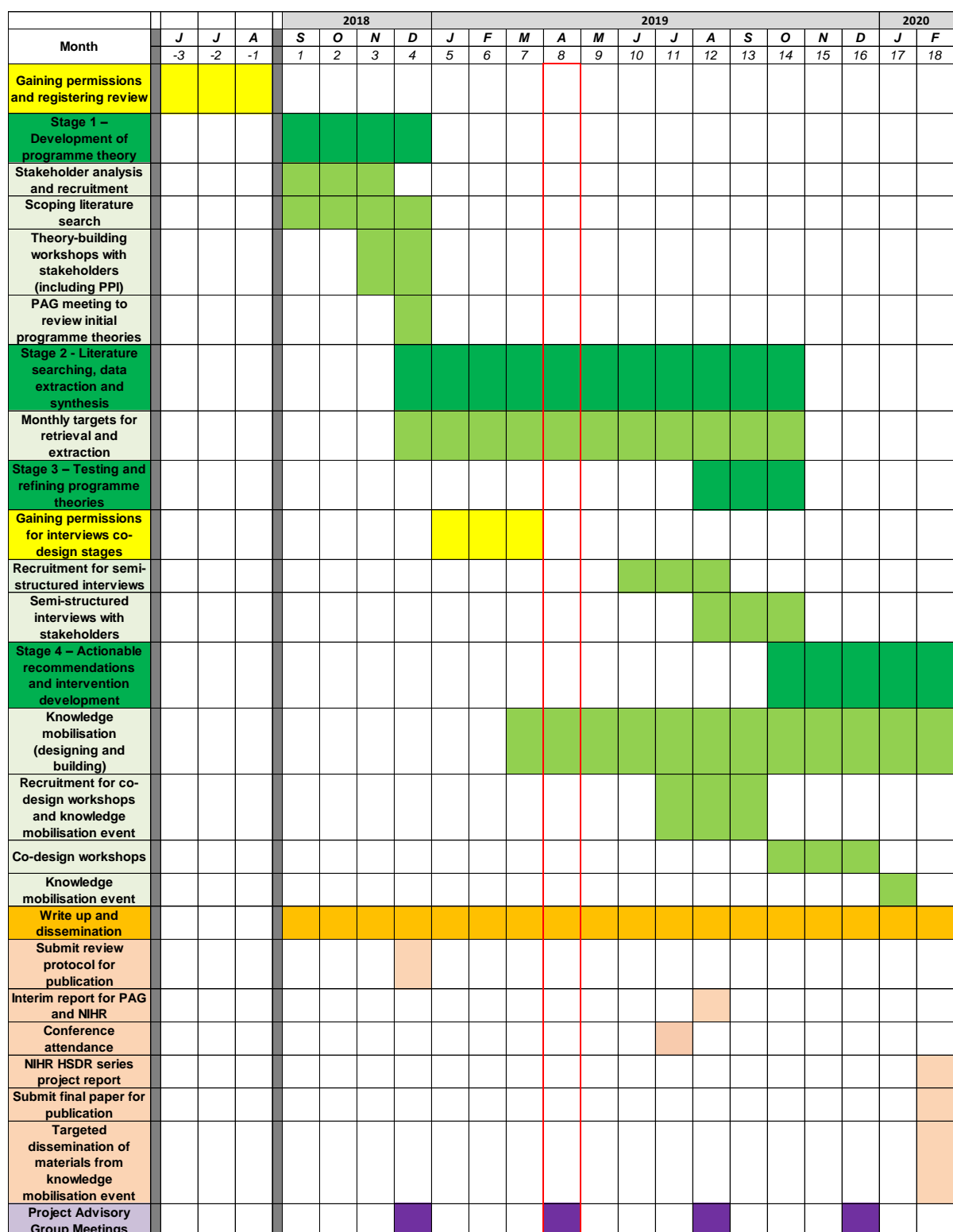


Figure 2. Gantt chart detailing study milestones and planned monthly progress throughout the study, current status shown in red.

STUDY PROTOCOL

Title: 'Function First' The role of primary care in reducing the decline in physical function and physical activity in people with long-term conditions; what works, for whom and in what circumstances? A realist synthesis of evidence (Stages 2-4 interviews and workshops)

Key words: Realist synthesis, Physical function, Physical activity, Primary care, Long-term conditions, Co-design

Background

Long-term conditions

Long-term conditions (also called chronic diseases) are the commonest cause of death and disability in the UK (1). A long-term condition has been defined as one that cannot currently be cured but can be controlled by medication and other therapies (2). Examples of long-term conditions include hypertension, coronary heart disease, asthma, chronic obstructive pulmonary disease, diabetes, depression, chronic kidney disease and osteoarthritis. In England, approximately 30% of people have a long-term condition (3). Long-term conditions comprise the biggest burden on the NHS involving more than half of all GP consultations, 65% of out-patient visits, and 70% of in-patient bed days (1). The prevalence of long-term conditions and multi-morbidity (more than one long-term condition) rises with age, and is projected to increase (4). As older people accumulate more long-term conditions, they also become increasingly frail and are at high risk of adverse outcomes such as falls, disability, admission to hospital and the need for long-term care (6, 7). Treatment and care for people with long-term conditions is estimated to take up around £7 in every £10 of total health and social care expenditure. The increasing prevalence of long-term conditions is one of the biggest challenges facing our health and social care systems (1).

Physical function

'Physical function', is a term used to describe an individual's capacity to undertake the physical tasks of everyday living (8). Poor physical functioning is associated with negative outcomes, including higher risk of 30-day hospital re-admission (9), increased morbidity and mortality (10, 11) and long-term disability (7, 12). Older adults with chronic disease are at high risk for progressive decline in physical functioning and subsequent disability (13). In 2011, approximately 25% of people with one long-term condition reported having 'problems walking about' and 'problems performing usual activities', rising to over 60% with three or more long-term conditions (52). In 2016, 24% of men and 31% of women in England aged 65 and over needed help with at least one 'Activity of Daily Living' (53). This data demonstrates the scale of the need for this research. Worsening physical function also affects older adults with long-term conditions in terms of overall health and independence, and may also impact how their symptom management (14). Thus, physical function is one of the most important factors for quality of life among older adults (14, 15), and optimising and preserving physical functioning is a central goal for all people with long-term conditions. Increasing awareness about the important relationship between physical function and overall health status is likely to lead to improvement in care for people with long-term conditions (16, 17).

Physical activity

A different but related concept is that of physical activity, defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (18). 'Physical activity' refers not to the capacity to do something, but to what one actually does. There are powerful attributes of increased physical activity in preventing and managing long-term conditions, with positive effects comparable to medication (19). Previous studies of middle-age and older adults show that more physically active people have better levels of physical functioning (8, 20-23). Indeed, physical inactivity is one of the strongest predictors of physical disability in older people (24, 25). The proposed process behind this association includes that physical activity helps to maintain muscle and cardiac function, improve gait, balance and mood, and

subsequently prevents functional decline (26-30). Moreover, physical activity prevents or improves conditions that underlie disability in older adults, including falls (31), hip fracture (32), cardiovascular disease (33) diabetes (34), obesity (35) and frailty (36), with longitudinal studies suggesting regular physical activity is associated with reduced mortality (37). Several studies have also demonstrated beneficial effects of physical activity on psychosocial functional outcomes in older adults (38-40).

Despite the known benefits of physical activity for improving physical function (36, 54-59), the proportion of the general population that are at least moderately active (participating in moderate physical activity for at least 30 minutes, five times per week) is low. Indeed in 2015/16, over half did not meet this recommendation. Moreover, 26% and 32% of adults were classified as inactive (fewer than 30 minutes physical activity a week) in England and Wales respectively, with increasing age associated with less physical activity (60). However, the true position is likely to be worse as individuals appear to over-estimate the amount of physical activity they do in self-reported surveys. Objective measurements of physical activity suggest lower levels of participation (61). The rates of physical activity in people with long-term conditions are even lower and an inverse association has been found between physical activity and multi-morbidity (62, 63). The worldwide economic burden of physical inactivity has been estimated to be at least £51.5 billion per year (64) and the estimated annual direct cost of physical inactivity to the NHS across the UK is £1.06 billion (65). The World Health Organisation has a target to achieve a 10% reduction in physical inactivity by 2025 (66). Our proposal responds to this, as well as to key health service policies and recommendations.

Current recommendations and the role of primary care

The Well-being of Future Generations (Wales) Act 2015 (67) puts in place seven well-being goals including 'a healthier Wales'. A strategic aim of this policy is 'to encourage more adults to be more active, more often, throughout life'. In England, Public Health England has launched 'One You', the first ever nationwide campaign to address preventable disease in adults. This aims to encourage people, particularly adults in middle age, to take control of their health by 'moving more' in order to enjoy significant benefits now and in later life (68). In addition, the importance of physical activity and physical function was emphasised in the 'Start Active, Stay Active' report from the four home countries' chief medical officers on physical activity for health (69). The variation in physical function that exists amongst people as they age was acknowledged and the report gives recommendations for groups of older adults with differing functional status and activity needs including: a) those who are already active through daily walking, an active job and/or engaging in regular recreational or sporting activity, b) those whose function is declining due to low levels of activity and too much sedentary time, and c) those who are frail or have very low physical or cognitive function, perhaps as a result of chronic disease such as arthritis, dementia or very old age itself. This report identified primary care as having an important role in terms of improving physical activity, including making physical activity an explicit element of regular behavioural risk factor screening, patient education and referral, as well as developing and maintaining strong links between primary care settings and local community-based opportunities.

The NICE guidelines for the clinical assessment and management of multi-morbidity recommend that functional assessments should be used in primary care to assess frailty, such as gait speed and self-reported health status (70). NICE have also issued guidelines for the prevention of frailty, disability and dementia in mid-life (71) and recommend that campaigns should promote the message that; sustained ill health in old age is not inevitable, the risk and severity of dementia, disability and frailty may be reduced, the earlier in life that healthy changes are made the better, and that health gains can be made by changing behaviours, even in mid-life. Moreover, NICE recommend future research should focus on determining the most effective and cost effective mid-life services and interventions, including how these can be delivered in a consistent and sustainable manner.

In the NHS, most of the healthcare for long-term conditions is delivered in primary care. The management of these conditions is strongly influenced by the Quality Outcomes Framework (72) which emphasises disease-centred outcomes and the recording of risk factors such as blood pressure and body weight, rather than the assessment of physical activity and physical function. Patients can be referred from primary care to exercise referral schemes (73). However, referral to these schemes is not done as a matter of routine, and the effectiveness of the schemes is limited by low rates of recruitment and retention (74-76). It may be that these gym-based schemes appear irrelevant to people's day-to-day lives and a different approach is warranted. As primary and community care is increasingly integrated, with further examples of integration including social care, leisure services and the third sector, interventions could also be widened to include these areas.

International examples

The 'Exercise is Medicine' (77) movement in the United States and the Canadian Chronic Care model, with the perspective of function as the 'sixth vital sign' (17) are two international examples of importance. A multi-component rehabilitation intervention including function-based individual assessment and action planning, rehabilitation self-management workshops, on-line self-assessment of function, and organisational capacity building has been explored within a Canadian primary healthcare setting (17). This functional approach is different from the medical model of illness, which focuses on diagnosis, categorisation, and medication of disease (78). Rather it concentrates on functional limitations, such as whether people can perform activities of daily living (79). In addition, in order to improve care for people with long-term conditions, it has been suggested that there is a need to shift away from a reactive, disease-focused, fragmented model of care towards one that is more proactive, holistic and preventive (80). Similarly, the Chronic Care Model, which has influenced health policy around the world, also stresses the need to transform health care for people with long-term conditions from a system that is largely reactive by responding mainly when a person is sick, to one that is much more pro-active, and focuses on supporting patients to self-manage (81).

A focus on function

Whilst managing disease remains important, placing more emphasis on functional limitations, such as whether people can perform activities of daily living, has the potential to improve care for people with long-term conditions. Solely concentrating on disease can lead to reactive, fragmented care; including a functional approach may promote more pro-active, 'whole-person' and preventive care.

Indeed, organisational interventions targeted on patient-specific difficulties (e.g. functional ability), appear more effective (41), especially when the intervention is more comprehensive and better integrated into routine care (42). Therefore, since ninety per cent of patient interaction is with primary care (43) and people with long-term conditions are in regular contact with primary care (2), focussing on this area of service delivery is likely to be effective.

Previous systematic reviews have explored the effects of physical activity interventions in sedentary adults and people with multi-morbidity, osteoarthritis, obesity and chronic pain in the primary care setting (44-47). In addition, barriers and facilitators to physical activity and the effectiveness of different intervention 'deliverers' (48, 49) have been explored. However, whilst the links between physical activity and physical function are evident and the benefits of physical activity are clear, the best way to help people in primary care with long-term conditions to reduce functional decline and improve physical activity is unclear.

In summary, physical activity benefits physical (and psychosocial) functioning, with insufficient physical activity levels most apparent in those with long-term conditions. Most people with long-term conditions have regular contact with primary care. Primary care interventions to increase physical activity are only used in a limited way in UK NHS. A better way for primary care to promote help reduce functional decline and promote physical activity is needed.

Approach and rationale

Optimising physical function and physical activity is likely to involve a complex intervention, drawing upon a range of resources that activate different participant responses (82). Therefore, a methodology which focuses on this complexity is required. Realist approach recognises how; 'patterning of social activities are brought about by the underlying mechanisms constituted by people's reasoning, and the resources they are able to summon in a particular context' (83). A realist approach will provide us with an explanatory account and understanding of 'what is it about a programme (or intervention) that works for whom, in what circumstances, in what respects, over which duration' (84-86). Employing this methodology will enable us to examine the interplay between different contexts and mechanisms that underpin interventions in primary care to improve physical activity and physical function for people with long-term conditions. It will also enable us to examine how these different contexts and mechanisms lead to different outcomes.

The rationale for using realist synthesis in this case, as opposed to systematic non-realist review, is that this approach enables identification of CMOs (i.e. the context, mechanism and outcomes; see more in the Methods section) offers a more contextualised explanation of what works (and does not work) and therefore addresses the need to focus on complexity.

It has also been recommended that the research community should shift the balance of its efforts from designing and testing small-scale interventions to change individual behaviour towards expanding the evidence on strategies for translating, disseminating, implementing, and scaling up effective policy and practice for physical activity promotion worldwide (87). As improving physical activity plays an important role in maintaining and improving physical function, this synthesis will consider these issues. It will also explore the potential for a 'culture shift' in the focus of NHS general practice from a disease-centred approach, which emphasises diagnosis, categorisation and medication, to one which promotes overall function and well-being.

'Co-production' is a systematic and interdisciplinary approach involving sustained engagement with stakeholders, and their systems, in order to generate implementable knowledge with impact in healthcare and health' (92). Our approach to this realist synthesis involves embedded co-production, where the programme theories will be developed with input from stakeholders and Project Advisory Group (PAG) as 'co-producers' throughout the review process. The resulting theories will then feed into the co-design stage, where ideas for service innovation will be developed. Therefore, this is a co-produced realist synthesis of literature, stakeholder experiences and views, resulting in evidence and knowledge that will inform imagination and ideas for the co-design phase. Stakeholders will also be involved in a workshop designed to help make the synthesis findings and the co-designed interventions useable and accessible (knowledge mobilisation). Therefore, this evidence synthesis will include already known information from varied sources of literature, but also new ideas for innovation and implementation from stakeholders.

To the authors' knowledge, this will be the first realist synthesis of physical activity interventions designed to improve physical functioning for patients with long-term conditions managed in primary care. In addition, it will combine findings from the realist evidence synthesis with co-developed service innovation ideas, to provide recommendations for primary care delivery. This proposal aligns to the priorities in current UK policy and the findings will provide new understanding regarding how best to plan, implement and sustain physical activity interventions in primary care in order to reduce functional decline for people with long-term conditions. The synthesis findings will lead to actionable recommendations for those involved in the organisation of health services, in particular primary care and their partners, for the benefit of patients.

Theoretical landscape

This is a theory-driven synthesis of evidence and therefore as Pawson explains, the main purpose of the review is explanatory, this starts with articulating the relevant programme theories (85). An initial sweep of the overarching theories and frameworks that are likely to inform the realist synthesis include;

- Theories and models relating to physical function e.g. International Classification of Function (79), environmental factors and individual compensation strategies (93)
- Health psychology theories e.g. Self-efficacy/self-determination theory (94, 95), sociocognitive theories relevant to behaviour change and adherence/maintenance e.g. health beliefs, planned behaviour (96, 97), COM-B (98)
- Sociological theory e.g. governmentality (99), habitus (100), social and peer support (101, 102)
- Behaviour change theories relevant to the health professionals e.g. intention and behaviour (103)
- Implementation theories e.g. diffusion (104), knowledge to action (105)
- Organisational theories e.g. how interventions fit into different ways of delivering services/pathways (106, 107)

The methodology employed in this study will guide the team to capture the influence of providers and differences in implementation of similar interventions in order to develop and test the programme theory and help answer the question; what works, how, for whom, and under which circumstances? In stage 1, workshops with stakeholders will capture experiences from different implementation approaches, and

the influence of providers will be sought to understand the macro context within which such interventions sit. In the literature review (stage 2), the design of the bespoke data extraction forms will ensure that we capture intervention details including any differences in implementation. Purposive sampling will further enable us to capture different implementation approaches and provider influences in data collected via semi-structured interviews (stage 3). These stages are described in further detail in the following sections.

Aims and objectives

- 1) To identify and produce a taxonomy of physical activity interventions that aim to reduce functional decline in people with long-term conditions managed in primary care.
- 2) To work with patients, health professionals and researchers to uncover the complexity associated with the range of physical activity interventions in primary care, and how they directly or indirectly affect the physical functioning of people with long-term conditions.
- 3) To identify the mechanisms through which interventions bring about functional improvements in people with long-term conditions, and the circumstances associated with how the interventions are organised and operate within different primary care contexts.
- 4) To understand the potential impacts of these interventions across primary care and other settings, such as secondary healthcare and social care, paying attention to the conditions which influence how they operate.
- 5) To co-produce an evidence-based, theory-driven explanatory account, in the form of refined programme theory to underpin and develop a new intervention through a co-design process with patients, health professionals and researchers.

Research plan and methods

We will conduct a realist synthesis, to determine what works (or not), how, why, and under which circumstances in physical activity interventions designed to reduce functional decline in patients with long-term conditions managed in primary care. We will follow the key steps for a realist synthesis which include; clarifying the scope of the review, developing initial programme theory, evidence searching and appraisal, extracting data, synthesising evidence to test and refine the programme theory, and drawing conclusions and recommendations (84). We will report using established guidance (88).

Programme theory “describes the theory built into every programme” (89). These will be developed as ‘context, mechanism and outcome propositions’ (CMOs). These initial theories will then be taken forward for testing and refining. The ‘context’ in this study refers to “settings within which programmes (or interventions) are placed or factors outside the control of programme designers (people’s motivation, organisational contexts or structures)” (90). A mechanism is defined as ‘how programmes (or interventions) change or provide the resources for people’s decision-making: what people do in response to the resources that the programme (or intervention) provides’ (89). ‘Outcomes’ may have single or multiple effects (83) and can be related to impact (e.g. a change in behaviour) or process (whether an intervention worked or not) (91).

Stage 1 - Development of initial programme theory

The first stage of the synthesis will involve developing initial programme theory/ies about how and why primary care interventions work (or may not work), for who, and in which circumstances, to improve physical function and physical activity amongst patients with long-term conditions. These initial ‘programme theories’ will be developed through;

- a scoping review of published and grey literature
- theory interrogation, collaboration and review with stakeholders

We will first review the existing literature to look for evidence to suggest how and for whom physical activity interventions work to optimise physical function in the primary care setting. It may be that interventions or services based in other areas of literature (such as secondary care, social services, the

voluntary sector, or exercise science) may also hold relevant insight for the development of the initial programme theories. Therefore, we will not restrict our searches to the primary care setting. So far we have identified a number of systematic reviews within the area of physical activity promotion, self-management and frailty (36, 47, 55-59) and anticipate the review will draw upon these and other areas.

We will conduct two stakeholder workshops to support the development of the initial programme theory/ies. A stakeholder analysis will be conducted to identify and target the most relevant and expert groups (108) in order to capture experiences from different implementation perspectives and understand the macro context within which primary care interventions sit. Cost-effectiveness will also be discussed. For example, it may be that linking primary care with social enterprises that are already funded outside of the NHS is a valuable area to explore, alongside whether cost savings can be made from the functional approach.

Creative methods will be employed to structure the workshops and elicit the views and experiences of all stakeholder representatives, including a facilitated session using LEGO® SERIOUS PLAY®. This will involve each individual building a model in response to a specific question about optimising physical function and physical activity and then explaining to the rest of the group what it means to them. For example, what helps and hinders whether interventions work or not? The model is then placed in the centre of a larger sheet of paper, in a circle. The model builder writes (or draws) around the model using arrows to indicate specific elements or components of their model. These will be captured photographically. The workshops will also be audio-recorded and transcribed in order to capture discussions surrounding the emerging theories. Approximately 18 stakeholders, including approximately 9 patient/public representatives, will be invited to participate in each of these workshops. One will take place at the University of Liverpool and one will take place at Bangor University.

We have planned a PAG meeting during this first stage which will be dedicated to developing the initial programme theory/ies. A protocol paper will be written and submitted at this stage detailing the methods used for this evidence synthesis.

Outputs from Stage 1:

- Stakeholder analysis
- Identification of initial programme theory(ies), expressed as conjectured CMOs
- Qualitative data and models collected from workshops
- Submission of the review protocol for open access publication

Stage 2 – Literature searching, data extraction and synthesis

Literature searching

Unlike the traditional systematic review, the realist synthesis uses a more inclusive approach and is a “more heterogeneous and iterative process, which is less amenable to prescription but which needs to be equally rigorous” (109). Therefore this stage will involve purposive searches of the literature relevant to promoting physical function and physical activity for people with long-term conditions in the primary care setting. We will examine published and unpublished literature including research articles, systematic reviews and documents detailing policy and local/national initiatives. We will seek further information and clarification by contacting authors of relevant reports and relevant organisations. We will collect and synthesise data to explain the conditions that enabled an intervention to be successfully implemented, such as intervention sustainability, durability and retention/resilience (110). We will also explore the literature using cluster search methods (111). The purposive search strategy will enable the initial programme theory(ies) developed in Stage 1 to be expanded.

Screening/search

Literature will be screened for relevance to the initial programme theory(ies) and cross-checked by two members of the research team. We will firstly focus on physical activity interventions that are part of primary care service delivery that include assessment of physical function. We will also target social care literature, as well as literature from the voluntary sector, secondary care, social care and sports science. The search strategy will be further developed and amended for use with the following health, social and sports science databases: Cochrane Library, MEDLINE, EMBASE, CINAHL, SportDiscus, PsycInfo, Sociological Abstracts, Web of Science, Applied Social Sciences Index and Abstracts (ASSIA), Social Care Online and Social Care Institute for Excellence. We will also extend our searches

to explore NHS re-ablement services and the grey literature to identify national and local services and schemes.

We will identify references from previous relevant reviews, with forward citation tracking for key research studies (defined in terms of theory relevance). Keywords will be developed from previous systematic reviews and the key themes which underpin the initial programme theory. These keywords will be adapted for each information source as necessary. The search terms to identify physical activity interventions will be constructed from a mix of database specific keywords identified in the preliminary searches underpinning this proposal. We will also use appropriate index terms where they are available.

The search for references will be enhanced by searching for papers evaluating physical activity interventions, designed to optimise physical function, but which also make specific reference to embedded implementation, information about sustainability and what makes them successful. We will also draw on the expertise of the project advisory group, patient and public representatives, other key researchers (nationally and internationally) and organisations to ensure that we have not missed evidence that may be relevant but not visible through traditional systematic searching methods.

We will be interested in finding evidence relevant to the following: Reports of interventions or studies based, or detailing assessments or methods suitable for adoption, in the primary care setting. For example, these may include physical activity, self-management interventions or frailty interventions. These studies may explore different modes of delivery and different professional 'deliverers' including, but not limited to, practice nurses, general practitioners, physician associates or peer-led, as well as the different contexts of service delivery. Our searches will also include full economic evaluations that have compared costs with consequences.

We will not search for, nor include, studies that have limited transferability to NHS primary care, such as interventions involving pharmacological agents or very technical, high-cost equipment. Our searches will include adults of all ages. We will translate non-English language papers where relevant and practical. We will not limit our searches by publication date and there will be no restriction on the type of publication or study type that can be included.

Selection, appraisal and data extraction

Consistent with the realist synthesis approach (84), the test for inclusion will be if the evidence is 'good and relevant enough' to be included (112). Relevance is the ability of the data to contribute to the programme theory (88). Assessment of relevance will involve seeking any "trustworthy nuggets of information to contribute to the overall synthesis" (85). Rigour or whether the quality of the evidence is 'good enough' is the research team's judgement of the credibility of the data, including fidelity, trustworthiness and value (113). Following the search, data to inform the programme theory/(ies) will be extracted using bespoke data extraction forms. These will be designed to ensure that we capture intervention details including any differences in implementation.

As suggested by Pawson (85), we will consider the following issues when deciding whether or not to include particular evidence; sample size, method of data collection, data analysis, claims made and whether evidence informs our programme theory. If any discrepancies arise, we will discuss amongst the project team whether the evidence provided meets the criteria to be included.

The study bespoke data extraction forms will be based on the content of the programme theories, thus providing a template for theory 'interrogation'. If the evidence is deemed 'relevant and good enough', the data will be extracted onto the data extraction forms and cross-checked by a second member of the team. A taxonomy of physical activity interventions, suitable for use in primary care, and designed to optimise physical function for people with long-term conditions will be developed.

Synthesis

This stage will involve synthesising the evidence to elicit relationships between the Contexts (e.g. the setting and circumstances, the environmental conditions and any organisational considerations), Mechanisms (e.g. underlying processes that could be related to physical, psychological or social aspects of physical functioning) and Outcomes (e.g. the intended and unintended consequences and impact) (CMOs).

Through the research team's experience of conducting realist synthesis (114-116), suggestions from Pawson (85) and underpinned by the principles of realist enquiry, we will use the following approach to synthesis, as follows:

- 1) Organisation of extracted information into evidence tables representing the different bodies of literature
- 2) Theming across evidence tables in relation to emerging patterns amongst CMOs to seek confirming and disconfirming evidence
- 3) Linking patterns to develop hypotheses (that support or refute initial programme theories).

Following this process, a set of synthesised statements will be formed and a narrative summarising the nature of the links between context, mechanism and outcome will be developed (i.e. what works, for whom and in what circumstances). This narrative will also summarise the characteristics of the evidence underpinning them.

This process is resource-intensive and involves ongoing, iterative discussion. This ongoing 'co-production' is built into our project plan and will involve ongoing consultation with the study management and project advisory groups.

Output from Stage 2:

- A taxonomy of physical activity interventions suitable for optimising physical function for people with long-term conditions.
- A set of proposed programme theories (or hypotheses) supported by relevant evidence for refinement in Stage 3.

Stage 3 – Testing and refining programme theories

In order to refine the final programme theories, we will consult with stakeholders through a set of up to 10 telephone interviews, including approximately 5 patients and 5 professional stakeholders. The stakeholders will be purposively sampled to obtain different perspectives relevant to the review question and will further enable us to capture different implementation approaches and provider influences. A semi-structured interview topic guide (see attached) will be developed based on the conjectured CMOs from the synthesis process and will aim to elicit the views of stakeholders on their resonance. Pawson and Tilley (83) summarise this process as a 'teacher-learner cycle' concept whereby the researcher presents the initial CMO configurations to the stakeholder ('teaching') and then verifies with the stakeholder where they need adjusting ('learning') to create an improved, refined version and a 'mutual understanding' of the developed programme theories. The telephone interviews will be audio-recorded and transcribed for analysis and narrative description of the key themes arising during refinement of the programme theories.

Output from Stage 3:

- A co-produced, refined set of programme theories accompanied by an evidence-based narrative to be carried forward to Stage 4

Stage 4 – Intervention co-design, actionable recommendations and knowledge mobilisation

The tested and refined programme theories arising from the evidence synthesis and stakeholder consultation will represent what works, for whom, how and in which circumstances. These will form the basis of recommendations for a physical activity intervention which is specifically designed to bring about improved physical functioning for patients with long-term conditions managed in primary care. The recommendations for service innovation, and plans for making the intervention useable, will then be designed collaboratively with stakeholders.

Intervention co-design

We will utilise the expertise of a team of design scientists to facilitate the co-design of an intervention. This will involve a series of face-to-face workshops at Pontio, Bangor University's arts and innovation centre (www.pontio.co.uk) or another suitable location at Bangor University. Informed by our stakeholder analysis, we will encourage widespread involvement from up to 26 purposively sampled individuals in each of these interactive sessions. These will include patients with long-term conditions,

primary care clinicians such as GPs, nurses and therapists; practice managers, health board managers and commissioners.

Three workshops will take place with one month intervening and ideally involving the same (or similar) people in each so that ongoing ideas can be developed and expanded during each workshop. These workshops will cover the following (see attached for workshop plan):

Workshop 1 (Immersion):

In this workshop, participants will immerse themselves into the detail of the lived experience of people with long-term conditions and the professional experience of people involved in primary care service and delivery. Participants will share perspectives, knowledge and experiences, and in particular, the programme theories that have been refined in the earlier stages of the review will be presented. This will bring all participants up to the same level in terms of programme theory development. All participants will make models or images that express and visualise their knowledge and experience so that they can be shared and understood by all other participants.

Deliverable: A collection of models and images that represent a shared understanding and appreciation of the evidence, experiences, practice and context relevant to primary care, physical function and physical activity for people with long-term conditions.

Design activity 1: Between workshops 1 and 2 the designers will explore a breadth of existing products and analogous practices to be brought to workshop 2 as provocations for new ideas.

Workshop 2 (Hack):

This will begin with a series of 'creativity' activities on the lived experiences and move into generating ideas and concepts using 2D visualisations and sketches. This will use the collection of models and images developed in workshop 1, together with any provocations supplied by the designers, to generate ideas and rough prototypes of what might work. We will explore how different combinations of models and prototypes might achieve some of the ideas, or get close to achieving some of the ideas, and consequently fulfil the recommendations included in the programme theories.

Deliverables:

Generation of images, models or rough prototypes to represent the ideas developed. These could be images, sketches or 3D models made out of paper, card, Lego or plasticine, or a digital model represented through a simple power point animation.

Design activity 2: Between workshops 2 and 3 the designers will take the models or rough prototypes and make adjustments and refinements to these.

Workshop 3 (Co-design):

In this workshop the prototypes will be refined and selected. This will involve all participants testing and refining the ideas and models further and use a shared prioritisation process to select the top three ideas. This will involve a 'Dragon's Den' style activity, where participants are split into teams. Each team would further develop a concept to present back to an invited panel of dragons (user experts who have not been involved in the study to date). This would give useful critical feedback and would also be made into a celebratory event to give participants a sense of closure.

Deliverable: Refinement and testing of the top three ideas for a functional intervention for primary care with one chosen following critical user feedback.

Design activity 3: The design team will make further adjustments based upon feedback and developments from the co-design workshop.

Knowledge mobilisation, dissemination and projected outputs

The realist review will explore what works, where, for whom and in what contexts and it is very likely that there will be significant context dependent factors. Therefore, the intervention will have core components and an 'adaptable periphery' that can adjust to these contextual factors. An extensive knowledge mobilisation and dissemination strategy will explore these implementation variations i.e. different forms of the intervention and different ways of implementing them to suit different contexts.

Moreover, it is essential to ensure that the information generated and the developed functional intervention are desirable (usable, acceptable, accessible), feasible (technologically, and in operational terms) and viable (economic). Therefore, in order to facilitate wider implementation, we will also consider what will work in practice and in context. The models or prototypes developed in the co-design

workshops will become 'boundary objects' for testing these implementation questions and for communicating the intervention. These 'boundary objects' are ideas or things that enables people from different backgrounds or perspectives to work together. Boundary objects can be 3D objects, 2D objects/images or documents and inhabit intersecting social worlds, satisfy the information requirements of each and are most effective when created by people that live or work on either side of the boundary. To assist with this, we will hold a workshop specifically dedicated to 'knowledge mobilisation' to ensure that the intervention is relevant, useable and accessible to stakeholders. The event will explore how best to implement this prototype intervention or new way of working, in different ways, for different contexts. We will invite up to 26 individuals to this event, including health professionals, academics, patient and public representatives. A workshop plan is included with this application.

A key output of the knowledge mobilisation event will be content for a suite of dissemination materials. We will use feedback from people outside of the project, including those who were involved in the 'Dragon's Den' workshop to help improve our communication about the findings of the realist synthesis and the co-designed intervention. The outputs of all workshops will be used to generate a portfolio of written, graphic and artefact (in mixed physical and digital formats) that would be produced from all perspectives and for all audiences (i.e. health professional, academic, patient and public). The knowledge mobilisation event would generate specific content for dissemination (such as sound bites, tone, key messages, images, story boards for films/animations, website content, including the details of signposting and resources needed required by different audiences). The design team would then use this feedback, output and content from all of the project workshops to generate actual media that could be used in academic papers, posters, films, websites or leaflets. It is anticipated that a short film and/or animation will be produced for wider dissemination purposes, with the targeting of dissemination and methods used to be led by the stakeholders involved.

This extensive knowledge mobilisation and dissemination strategy will enable us to reach a wide range of individuals, thus generating additional insight, feedback and momentum for the next 'feasibility' phase of the research.

Output from Stage 4:

- Ideas from the co-design workshops and recommendations for future physical activity intervention in the primary care setting to focus on improving physical function
- Targeted dissemination to primary care and other groups where relevant, facilitated by a knowledge mobilisation workshop

SAMPLING AND RECRUITMENT OF STAKEHOLDERS – PHASE 1

Stakeholder engagement is integral to the realist approach in order to inform the development and testing of programme theories (83). Stakeholder engagement throughout the synthesis will allow us to explore views about physical function as an outcome (including consideration of the physical, psychological and social factors). In addition, it will aid the understanding of potential barriers and facilitators to a functional approach in improving physical activity in the primary care setting. Stakeholders will also be involved in a series of co-design workshops designed to develop and select ideas for a physical activity intervention in primary care to optimise physical function for patients with long-term conditions. The study flow diagram (Figure 1, page 6) outlines the stages at which stakeholders are involved in the evidence synthesis.

Eligibility

A stakeholder analysis will be conducted to identify and target the most relevant and expert groups (108). It is likely that stakeholders will include representation from patient groups, primary care professionals working in GP surgeries, community nurses, community physiotherapists and occupational therapists, policy-makers, voluntary organisations, council-funded initiatives (e.g. exercise referral scheme), social care, commissioners of services and health boards/trusts from across the UK. We plan to conduct two stakeholder focus groups, one in England (Liverpool or Sheffield) and one in Wales (Bangor), with twelve people in each. The co-design and knowledge mobilisation workshops will take place at Bangor University. Stakeholders will need to be able to communicate through the medium of English or Welsh.

The principle inclusion criteria will be as follows:

- Over 18 years of age
- Ability to communicate in English
- Experience of using primary care services for a long-term condition or experience of a relevant programme designed to facilitate improved physical activity or physical function (patient/public/service-user participants)
- Relevant experience or expertise within the area of enhancing physical activity, physical function and the role of primary care (professional participants)

The principle exclusion criteria will be as follows:

- People who lack capacity to provide informed consent
- People with severe learning difficulties or mental health conditions
- People who are unable to communicate in English or Welsh

Recruitment

Patient participants with long-term conditions will be recruited for the stakeholder workshops and interviews from primary care patient participation or engagement groups in North Wales and Liverpool. Professionals will be identified through local research networks, internet searches, and the personal networks of the study management and advisory groups. Twitter may be used to raise awareness of the study amongst potential participants, indicating that people can make contact with the research team should they like more information. **A recruitment poster (attached), amended to invite the different stakeholder groups will also be used to facilitate recruitment.**

Participants from primary care patient engagement groups will be identified by the group co-ordinator or practice manager, who will pass study information on to these groups. The research team may also approach additional patient groups, including those associated with Collaborations for Leadership in Applied Health Research and Care's (CLARCH - NW Coast) and other community groups. If insufficient participants are recruited from the patient engagement groups, then the practice management team will approach additional potential participants with long-term conditions in the practice population, by means of a letter of invitation on practice headed note paper and including the participant information sheet, to ask whether they are willing to be contacted by the research team.

Informed consent will be obtained from all participants. The process of gaining obtaining informed consent will involve provision of a REC-approved participant information sheet and consent documents, followed by discussion between the potential participant or his/her legally acceptable representative and an individual knowledgeable about the research, about the nature and objectives of the study and possible risks associated with their participation. Verbal consent will be an option for the telephone interviews. This would involve going through consent form as part of interview schedule, ticking the boxes as the participant agrees, the researcher signing and indicating verbal consent has been given, and then sending a copy to the participant for their records. The potential participants will be given as much time as they need to consider the information in the information sheet and will be encouraged to ask questions. Potential participants will be reminded about the study after one week. Participants will be assessed for capacity and those who lack capacity will not be invited to participate.

All participants will be reimbursed for their travel and accommodation expenses (if required). For all study workshops, patients and members of the public will be offered a £30 shopping voucher as a 'thank you' for their time. All stakeholders participating in telephone interviews will receive a £30 shopping voucher.

Potential participants will be provided with bilingual (Welsh and English) study documents. However, due to the nature of the data collection and to maintain methodological validity, we will ask that participants communicate in English when participating in the study workshops. However, it will be possible for the study interviews to be conducted in the Welsh language and Welsh-speaking facilitators will be available in the workshops should participants prefer to explain something using the Welsh language. This is clearly outlined in the participant information sheets.

ETHICAL AND REGULATORY CONSIDERATIONS – PHASE 1

This protocol will be subject to independent, expert and proportionate peer review and will be covered by Bangor University's certificate of employers' liability insurance. The project will be firstly submitted to the School of Healthcare Sciences research ethics committee at Bangor University for review and approval. Following this, we will obtain NHS ethics and research and development approval.

As this is an evidence synthesis, the methods involving reviewing and synthesising literature-based evidence will not raise any significant ethical concerns. As appropriate, care will be taken to address topics surrounding long-term conditions, physical activity and physical function during the workshops and interviews in a sensitive way.

Following participation in all project phases, a verbal debrief will take place involving two elements. The first will align with an 'after action review' structure, whereby participants will be encouraged to reflect on a) what they expected to happen, b) what actually happened and c) how it could be done differently. The second element will focus on the process moving forward, including what happens next with the findings, how participants can find out more about the project and arrangements for the following participation opportunities/commitments (e.g. the next in the series of workshops). The project team will also facilitate appropriate support and signposting through their general practitioner in case of any distress experienced, or if any further advice is required. Furthermore, the participant information sheets provide further detail of the following distress procedures:

- a) Topics will be dealt with sensitively by experienced researchers.
- b) Provision of a comfortable 'break-out' space with refreshments that participants will be encouraged to go to at any point if they require physical and or emotional/mental break. A member of the team will be on hand if desired.
- c) The project team will ensure appropriate support is available in case of any distress experienced, including reassurance and reiterating the options to stop or take a break.
- d) Opportunity at the end of each of the workshops to discuss anything further, including contacting primary care team and follow-up by the research team the following day.

Participation in the workshops and interviews will involve a time commitment. However, steps have been taken during the work-up of our protocol to minimise participant burden but also make the experience enjoyable and productive. We will also endeavour to arrange the workshops at a time convenient to participants and if a participant would like to bring a support person (or 'carer') with them, this will be facilitated.

The cost burden will be minimised for all participants as we have budgeted to pay for participant's travel expenses (including accommodation if needed). We will also offer patient/public representatives a £30 shopping voucher as a 'thank you' for their time. We will provide lunch and refreshments as appropriate.

We will ensure that our recruitment processes (including gaining informed consent as described above), follow the principles of Good Clinical Practice (GCP) and Bangor University's standard operating procedures for the invitation and recruitment of professional and patient stakeholders. Our recruitment materials will be developed with our PPI co-applicant team to ensure they are appropriate for public and patient representatives. The project manager has current GCP training and has wide-ranging experience in the recruitment of patients and professionals for health-related NHS research.

We will be audio-recording and transcribing the two stakeholder workshops in Stage 1, the ten stakeholder interviews in Stage 3 and parts of the co-design and knowledge mobilisation workshops in Stage 4. We will also seek consent to video-record elements of the co-design and knowledge mobilisation workshops (of hands only to preserve anonymity) in order to facilitate descriptions and the development of dissemination material. Participant anonymity will be maintained and whilst direct

quotes from the transcripts may be used, participants will not be identified in any reports. Personally identifiable data will remain confidential and will be treated and stored according to the Data Protection guidelines of Bangor University.

Any protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Data protection and patient confidentiality

All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The data custodian will be the Co-CI and project manager, Dr Rebecca-Jane Law. Electronic copies of data will be stored securely on Bangor University servers. All files stored on the University network are backed up by IT services and mitigate the risk of information loss or disclosure. All computers are password-protected. Paper records will be stored in a locked filing cabinet, accessible by the data custodian only. All recorded discussions and videos will also be treated confidentially and will only be shared with members of the research team as necessary. The personal data of all participants will be kept strictly confidential and discussions will be transcribed anonymously, with each participant given an anonymous code. With the consent of participants, researchers may use a direct quote from the discussion when reporting the results, however no personal information will be detailed. Good Clinical Practice guidelines and Bangor University's Data Protection Policy and Information Security Policy will be adhered to.

Researchers will only have access to participant's personal data if they contact the research team to express their interest in the study.

Patient participants will give consent for their GP to be informed of their participation in the study.

The qualitative data will be analysed at Bangor University, primarily by Dr Rebecca-Jane Law. Other members of the study management group may be involved in analysis of non-identifiable data.

General Data Protection Regulation (GDPR) guidance will be followed, including the addition of 'transparency wording' according to GDPR guidance to all participant information sheets.

PATIENT & PUBLIC INVOLVEMENT

This project involves PPI representation at every stage in order to contribute to the co-production of the initial programme theories, refining and testing, developing recommendations, co-design of ideas and recommendations for primary care service innovation, knowledge mobilisation and dissemination. In addition, the PPI co-applicant team will be involved throughout as equal project members. PPI representatives will attend Project Advisory Group meetings and will be invited to help researchers identify additional patient groups, charities and other relevant stakeholders for the workshops, develop and refine working theories and help develop participant documentation as appropriate. They will be invited to become involved in facilitating workshops and will have active input in the knowledge mobilisation phase. We will encourage and acknowledge PPI contribution in scientific papers and reports.

Dr Rebecca-Jane Law, the joint Chief Investigator, will be the named contact for PPI and will offer support and training. The PPI Team will receive an honorarium for their input and travel expenses in accordance with Bangor University (BU) expenses policy. Honoraria and expenses have been calculated using the INVOLVE calculator. We will involve additional PPI representatives in the stakeholder interviews and workshops through public involvement organisations in England and Wales (INVOLVE and Involving People, respectively), and other networks and organisations where appropriate.

DISSEMINATION POLICY

Upon completion of the study, the data will be analysed and tabulated and a final study report prepared. This will be made available in the NIHR Journals Library.

A publication plan will be developed with the co-applicant team and is likely to include the following open access publications; a protocol paper and a final 'findings' paper to be submitted in February 2020. Authorship of manuscripts submitted for publication will be determined according to The International Committee of Medical Journal Editors authorship criteria.

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