STUDY PROTOCOL

First Contact Physiotherapy in Primary Care. A realist evaluation of effectiveness and costs (FRONTIER)

16/116/03

VERSION 3 | SEPTEMBER 2020

Protocol version tracker

V1	Full original study protocol (WP3 protocol v1.2)
V2	Revised study protocol containing changes through approved substantial amendment (SA01) to revise sample size for WP3 (WP3 protocol v1.3)
V3	Revised study protocol containing changes through approved substantial amendment (SA02) to add an additional recruitment option to the recruitment process for WP3 (WP3 protocol v1.4)

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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.

Name	Role & Organisation	Signature	Date
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STUDY SUMMARY

Study Title	First Contact Physiotherapy in Primary Care (FRONTIER): A Realist Evaluation of effectiveness and costs
Internal ref. no. (or short title)	FRONTIER
Study Design	Realist Evaluation of clinical and cost-effectiveness of FCP
Study Participants	Providers of First Contact Physiotherapy (FCP) service; Key stakeholders who influence or are influenced by FCP, including providers, commissioners, patients, clinicians, practice staff.
Planned Study Period	Three years
Research Question/Aim(s)	To evaluate 'First Contact Physiotherapy' in general practice for patients with MSKDs, and provide evidence for the adoption of appropriate service delivery models with potential to: a) provide optimal patient management b) show meaningful patient benefit c) relieve GP workload pressure d) promote better use of healthcare resources e) positively impact on whole systems MSK practice

FUNDING AND SUPPORT

FUNDER(S)	This study is fully funded by NIHR Health Services & Delivery Research
FINANCIAL AND NON FINANCIAL SUPPORT GIVEN	£764,225
HOST	Bristol, North Somerset & South Gloucestershire CCG

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STUDY STEERING COMMITTEE (AND DMEC)

The Study Steering Committee will provide oversight of the entire study. They will also function as the Data Monitoring and Ethics Committee for WP 3 (approvals applied for separately).

Name	**Role**	**Institution**
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Dr Emma Gibbard	Evaluation expert	Research & Innovation Services, University of Bath
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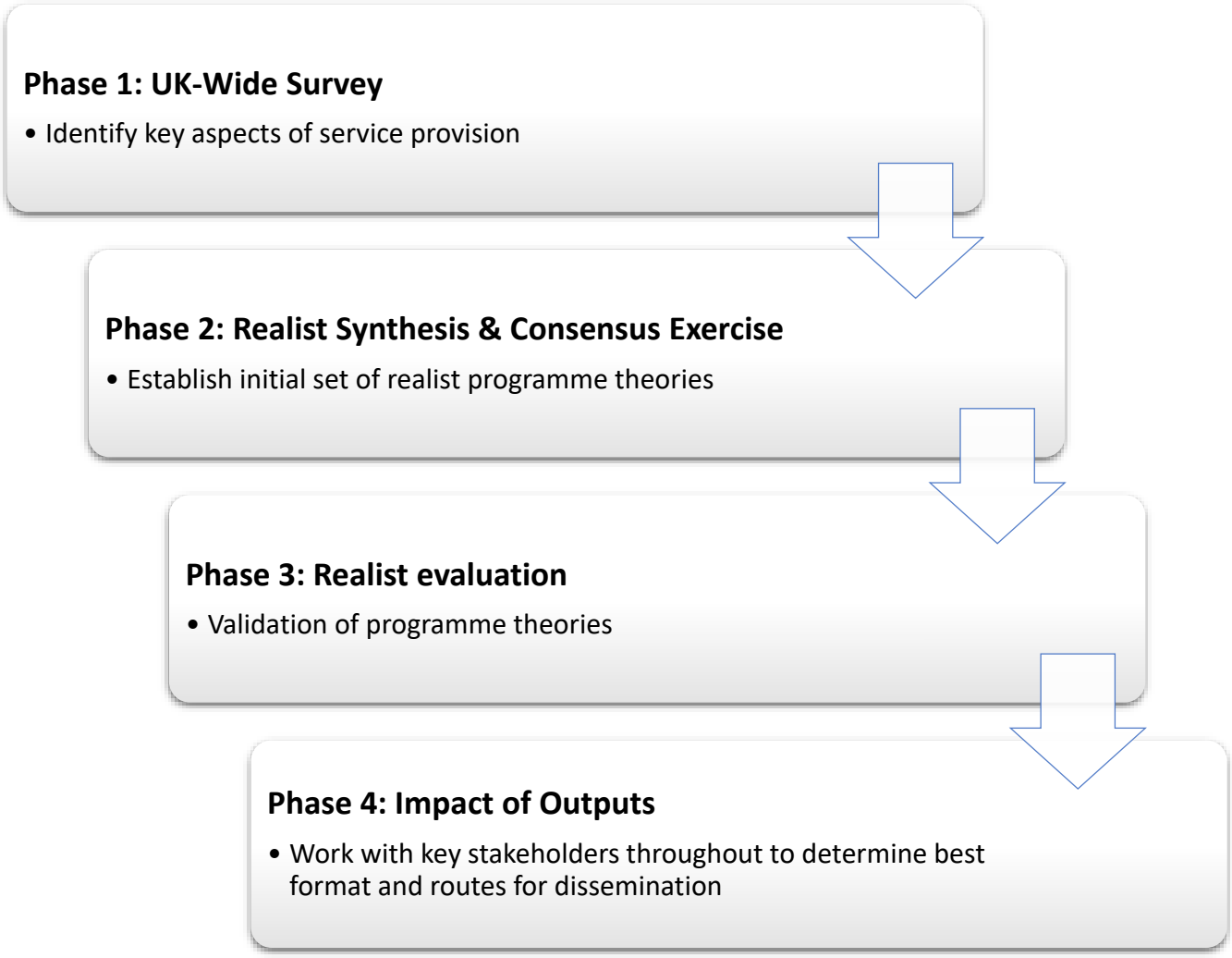
KEY WORDS: First Contact Physiotherapy; Primary Care; Musculoskeletal; Realist Methodology

STUDY FLOW CHART



This application relates to Phase 3 of the research plan outlined above. Stages 1 and 2 have received UWE FREC approvals (HAS 18.07.204), and stage 4 will require UWE FREC in the future. This information is provided to understand the context of the FRONTIER research study.

1. Summary

Musculoskeletal Disorders (MSKDs) are the leading cause of disability in the UK. They account for 10.8m lost work days annually and consume a significant amount of the health budget (approximately £5billion per annum is spent by NHS England). In 2014 there were 340m GP consultations in England, an increase of almost 12% over five years; approximately one third related to MSKDs. Given the increasing demand for GP services, and current difficulties surrounding GP recruitment and retention, alternative implementable and affordable models of care are essential.

One service initiative that is gaining commissioning attention is First Contact Physiotherapy (FCP), whereby patients attending GP surgeries for MSKD are treated by experienced physiotherapy practitioners on a first point of access basis; thereby providing timely specialist advice and reducing demands on GP time. A national search conducted by the applicants (in December 2016), found 85 locations in England and further initiatives in Wales offering FCP, but considerable variation existed in the way in which it was both implemented (e.g. staff seniority, duration of sessions, staff availability) and funded (e.g. shared between practices (federated), NHS seconded or privately employed by GP surgery). Importantly our 2016 search also revealed two key delivery models that are being implemented: (1) some locations employ expert physiotherapists who deliver assessment and physiotherapeutic management with or without onward referral; (2) others employ advanced expert physiotherapists who have additional validated competencies that permit them to prescribe, inject, order/interpret investigations (e.g. imaging) and list for surgery.

Local audits of both FCP models generally indicate that they reduce GP appointments and requests for unnecessary investigations, improve patient satisfaction and incur cost savings, in comparison to standard GP led approaches. Further robust research is needed however to examine the diversity and complexity of FCP models across the UK and determine the impact of emerging FCP models on patient outcomes, costs and systems level impact on MSK services. This research will provide robust evidence by conducting a realist evaluation (a theory driven methodological approach, used to evaluate social programmes) of delivery models to identify how FCP works, for whom, under what circumstances, how and with what resource implications.

The research will be conducted in four work-packages (WP):

1. A UK-wide survey scoping exercise to identify key aspects of service provision. This will facilitate purposive sampling of delivery models (case studies) that will be subject to further in-depth investigation.

2. A rapid realist review of identified aspects of service provision, derived from the scoping exercise, to establish the initial set of realist programme theories underpinning FCP models of care. This will be followed by a consensus exercise with key stakeholders to validate the programme theories, in terms of the resource-response mechanisms in various contexts (context-mechanism-outcome configurations).

3. In depth case study of three key delivery models (FCP; FCP with additional qualifications [FCPAQ], which for the purposes of this study is defined as the ability to prescribe and inject; and usual GP care), each at four different general practices (sites), using realist evaluation to examine outcomes. Data will be collected (quantitative and qualitative) on what works, for whom, how and in what circumstances, accounting for aspects of the context that have causal impact: (e.g. privately employed or federated, practice size, deprivation), and at what cost. Realist qualitative interviews will be conducted with five stakeholder groups involved in service provision across sites: (i) clinic receptionists; (ii) GPs; (iii) physiotherapists; (iv) patients; and (v) commissioners. Patients (n=580) attending with MSKD, will be followed for 6 months to track changes in pain and functioning using the SF36-Physical Component Summary (primary outcome measure), and compared across the care models. Secondary outcomes will include mental health, patient safety, time off work/change of work practices, health related quality of life and patient satisfaction, and will be collected with validated outcome measures. The scope of the economic evaluation will be informed by the realist programme theories to determine the costs and cost effectiveness given a range of associated processes, contexts, and outcomes.

4. An integrated evaluation of the outputs from the other work-packages. Focus groups with key stakeholders in years 1, 2 and 3 will determine the most appropriate format and dissemination route for information gained throughout the study. We will assess any impact this has had on practice in focus groups in subsequent years (i.e. year 2 focus group will reflect on the outputs from year 1 etc).

Results will be used to develop an evidence-informed commissioning pack to assist implementation decisions. Where possible we will present data relevant to outcomes based commissioning processes.

2. Background Information

Musculoskeletal Disorders (MSKDs) are the leading cause of disability in the UK (5, 16); they account for approximately 30% of General Practice (GP) consultations with many patients repeatedly consulting due to non-resolution of their problem (9-10); low back pain (LBP) is the most burdensome of these conditions (5). The economic impact is vast: accounting for 30.8million lost work days annually (17); costing NHS England almost £5 billion per annum (18); and approximately £8.6 billion in personal independence payments in England, Scotland and Wales annually (19).

The volume of people with MSKDs is contributing to the significant financial and service delivery burden faced in primary care (11) with General Practice experiencing unprecedented workload pressure. In 2014 there were approximately 340 million GP consultations in England, an increase of almost 12% in five years – representing the single greatest rise in any NHS sector (9, 11). This is compounded by current recruitment and retention difficulties (12) which are likely to increase. Recent figures suggest that 13% of GPs under the age of 50, and 60% of those aged over 50 expect to leave their position within the next five years (13). The impact this is likely to have on patient care is substantial, and will inevitably affect waiting times, safety and levels of satisfaction, that are already causing concerns (14). Given the exponentially increasing demand, coupled with the difficulties associated with GP recruitment and retention (11-13), alternative models of care that are implementable with relative ease, timeliness and affordability are essential. The pressing need for appropriate management is recognised by many of the Clinical Commissioning Group (CCG) Sustainability and Transformation Partnerships, with primary care workforce initiatives representing an area of priority (25), and the area has been highlighted by the Primary Care Workforce Commission as requiring further evaluation and understanding (33).

By definition, GPs have an extensive knowledge of the initial and ongoing management of multiple conditions. However, evidence suggests there is considerable variability in GP treatment of MSKDs, with care being offered that is inconsistent with national guidelines, and an under use of cost-effective strategies (such as exercise and self-management) (29). Furthermore, data suggest that many referrals to secondary care orthopaedic and scanning services may be inappropriate, resulting in increased waiting times and the potential for delay in cases that do necessitate urgent attention (14). There is a growing belief that GPs may not be the most appropriate healthcare professionals to manage the MSKD population, given their limited specialist musculoskeletal training (8, 30). By contrast, there is emerging evidence that physiotherapist practitioners expert in MSKDs are effective in making diagnoses and in achieving successful clinical outcomes; demonstrate good levels of patient satisfaction; and save money on unnecessary referrals (31-32). However, given the complexity of patients who may present with MSKD alongside multi-morbidities, it is as yet unclear whether non-physician led assessment and examination may lead to sub-optimal management. To date there is no systematic review specific to this emerging model of FCP and much of the available evidence is based on single case report and local audit data. This is reflected in 'The future of primary care. Creating teams for tomorrow' report (33), which recommends further research in this area.

3. Why this research is needed now

An emerging model and workforce development is **First Contact Physiotherapy (FCP), a rapidly developing approach to managing MSKD in primary care (15), whereby a specialist MSK physiotherapist <u>located within general practice</u> undertakes the first patient assessment, diagnosis and management without the requirement for prior GP consultation**. Furthermore, the expanding competency framework within physiotherapy means that in addition to the traditional skills of assessment, exercise provision, education and manual therapy, some FCPs can be accredited to prescribe medication, order scans, inject joints and list for surgery (15). Whilst FCP continues to expand across the UK, and is gaining significant commissioning momentum, there is at present limited evidence on the effectiveness of this approach and the context within which it is applied; local audits suggest this model produces potential cost savings and service benefits. Pilot schemes throughout the UK indicate freeing up of GP appointments; reduction in secondary care referrals; fewer scan requests; increased patient satisfaction; and potential cost-savings of approximately £1000 per week per GP surgery (26). Moreover, there is institutional support for the role from the Royal College of General Practitioners, Chartered Society of Physiotherapy and commissioning groups across the UK (27). However, current observations from service audits and a single case study carried out by the applicants suggest that local context (e.g. time to appointment, service publicity, patient awareness, receptionist triage, ease of access to other NHS services, patient demographics) is relevant to the effectiveness, and acceptability of the model.

Due to the lack of robust research evidence investigating the FCP service initiative, further investigation is required; of particular importance is the choice of model in relation to contextual variations within and across sites in the UK. Current audits of the various service delivery models suggest variables such as competency levels (i.e. whether or not clinics employ FCPs with additional qualifications); extent of treatment provision (i.e. diagnosis and immediate treatment in surgery or diagnosis only with onward referral for treatment); and employment status (i.e. employed via single GP practice, deployed from NHS physiotherapy departments or federation/cluster roles) impact upon their functioning within sites, which we argue is essential to study with robust methodology. The complexity of this emergent service delivery initiative, including the likelihood of intended and unintended outcomes, produces a compelling argument supporting the use of realist evaluation methodology; an approach that can manage an analysis of the variation between sites employing different FCP models as well as the mechanisms within each model. We believe the evidence gained from this methodological approach will expedite the impact this has on clinical and commissioning practice, and will facilitate the NIHR 'Push-the-Pace' initiative (28).

4. Aims and objectives

This project will address the lack of robust research evidence in this area by conducting a realist evaluation establishing the clinical effectiveness and costs of common FCP models of delivery.

4.1 Aim: To evaluate 'First Contact Physiotherapy' in general practice for patients with MSKDs, and provide evidence for the adoption of appropriate service delivery models with potential to:

- provide optimal patient management
- show meaningful patient benefit
- relieve GP workload pressure
- promote better use of healthcare resources
- positively impact on whole systems MSK practice

4.2 Objectives:

Work Package 1: Survey exercise

i. Conduct a survey to scope existing provision and key aspects of models of FCP provision across the UK. This information will inform the selection of models for in-depth evaluation in WP3.

Work Package 2: Realist Synthesis and Consensus exercise

i. Conduct a rapid realist review in response to WP1 survey results, to synthesise information to date regarding FCP, and produce a set of realist programme theories regarding what works, for whom, in what context, and with what resources.
ii. Engage with key stakeholders (patients, physiotherapists, GPs, commissioners, practice managers, reception staff) to validate the programme theories and to gather further evidence about how FCP models are currently working.

Work Package 3: Realist Evaluation with in depth case study approach

i. Empirically test the validated "programme theories" arising from WP2 using a series of nationwide case studies at GP practice sites (N=24).
ii. Collect longitudinal cohort data for six months from patients attending GP surgeries with MSKD to determine the impact of FCP on clinical outcomes, quality of life, return to work and service satisfaction.
iii. Gather qualitative evidence from key stakeholders (patients, GPs, physiotherapists, commissioners, and reception staff) in the case study sites to understand better the barriers and facilitators to FCP and the impact FCP has on pathways and equitable access to care.
iv. Analyse implications of models of FCP for healthcare resource utilisation and costs, from the NHS perspective, compared to usual (no FCP) care, and assess cost effectiveness.
v. Identify patient management safety concerns associated with various FCP models.
vi. Understand the education and development needs of physiotherapists and other service staff (e.g. reception staff) for optimum FCP functioning, given the evolving primary care workforce (macro-context).
vii. Present findings regarding effectiveness and contextual factors to help NHS decision-makers commission services that are safe, effective and cost effective for their areas.

4.3 Research Questions:

a) What models of physiotherapy provision (FCP and non-FCP) are in operation across the UK? (WP1)

b) Does FCP provide equitable patient management compared with usual GP care? And if so, how? (WP2-3)
c) Does FCP show meaningful patient benefit? And if so, how and for whom? (WP2-3)
d) Does FCP relieve GP workload pressure? Are there unintended consequences to GP workload that need to be understood? (WP2-3)
e) Does FCP promote differences in healthcare resource usage? If so, how? (WP2-3)
f) Does FCP positively affect whole systems MSK practice? If so, how? (WP2-3)
g) Are there risks associated with FCP models? If so, what are they and how do they accrue? (WP2-3)

5. Research Plan

We will conduct a mixed methods, realist evaluation of First Contact Physiotherapy (FCP) in general practice, to investigate FCP and FCP with additional qualifications of injection therapy and prescribing (FCPAQ), and 'usual' GP care (no FCP), taking into account the context within which the models are implemented.

5.1 Methodological Concept: Realist Evaluation

Realist Evaluation is a theory-driven approach, conducted in a systematic and robust methodological way (2), concerned with understanding the interaction between contextual elements and underlying programme mechanisms that influence outcomes of interventions (20). It borrows from constructivist (theory building) and positivist (theory testing) paradigms in an analytic process termed as 'retroduction'. Retroduction offers causal explanations about generative forces that underpin intended as well as unintended outcomes (21). Central to the realist approach is the concept of determining 'What works, for whom, in what circumstances, how and why?' (1).

Realist Evaluation is about understanding 'complex interventions thrust in complex environments' (20). The methodology was chosen for this study due to the contextual variation within and across sites using FCP models and for identifying the key components of service redesign that should be customised to contexts.

Work package 1 (scoping survey) will establish the variety of FCP models in operation in the UK. The data derived from this study will be used to inform the case study selection for in-depth evaluation in work package 3.

Work package 2 (realist synthesis and consensus exercise) will be dedicated to developing candidate realist programme theories for FCP models, which will be validated by key stakeholders. In accordance with Pawson and Tilley (22) the initial programme theories will take the form of 'if…then' statements organised according to FCP service components and key context influencers. Through validating and refining these statements with key stakeholders, the programme theories will progress to hypothesized context-mechanism-outcome (CMO) configurations. CMO configurations will unpack the programme theories further, to explain contextual factors and the mechanisms through which change (or outcomes) occur (23). An initial set of definitions for context, mechanism, and outcome is presented here:

- **Context** pertains to the backdrop of the programme and variations of this across sites. Elements of context include that which existed before the implementation of FCP models and are outside of the mandate of service redesign (e.g., rural vs. urban, commissioning structure, pre-existing practice skill mix, appointment structure).
- **Mechanism** is defined as the 'reasoning of stakeholders in response to resources offered' (22). Six stakeholder groups have been identified [1] clinic receptionists; [2] GPs; [3] physiotherapists/ESPs [4] patients [5] practice managers and [6] commissioners. Mechanisms in terms of how each of these

stakeholder groups respond to new resources stemming from the FCP model will be investigated. Elements of the mechanisms will include resources offered through the intervention components (e.g., standard physiotherapy service delivery, extended scope delivery, FCP training resources, FCP dedicated funding) and the attitudes and feelings of the stakeholders in response. Responses by receptionists may relate to feelings related to competency in directing referral; responses by GPs may include their feelings toward risks and benefits of FCP, shifting roles and professional identities; responses by physiotherapists and ESPs may include feelings of empowerment or disempowerment in their evolving roles; responses by patients may include feelings of confidence in the service, satisfaction and positive attitudes toward self-management goals; and responses of commissioners may include relative cost benefit and impact on other services. In line with Pawson and Tilley's (1997) interpretation of mechanism, these responses and feelings will be captured in terms of how they may facilitate or impede the functioning of FCP models within sites.

- **Outcomes** will include intended outcomes and other outcomes of interest, as well as unintended or unexpected outcomes, and potential negative outcomes in terms of staff and patient satisfaction, risk, service delivery, and health outcomes. A preliminary identification of elements for CMO configuring is presented in table 1.
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Table 1: Preliminary CMO configurations

Context Features of the conditions in which programmes are introduced that are relevant to the operation the programme mechanisms	**Mechanism** Causal forces/ processes/ interactions including decisions/ reasoning (beliefs, experience, opportunities, information, access)	**Outcome** Intended and unintended short/medium/long term changes resulting from an intervention
• **National** ○ NHS policy (focus of resources, specific campaigns (e.g. diabetes), patient eligibility) ○ Guidelines from professional bodies (e.g. Chartered Society of Physiotherapy (CSP), Royal College of General Practitioners) ○ Guidelines about standards or best practice (e.g. NICE) • **Local** ○ Funding/commissioning ○ Local priorities for service provision ○ Other local provision of physiotherapy services (e.g. private) ○ Other local provision in general practice (making the service marketable/offering different services to other general practices (practice manager) ○ Skills of staff in practice (e.g. injection/prescription) ○ Sociodemographic factors (rural/urban location, culture, affluence) ○ Population size served by practice • **Different service models** ○ Appointment times ○ Number of clinics ○ Number of physiotherapists ○ Appointment content	• **Patient** ○ Beliefs about the ability of physiotherapists (negative - positive) ○ Prior experience of physiotherapy ○ Understanding of physiotherapy ○ Awareness that frontline physiotherapy service is available ○ Satisfaction with care ○ Satisfaction with outcomes of care ○ Perceptions about self-management/self-efficacy ○ Patient presentation (complex or simple) • **General practice staff** ○ Awareness of frontline physiotherapist service ○ Local staff training ○ Local staff dynamic ○ Size of practice ○ Ability to provide accurate information to patients about frontline physiotherapist service ○ Promotion of frontline physiotherapist service ○ Posters/letters ○ Patient pathway ○ Receptionist role ○ Practice staff aware of and suggesting service ○ Perception of the role of the GP/other staff members	• **Patient** ○ Satisfaction with care ○ Satisfaction with outcomes of care • **Frontline physiotherapists** ○ Appropriate guidance about role remit ○ Increase skills ○ Job satisfaction ○ Appropriate training and support to perform the role • **General practice staff** ○ Perception of the effectiveness of frontline physiotherapy service • **Local** ○ Save money (CSP tool) ○ Reduce unnecessary referrals ○ Reduce unnecessary investigation ○ Reduce GP appointments ○ Making most of available resources e.g. reduce non-attendance rates • **National** ○ Save money ○ Manage demands of aging population ○ Help to ease difficulties with staff recruitment and retention in general practice

○ Training ○ Patient pathway ○ Funding	○ Perception of the role of the physiotherapist • **Frontline physiotherapists** ○ Skills, banding, and competencies of physiotherapists ○ Cost of employing therapists at different bands ○ Local/national training opportunities (e.g. prescribers course availability/funding)	

Work package 3 will consist of a Realist Evaluation with in depth case study approach. We will empirically test the validated "programme theories" using a series of nationwide case studies (N=39). This will follow a mixed methods approach including longitudinal cohort data for six months from patients attending GP surgeries with MSKD to determine the impact of FCP on clinical outcomes, quality of life, return to work/change in working patterns, perceived safety and service satisfaction. We will also seek to understand the education and development needs given the evolving primary care workforce; and assess the healthcare resource utilisation and costs, from the NHS perspective, compared to usual (no FCP) care.
Qualitative evidence will be gathered from key stakeholders (patients, GPs, physiotherapists, commissioners, and reception staff) in the case study sites to understand better the barriers and facilitators to FCP and the impact it has on pathways and equitable access to care.

Work package 4 will consist of focus groups with key stakeholders within each year of the study, when information becomes available to disseminate. We will work with key stakeholders to determine the most appropriate dissemination formats and routes to dissemination to ensure maximum impact and utility for each stakeholder group. In focus groups in subsequent study years (2 and 3) we will explore how this information was used and any impact that was achieved (i.e. in year 2 we will explore the outcome from dissemination in year 1 etc.)

5.1 Work Package 1 – UK Wide survey (UWE FREC REF No:HAS.18.07.204)

Research Question: What models of physiotherapy provision (FCP and non-FCP) are in operation across the UK?
Design: Nationwide survey of physiotherapy providers
We will conduct a survey of MSKD physiotherapy providers across the UK to determine models of physiotherapy provision (to include FCP and non-FCP delivery models). The research team (including clinical commissioners, patients, physiotherapists and GPs) will design the survey tool to ensure it is accessible to respondents. Prior to distribution we will pilot the tool locally (Bristol, North Somerset and South Gloucestershire CCGs Musculoskeletal Network) and make any necessary amendments before wider distribution. The tool will include open and closed questions to collect data including geographical location; patient demographics; current service providers (NHS, private, Any Qualified Provider); referral pathways; staffing (including numbers, grades and competencies); access to services; service aims; financial arrangements (block contracts, cost per case). We will also include an option for respondents to confirm whether they may be willing to be involved in the later stages of the study (WP3) as possible case study sites for more extensive evaluation.
Sample: We currently hold two databases of physiotherapy providers in the UK. The first was compiled by the research team through internet searches of CCG and physiotherapy providers websites, and includes contact information and basic details of FCP models across the UK (n=85 providers (in 2016)). The second database, established from a Freedom of Information request from CCGs led by the Chartered Society of Physiotherapy,

includes physiotherapy services commissioned by CCGs (n=212). In addition to these databases, we will also target physiotherapy service providers in Scotland and Wales via their respective health boards and in Northern Ireland via the health and social care trusts. The team have experience of conducting large-scale surveys including healthcare providers (Walsh et al, 2009) and service users (Pearson et al, 2016).

Process: A copy of the survey and a pre-paid postal return envelope will be sent to the lead physiotherapy service provider within each service provider, we will also provide a link to an online version (in Qualtrics) if respondents prefer to respond in this format. Each survey will include a unique identification number to enable the research team to track respondents. We will send reminders to non-respondents after three weeks.

Data management: Responses will be entered into an Excel spreadsheet and distinguished according to location and patient population size/coverage; FCP or other physiotherapy provision; key service characteristics including standard physiotherapy or ESP; appointment times; service remits; funding arrangements; provider. This information will inform case study selection in WP3 to ensure inclusion of a broad representation of common service provision. Relevant free text responses will also be used to inform WP2 programme theories and CMOs.

5.2 Work Package 2 – Rapid Realist Synthesis and Consensus exercise

Research Questions:

Does FCP improve patient management over usual GP care? And if so, how?
Does FCP show meaningful patient benefit? And if so, how and for whom?
Does FCP relieve GP workload pressure?
Are there unintended consequences to GP workload that need to be understood?
Does FCP promote better use of healthcare resources? If so, how?
Does FCP positively affect whole systems MSK practice, If so, how?
Are there risks associated with FCP models? If so, what are they and how do they accrue?

Design: Realist Synthesis (RS) and Consensus

RS applies realist logic to available evidence in order to answer specific research questions. This evidence may be elicited from primary research, grey literature and key stakeholder opinions to form 'programme theories', or 'what is suspected to cause something to happen'. Methodologically, the review initially elicits main ideas from the literature that went into the formation of the programme theory. This programme theory sets out how and why an intervention (in this case FCP) is thought to 'work' to generate the outcomes of interest. The RS approach is considered appropriate for this study as FCP involves a complex intervention provided in a variety of models, yet at present it is unclear what works in different contexts. Furthermore, in the absence of a coherent body of empirical research, but with availability of multiple grey literature accounts and disparate qualitative work, traditional systematic reviews would be of limited value.

Aim: (1) To identify how FCP works, for whom, in what circumstances, how and why. (2) Test the 'programme theories' relative to available literature and stakeholder involvement

Process: The RS will be carried out in accordance with RAMESES publication standards (24)

Theory initiation and development: We will build our initial programme theories of how FCP may work in reducing GP workload, improving patient outcomes and making better use of healthcare resources. This will be based on our previous work (see Table 1), ongoing interactions with key stakeholders in this area and any policy or professional guidelines produced that will inform theory.

Search Criteria: A Librarian and Information Specialist with NHS expertise will be consulted to assist in the development of a series of key word searches. These will include primary care, general practice, extended scope practitioner, first contact practitioner, advanced practitioner, first point of contact, direct access,

physiotherapist, frontline. We do not intend to set any inclusion/exclusion criteria, but will be mindful of the relevance of non-UK derived literature given the unique context of the NHS.

Databases: The review will include academic and grey literature sourced from a variety of Medical databases, including: Allied and Complementary Medicine (AMED), British Nursing Index (BNI), Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCRCT), CINAHL, MEDLINE, PsycINFO, SCOPUS, EMBASE and Web of Knowledge. Given the likelihood of grey literature in this area, we anticipate the necessity to search a variety of websites, for example the Chartered Society of Physiotherapy, CCG home pages, Royal College of General Practitioners website.

Screening and data extraction: To ensure rigour in paper selection, two members of the research team will screen the identified studies based on the question 'Does the paper address the theory under investigation'? A third team member will be consulted to resolve disagreements. Extraction will be undertaken through a series of note taking, annotation and conceptualisation processes to populate the evaluative framework with retrieved evidence.

Data synthesis: This process allows programme theory refinement in relation to CMO development through use of compiled evidence. Two team members will work together to compare and contrast the evidence gained from included studies, integrate both confirmatory and contradictory findings and revise programme theories as required.

Consensus methods: To validate the programme theories generated from the RS and to gather further evidence about how FCP models are currently working, we will engage with key stakeholders (patients, physiotherapists, GPs, commissioners, practice managers, reception staff) using nominal group technique (NGT). NGT is a formal approach to consensus development involving a structured process of information gathering, idea generation, discussion and decision making.

Recruitment and participants: Approximately 20 key stakeholders (physiotherapists, patients, commissioners, GPs, practice managers, reception staff) will be identified and invited to attend a one-day consensus event. We will recruit professional participants from our regional Musculoskeletal Network through our collaborative links with NHS England and the Arthritis and Musculoskeletal Alliance. Patient and public participants will be recruited through People in Health West of England, a local initiative promoting public involvement in research.

Data collection: During the one-day consensus event, it is anticipated that following process will be followed: 1) We will present our candidate programme theories to key stakeholders. In accordance with Pawson and Tilley (22) the initial programme theories will take the form of 'if…then' statements organised according to FCP service components and key context influencers; 2) Participants will be asked to individually rank their level of support for each candidate theory; 3) Facilitated group discussion will enable programme theories to be confirmed, refuted and added to; 4) A second round of individual ranking will be performed if necessary. The event will be facilitated by two members of the research team and will be audio-recorded.

*Data analysis: A*udio-recordings will be transcribed verbatim. Confirmation and amendments to programme theories will be based on ideas generated during group discussion.

Development of Interview guides: The developed and agreed programme theories will be used to develop a series of interview guides for each of the key stakeholders (see above) which will be used in work package 3 to guide the content of semi-structured interviews.

5.3 Work Package 3 – Realist evaluation

Study design

Mixed methods case study Realist Evaluation of FCP in primary care. To assess the clinical and cost-effectiveness of FCP service delivery models and non-FCP physiotherapy provision, we will recruit patients within GP practices who are actively undergoing physiotherapy management for a current MSKD and collect longitudinal data over a 6 month period. Each case study will also combine qualitative interviews with key stakeholders guided by pre-determined programme theories.

Case study sampling and recruitment

Sampling: We require 39 case study sites across the UK, representing key sampling criteria (e.g. geographical location) that are likely to impact on service delivery. Case study sites will be sub-categorised into three strands:

i. FCP (n=13)
ii. FCP has additional qualifications [FCPAQ] (i.e. non-medical prescribing, injecting) (n=13)
iii. No FCP service is available, physiotherapy provision via a different pathway [PT] (n=13)

In order to achieve a wide geographical sample, case study sites will be selected from England, Wales, Scotland and Northern Ireland. Amongst these, we will also ensure a range of urban and rural environments are included, and a range of sample deprivation based on GP population postcode deprivation index.

We will also record the duration that the service has been established as embeddedness is likely to impact on service outcomes. These will not be selection criteria for the sampling matrix, but the impact of service duration will be explored qualitatively.

Recruitment

In a previous work-package (WP1) we compiled a database of FCP practice sites who have expressed an interest in participating in this stage of the research. We will categorise these respondents according to the sampling criteria presented above, and using an off-site random allocation service will randomly select sites to approach. When there is only one matched case study site to the sampling criteria, we will approach that site only. We are confident that we can recruit sufficient sites from our survey return but will also approach the NIHR local Clinical Research Network (CRN) for support in recruitment of sites as required.

Thirteen case study sites that do not provide FCP services (PT) are also required; these sites will be recruited through the CRN according to the previously described criteria.

Quantitative Design

We will recruit a consecutive longitudinal sample per practice case study, to measure clinical outcomes and resource utilisation over a six-month period with patients consulting with MSKD. Analysis will determine clinical and cost-effectiveness of FCP and non-FCP services, and identification of patient satisfaction and any safety concerns regarding models of care.

Inclusion Criteria

(i) Patients consulting with a suspected MSKD episode, defined as any acute or chronic disorder related to the spinal or peripheral musculoskeletal system;
(ii) Not consulted for the same problem in preceding 3 months;
(iii) 18 years and over;

(iv) Willing to provide informed consent for healthcare records to be viewed by specified members of the research team for the purpose of this study.

Exclusion Criteria

(i) Under 18 years of age;

(ii) Receiving palliative care for a terminal illness;

(iii) If non-English speaking and unwilling to provide informed consent and communicate through an interpreter;

(iv) Unwilling to provide informed consent for healthcare records to be viewed by specified members of the research team for the purpose of this study.

Recruitment

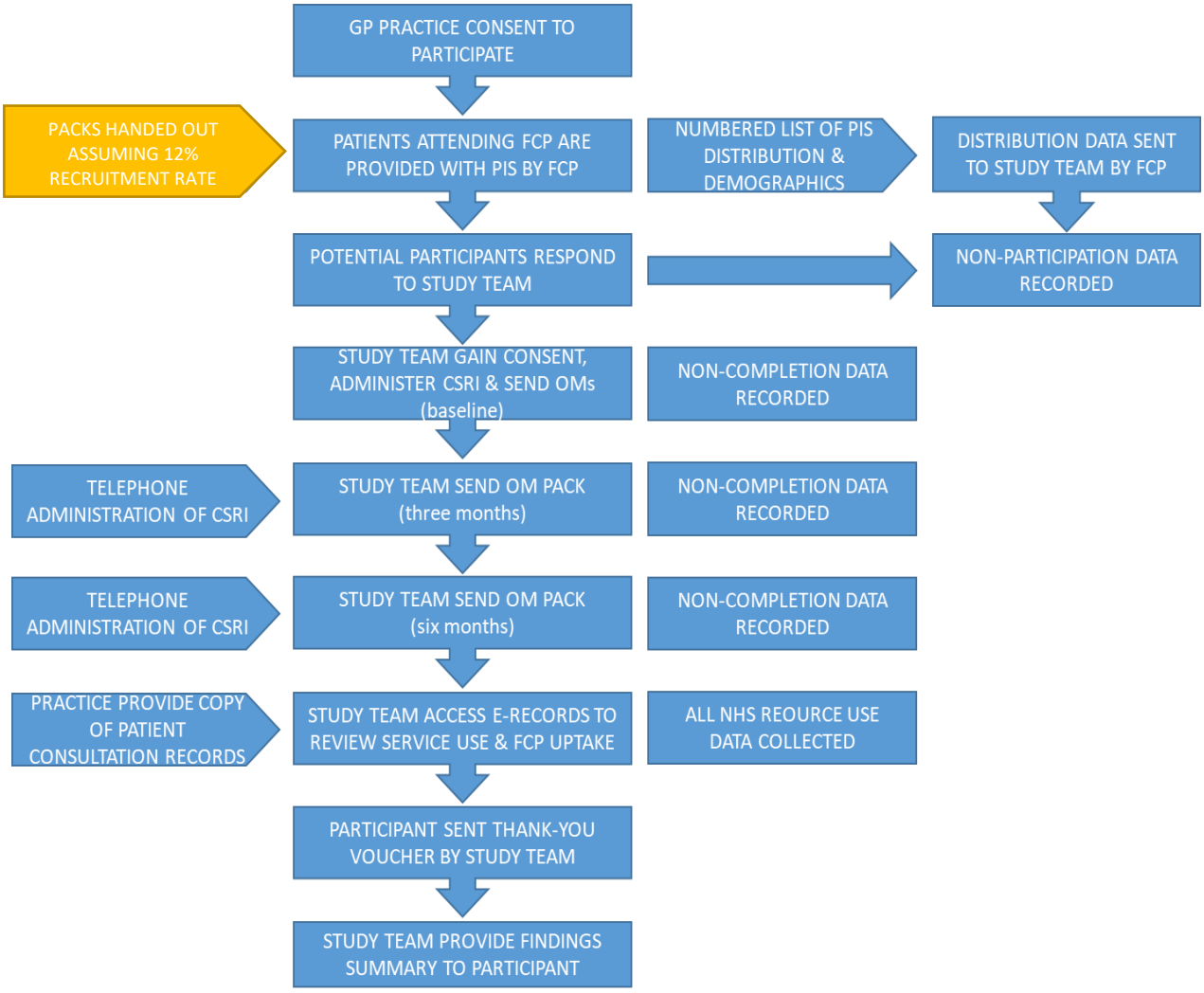
All patients attending their GP practice consulting with an MSKD and meeting the study criteria will be eligible to participate.

In practices with FCP, all new patients consulting the physiotherapist will be provided with a participant information pack by their treating physiotherapist. This pack will include an information sheet explaining the study, contact details of the study team and a consent form with return envelope. Potential participants who require further information will be encouraged to contact the study team to discuss participation. If eligible and willing to participate, they will be required to return the signed consent form to the study team. On receipt of this form, we will contact the potential participant to confirm eligibility, and if eligible will complete the health economics questionnaire (CSRI) over the phone. We will then send a set of outcome measures with a return envelope for completion by the participant. At the participants request we can also provide the outcome measures via email for electronic completion. We will track the number of packs distributed and collect basic anonymised demographic data for all approached patients, enabling us to calculate recruitment rates and report the profile of non-participants. At the end of the data collection period we will also work with database managers in FCP practices to determine the amount of patients who continued to consult their GP for MSKD rather than the FCP, so we can present a descriptive analysis of service engagement. See figure 1.

When the patient consults, the physiotherapist also has the option to provide a recruitment pack and ask whether the patient would like a member of the study team to contact them to explain the study further. For those who would like that, the patient verbally consents to their name and telephone number only being passed to the study team. This will be managed from .nhs to .nhs secure email. The telephone call will simply include further detailing of the study after which the patient can determine whether they would like to participate.

We will monitor recruitment within each study site to ensure even distribution across sites. Where recruitment is slow because packs are not being distributed, we will visit practices to discuss how this process could be best facilitated. Where recruitment is limited due to patient uptake, we have sufficient time to extend the recruitment period for a maximum of 6 weeks to facilitate the process. We will also where possible advertise the study within the practice, encouraging patients to request an information pack.

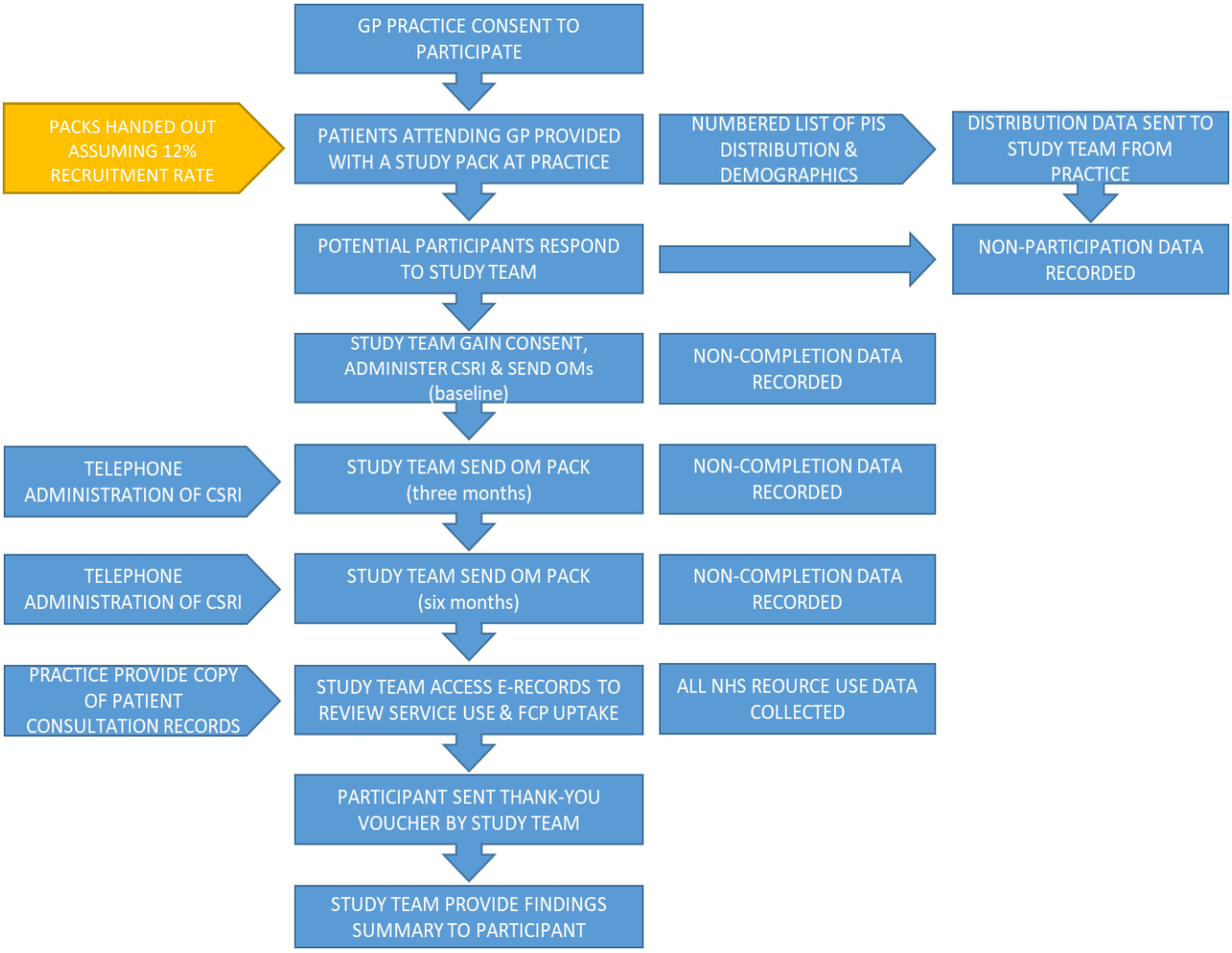
Figure 1 below shows participant throughput in FCP practices



For GP practices that do not have a FCP model, we will provide study information packs to GP surgeries and request GPs or reception staff to distribute to individuals consulting with an MSKD based on the preference of the individual practice. As above, when the patient consults, practice staff also have the option to provide a recruitment pack and ask whether the patient would like a member of the study team to contact them to explain the study further. For those who would like that, the patient verbally consents to their name and telephone number only being passed to the study team. This will be managed from .nhs to .nhs secure email. The telephone call will simply include further detailing of the study after which the patient can determine whether they would like to participate.

We will track the number of packs distributed to recruit the required sample size to provide us with information on recruitment rates. This pack will include an information sheet explaining the study, contact details of the study team and a consent form with return envelope. Potential participants who require further information will be encouraged to contact the study team to discuss participation. If eligible and willing to participate, they will be required to return the signed consent form to the study team. On receipt of this form, we will contact the potential participant to confirm eligibility, and if eligible will complete the health economics questionnaire (CSRI) over the phone. We will then send a set of outcome measures with a return envelope for completion by the participant. At the participants request we can also provide the outcome measures via email for electronic completion. At the end of the data collection period we will also work with database managers to determine the amount of patients who consulted their GP for MSKD, so we can present a descriptive analysis of service use. See figure 2.

Figure 2 below shows participant throughput in non-FCP practices



Sample size

The aim of this research is to determine that FCP is not substantially worse (non-inferiority analysis) than GP based practice. For the purpose of assay sensitivity, the study is designed as a three arm design which includes usual GP care, FCP and FCPAQ. This sample size computation also accounts for the similarities of patients within each GP centre and treats each GP centre as a cluster within which patients are nested.

Based on Bishop et al (36) a non-inferiority margin of 2 units in SF-36 scale, that is the standard practice is either superior or worse no more than by 2 unit is assumed. Previous research in MSKD, such as Angst et al. (45) has estimated a minimal clinically important difference from 4 points for the SF-36v.2 PCS subscale. The standard deviation of the difference between the SF-36 score between models are assumed to be 6.5 based on Salisbury et al (7). In a one sided 0.05 significance non inferior hypothesis test, to achieve 80% power, 132 subjects are required. To account for the hierarchical nature of the design, i.e. patients are nested within GP centres, this number should be inflated by the design effect.

The design effect for a cluster size of 14 and an intra cluster correlation coefficient (ICC) of 0.0075 (29) will be 1.09, requiring a total sample size to 145 per arm. After allowing for attrition of 20%, the total subjects required per arm is increased up to 181, making the total of at least 13 GP centres per arm, and a per practice sample size of approximately n=14.

It is suggested to randomise 13 GP centres to each physio model and recruit 14 patients with MSKD within each GP centre. In our pilot study, 814 patients consulted with MSKD over 6 months (practice population ~6200). Similar studies in primary care (7, 36) report estimates of 40% of consulting patients being eligible and consenting, we are confident in recruiting the required sample, enabling comparisons between sites and models.

In the analysis, GP centres are included as a random effects in a General Linear Mixed model to account for similarity of patients within each GP centre. The sample size computation was performed using a combination of nQuery 8 and SAS version 9.4 software.

Assessment Points

Data will be collected from participants at the time points indicated in Table 2. All outcome measures are self-complete with the exception of the CSRI which will be telephone administered by the research team. In order to achieve maximum data collection we will also follow-up participants who have not responded by telephone to either remind them to return the questionnaires, or offer telephone support for completion. Respondents who return incomplete questionnaires will be called to collect missing data. On completion of the six-month outcome data, patients will be sent a £10 thank you voucher for their participation in the study.

All FCP practices should currently be using the 'standardised national data collection tool' for FCP (46). This template has been developed by the Chartered Society of Physiotherapy and NHS England to fulfil the NHS mandate of new service design for data collection regarding service use, patient direction and safety issues. If practices do not currently use the template, we will install this on their system and provide support for use. Data uploaded on this template will be extracted at the end of the data collection period.

Outcome Measures

A variety of self-reported, validated outcome measures will be used to determine the relative clinical effectiveness of the service delivery models. Table 2 details the patient reported outcome measures (PROMs).

Table 2: Patient Reported Outcome Measures

Patient Reported Outcome Measure	Measurement Domain	Assessment points
Primary Outcome Measure		
SF-36 Physical Component Summary (37)	Physical function	0, 3 and 6 months
Secondary Outcome Measures		
SF-36 Mental Component Summary (37)	Mental health	0, 3 and 6 months
EQ5D-5L (38)	Health related quality of life	0, 3 and 6 months
Roland-Morris Disability Questionnaire (6)	Health status for low back pain	0, 3 and 6 months (LBP patients only)
General Practice Assessment Questionnaire (39)	Satisfaction with receptionists, appointments, opening times, communication with healthcare staff, continuity of care and enablement	0, 3 and 6 months
Client Services Receipt Inventory (CSRI) (40)	Healthcare utilisation	0, 3 and 6 months
Return to work (self-report of absenteeism/change of work practices due to MSKD)	Function	0, 3 and 6 months
PREOS-PC (41)	Patient reported safety in primary care	0, 3 and 6 months

Healthcare Utilisation

Healthcare records will be searched for each participant to collect attendance information, prescription, referrals and investigation data related to their MSKD. We will adopt a pragmatic approach to this process, working with each individual practice (case study) to determine the most feasible method of data collection. The probable mechanism will consist of anonymised (study ID only) download of the medical records (including professional correspondence) for the duration of study participation. These data will be used in conjunction with self-report (customised CSRI) to ensure full data capture (e.g. accessing of private physiotherapy, exercise sessions or over the counter medications). In case of discrepancy between patient report and documented information on GP records, we will default to GP records as previous research has suggested these data are more reliable that patient recall (47).

Data analysis

The quantitative data generated in this work package will be integrated with data from the realist qualitative interviews across sites (see sub-section 7). The realist evaluation process will adhere to the recently developed RAMESES II reporting standards for realist evaluation (2) as well as quality guidelines and training materials for realist evaluation that are publicly available at www.ramesesprojects.org.

Quantitative: Summary statistics will be compiled as follows by site: *(i) Recruitment/Retention*: Recruitment duration (start and finish date), number of patients eligible (according to study criteria) during this time, number of eligible patients approached, number of patients agreeing to participate and then completing baseline assessment, number of patients achieving completion (with accompanying inclusion rates), and date of baseline measurements for first and last completed patient. *(ii) Demographic/Diagnostic*: Descriptive statistics (numbers, means, standard deviations, medians, ranges, proportions as applicable) will be tabulated for all demographic and clinical features, along with number of days from baseline assessment to 3 months and to 6 months assessment. We will retain participants who fail to complete 3-month outcome measures, but complete the 6-month primary endpoint data collection. All of these summary statistics will also be accumulated across the three service model groups and in total.

Statistical comparisons will be performed as follows: Drop-out analysis: The overall drop-out rates across each of the three service model groups will be compared using a chi-squared test. The demographic and clinical features of the three groups will be compared in order to establish possible reason(s) should a statistically significant difference be seen in drop-out rates, and to be aware of inequalities between the three groups in preparation for their comparison for outcome measures.

Primary Outcome analysis: The change in SF-36 Physical Component Score from baseline to 3 months and from baseline to 6 months will be compared between the three service models using a 1-way analysis of variance. If a significant difference is seen, post-hoc unpaired t-tests comparing each pair of service models will be performed in order to determine the superior service model(s). Further comparisons of the three service models will be undertaken in the context of stepwise linear regression modelling, incorporating the demographic and clinical features of the patients, including their baseline SF-36 Physical Component Score. Dummy variables may also be included to represent individual sites. Regression analyses will include multilevel modelling in the form of a general linear mixed model with site as a random effect.

Secondary Outcomes analysis: The change in SF-36 Mental Health Score and in EQ5D-5L Health Related Quality of Life from baseline to 3 months and from baseline to 6 months will be compared between the three service models using a 1-way analysis of variance. If a significant difference is seen, post-hoc unpaired t-tests comparing each pair of service models will be performed in order to determine the superior service model(s).

A similar analysis will be performed for the Roland-Morris Disability Questionnaire score (for LBP patients only) due to the high prevalence and consultation rates for this disorder, for the General Practice Assessment Questionnaire (7, 9-10). For each of the three service models, the proportion of off work patients at baseline who reported having returned to work at 6 months will be compared using a chi-squared test. Costs analysis: Comparisons of costs between the 3 service models will be performed using appropriate statistical tests (according to the distributions of the relevant cost variables).

Health Economics analysis*:* Initially, we will conduct an analysis of the practice workforce team, and secondly a patient level analysis of outcomes for the sample of MSK patients recruited to the study will be undertaken.

Analysing these datasets sequentially is consistent with the overall case study design of the proposal. The analysis of the practice workforce will compare within and between the models of care, and the extent to which physiotherapists are integrated and used in front line care services. Information will be gathered for this analysis by conducting interviews with the practice managers and taken alongside reference to routine returns to the NHS Digital workforce minimum data set. Total practice human resource costs will also be estimated from the workforce data, and the proportions attributable to physiotherapy input shall be explored. The practice workforce configurations will be analysed descriptively, and undertaken with reference to the size and structure of the practice populations; how MSK consultations are allocated between different staff members; and MSK referral rates outside the practice. The purpose of this practice analysis is to provide an overview of the workforce composition and costs, and to understand how MSK conditions are managed across the case study sites.

Whole system resource use related to the presenting MSK condition will be captured prospectively for each patient through GP records reviewed at the end of the 6 month follow up period. However, GP records will not cover all service use items of interest so a customised version of the Client Service Receipt Inventory (CSRI) (45) will gather supplementary information. In particular it will cover voluntary and informal care received, medications and devices purchased over-the-counter and utilisation of private providers or the complementary medicine sector, including out-of-pocket expenditures.

The CSRI data will be gathered by telephone interview at baseline (0 months), 3 and 6 months, and will also capture time off work or undertaking usual activities. Patient research partners will be involved in the design of the final version for this study. Participants (patients and/or carers) will be provided with a diary for recording service use on a daily basis, as an optional *aide memoire*.

The analysis of the individual patient level data will be reported as a cost-effectiveness analysis using the primary outcome, SF-36 PCS, and will also be presented as a cost utility analysis, using the data collected from the EQ-5D-5L for the elicitation of the required QALY information. Details on how costs and outcomes will be gathered and the economic analysis plan, are given above. Adjustments will have to be made for any baseline variations in patient characteristics, if these are identified during the analysis. Differences in accrued QALYs between the groups will always be estimated whilst controlling for differences in baseline EQ-5D scores. The structure and type of regression model employed will be determined by the data collected and available for analysis. Given the multi-level analysis being undertaken within this study, as detailed within the statistical plan, any differences identified between any of the service models with regard to costs and/or health outcomes will be explored by an appropriate regression analysis. The base case economic analysis will adopt a direct NHS resource use cost perspective. The sensitivity analysis will explore whether or not a broadening of the analysis to a more societal perspective through the inclusion of patient out-of-pocket expenditures and productivity effects has any impact the economic conclusions.

A cost-consequences analysis will also be conducted to enable the full range of outcomes and costs, and how these are distributed across stakeholders, to be taken into consideration.

Qualitative Design

We will conduct a series of semi-structured interviews with patients and professionals to contribute evidence to programme theories of how the intervention works, for whom, in what circumstances and why.

Patient Participants

On completion of the 6-month data collection, we will send postal invitations to a stratified sample of patients who have completed the quantitative data collection to participate in a telephone interview regarding their experiences of FCP/non-FCP (n=1 per case study site). Stratification will include age, gender, diagnosis and treatment outcome. On receipt of informed consent, a research fellow will conduct the interview (lasting approximately 30-40 minutes) at a convenient time for the participant.

The interview schedule will be guided by programme theories derived from an earlier phase, and we will collect qualitative accounts of patient interpretations of why a programme 'works' and challenges and facilitators to the programme success. Where possible, and subject to ethical approval, we will interview a sample of participants who withdrew from the study (failure to submit 3&6-month data) to better understand their reasons for withdrawal associated with research participation and/or the healthcare treatment they received. We will identify these participants from a database which states their consent to being contacted for future research unless they have explicitly stated they do not want to be contacted again regarding the FRONTIER study.

Key professional participants

We will interview key professionals at each case study site (N=4) to inform our inquiry. Interviews will take place either in person or by telephone depending on participant preference. Interviews within each practice will be undertaken on completion of patient recruitment within their practice. The participants for each case study site will consist of:

i. GP (n=1)
ii. Physiotherapist (n=1). For non-FCP sites we will interview physiotherapy providers according to the local model (n=1 selected from the local physiotherapy department and representative of typical skill mix)
iii. GP reception staff (n=1)
iv. Practice manager (n=1)

This will provide a significant qualitative sample (n=~210) across a range of service models, local contexts and participant characteristics (patient and professional). We will consider data saturation throughout, and will continuously review the sample size to prevent unnecessary data collection.

Qualitative analysis

Interviews will be audio recorded, transcribed, anonymised and imported into NVIVO for analysis. The research fellows will independently review transcripts, and a selection will be double coded to ensure consistency in interpretation and coding allocation. Data will be analysed in relation to programme theories, and evidence gathered that either confirms or refutes these statements. Analysis may identify new and emerging theories that were not explicit in the realist synthesis and consensus exercise; these theories will be reported.

Final data synthesis

The realist approach embraces mixed methods and it would be an expectation that qualitative, quantitative and health economics data would be incorporated into the realist analysis using CMO configurations, to

produce the final evidence-informed theories about how the service design works, for whom and across variations in context. The report will be presented in association with the study aims determining how to:

- provide optimal patient management
- show meaningful patient benefit
- impact on GP workload pressure
- promote better use of healthcare resources
- positively impact on whole systems MSK practice

The integration of the data sources will also inform new guideline development, providing a robust vision about how to implement effective and cost-effective FCP models of care.

5.4 WP4 – Evaluation of Outputs

Consultation exercise

A number of outputs that will be generated from this research, and it is envisaged these will have lasting or significant changes (intended and unintended). The format of these outputs will be guided by the requirements of the key stakeholders and the impact of each will be collected from the same groups. We will use the consultation exercise to determine this information.

Participants

We will recruit 6 to 8 individuals from clinical commissioning, major charities, clinical practice, patient groups and professional bodies. Recruitment for the first Focus Group will be through our professional networks and also via the Arthritis and Musculoskeletal Alliance Organisation to ensure broad representation. We will recruit participants who have an interest in this area and a responsibility for using and sharing the derived information, to influence service design, publicity and/or delivery. In advance of participation, all potential participants will be provided with information sheets, and opportunity to discuss the consultation exercise with study organisers. Consent will be gained in advance of participation.

Focus group consultation

In years 1, 2 and 3, we will conduct a focus group consultation (FG) with key stakeholders. Therefore across the lifetime of the project we will conduct three FGs that will be scheduled to coincide with time points when we have relevant data available to disseminate. The purpose of the first FG will be to determine the most appropriate format and routes for dissemination in order to maximise impact of the outputs produced from the research. In the FG's planned for years 2 and 3 the same stakeholders from the first FG will be consulted to determine whether the outputs have influenced decision making processes in their respective organisations and how. If it is deemed within the second FG (i.e., year 2) the format and routes of dissemination are not achieving the envisaged impact we will use this FG to reconsideration the format(s) and routes moving forward into year 3. We do not intend to transcribe FGs but will record the discussions and take detailed field notes of proceedings.

6. Research Governance

All appropriate ethical and governance requirements will be in place in advance of recruiting study sites or participants

Data Management

In all instances for the duration of the FRONTIER project, data will be retained in accordance with University (UWE) and Funder (NIHR) policies. In all outputs, reports, publications and other available documents details will be provided of methodology used, analytical and procedural information, definitions of variables, vocabularies, units of measurement, etc so that users are able to make sense of available data. This will be included within above documents, as supplementary data, on our study website, or by other means. Where relevant and permissible, data will be added to the University Research Data Repository.

Ethics and Legal Compliance

Overall, ethical considerations relating to the FRONTIER study relate to carrying out research with human participants, specifically ethical approval, consenting participants, and data collection, management and storage processes. Throughout the study, data will be managed and stored in accordance with University and Funder requirements, as per the study Data Management Plan (available on request). Electronic data will be stored on a team-site through OneDrive, password protected University H:Drives, S:Drives, and hardcopies of data will be stored in filing cabinets within locked offices at the University of the West of England. The Chief Investigator will act as custodian, and take full responsibility for the data to ensure appropriate compliance.

Data storage and back-up

Data storage and back up procedures for the FRONTIER study follow University recommended guidance and procedures. All data generated as part FRONTIER project will be stored on OneDrive and or the UWE password protected H:Drive or S:Drive. All of the immediate study team are University staff and therefore have access to 1TB of One Drive storage which provides sufficient storage space for study data. OneDrive data can be accessed online through password protected mobile apps and on University issued PCs and/or Laptops. In the event of off-site working or data collection, as per University recommendations, data may be temporarily held on external devices such as pen-drives and encrypted audio recorders. For safety and security it will be common practice of the study team that data are uploaded to University systems using a University laptop as soon as possible after collection. In the case of collection of identifiable research data (e.g. research interviews), audio-recordings will be uploaded to OneDrive immediately and the original recording deleted, before the researcher leaves the external site. If upload is not possible, all files are encrypted, and upload will be undertaken at the earlies possible convenience. The UK Data Service Guidance on data storage will also be consulted for other best practice. In relation to back up and recovery of data in the event of an incident, S: drive is backed up by UWE daily. OneDrive is not backed up as such but it is resilient as it is cloud based, with the basic protection offered by the "restore previous version" functionality.

Study database and data use

The database will be developed in collaboration with the expert statisticians within the FRONTIER study team. No confidential personal data that identifies individual participants will be included in this database apart from the unique participant study ID. This will be linked to a separate database, containing data linking the participant study ID, to the relevant confidential personal data which will be held by the immediate study team. All qualitative data will be analysed by the immediate study team. All identifying information will be removed from transcripts and replaced with unique participant study ID. No confidential personal data that identifies individual participants will be included in any of the qualitative analyses (including analysis performed in databases/Excel/NVivo) apart from the unique participant study ID. This will be linked to a separate database containing data linking the participant study ID to the relevant confidential personal data.

In relation to reuse of data and further collaboration outside of the direct FRONTIER study team, the FRONTIER study is collaborating with individuals based at Manchester University and the University of Surrey on work looking at the primary care workforce. As part of this collaboration, it is anticipated that respective research teams may (and may not be limited to) the following: discuss aspects of the individual projects across teams, collect data to serve dual needs and interests across projects (e.g. certain patient-reported outcome measures), and share de-identified qualitative and quantitative data. This will occur across the study timeframe. Additionally, de-identified data may be shared as per license agreements and regulations for relevant study outcome measures.

7. Patient and Public Involvement

Patient and public involvement (PPI) is a core principle of our research and essential to ensure public accountability and transparency. For this study, PPI will directly improve the quality of our research, making it relevant to people affected by MSKD and to those who give them support. Patients and public have endorsed our research as important and have helped us refine our proposal in a pre-application focus group. Continuing to support the research throughout each phase of work, we hope that our patient partners will enable us to conduct the research using methodologies acceptable and sensitive to our patient groups and to compile and assist in presenting findings in ways that are accessible to a range of audiences. Meaningful inclusion throughout the project will also help us understand patients' ongoing service needs and make sure that the perspectives of those affected by MSKD are represented in future commissioning decisions.

From the outset, people with MSKD have made a valuable contribution in shaping and developing our proposed project. We will embed PPI throughout the project, and will actively work with two patient representatives at all stages. At the start of the project they will join the Project Management Group (PMG) to ensure the patient perspective is fully reflected throughout, and to capitalise on their expert views and experience of care management and treatment pathways. We have included costs to allow this, both for meeting attendances and for activity time in relation to project tasks. This will allow our patient representatives to have meaningful input initially into refining the research protocol and documents to make them more acceptable and accessible to patients in readiness for submission to ethics. In Work package 1 of the study they will have significant input into the group consensus exercise to validate the "programme theory" arising from the planned realist review and to provide a viewpoint on patient-related factors influencing the model. For Phase 2, our patient representatives will advise the PMG on the wording of the qualitative questions to be asked in patient interviews to ensure they are directly relevant to the FCP experiences of those with MSKD. Furthermore, they will assist in the interpretation of qualitative findings so that outputs are meaningful to patients and the public. Towards the end of the main project our patient representatives will advise on appropriately targeting the dissemination of findings and will be involved in local public- and patient-organisation dissemination events.

We are also aware of the impact that involving patient and the public may have on the individuals who work with us. We are mindful of our responsibility to provide opportunities for them to extend their knowledge, understand the research process and to develop practical skills. For this we will ensure that we provide appropriate and adequate resources and support at every opportunity. All PPI activities and support will be provided and led by Dr Llewellyn (co-app) who has extensive experience facilitating PPI in research. We have included costs for our two PMG patient representatives to attend the University of the West of England for a full day's training in preparation for the project. All our PPI representatives will have access to a further range of networking events and training, which are organised through the People in Health West of England (a local CLAHRC West initiative), and individual support will be available according to their needs. Their time and expenses will be reimbursed at INVOLVE rates.

Foster is a co-applicant for this proposal and will join the PMG along with another patient/public representative (to be appointed). Mr Foster has experience of working on other research projects both as a participant and steering group member. We intend to invite another patient, similarly experienced in the care pathways for MSKD, to join Mr Foster to share responsibility and provide peer support

8. References

1. Pawson, R. (2006) Evidence-based Policy: A Realist Perspective. London: SAGE.
2. Wong G, Westhorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II reporting standards for realist evaluations. BMC Medicine 201614:96 DOI: 10.1186/s12916-016-0643-1
3. Kelly E, Stoye G. Does GP Practice Size Matter? GP Practice Size and the Quality of Primary Care. FS Report 2014 R101. DOI10.1920/re.ifs.2014.0101
4. Hippisley-Cox J, Fenty J, Heaps M. Trends in Consultation Rates in General Practice 1995 to 2006: Analysis of the QRESEARCH database. Final Report to the Information Centre and Department of Health. July 2007
5. Murray C, Vos T, Lozano R et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990 – 2010: a systematic analysis for the Global Burden of Disease Study 2010. The Lancet 2013. (12)61689-4 pp. 1990–2010
6. Roland M, Morris R. A study of the natural-history of back pain: development of a reliable and sensitive measure of disability in low back-pain. Spine 1983; 8: 141–44
7. Salisbury C, Montgomery A, Hollinghurst S, Hopper C et al. Effectiveness of PhysioDirect telephone assessment and advice services for patients with musculoskeletal problems: pragmatic randomised controlled trial. BMJ 2013; 346:f43
8. Malhotra A, Maughan D, Ansell J, et al. Choosing Wisely in the UK: the Academy of Medical Royal Colleges' initiative to reduce the harms of too much medicine BMJ 2015; 350 :h2308
9. Jordan KP, Kadam UT, Hayward R, Porcheret M, Young C, Croft P. Annual consultation prevalence of regional musculoskeletal problems in primary care: an observational study. BMC Musculoskeletal Disorders 2010; 11:144.
10. Thomas E, Peat G, Harris L, et al. The prevalence of pain and pain interference in a general population of older adults: cross-sectional findings from the North Staffordshire Osteoarthritis Project (NorStOP) Pain. 2004; 110:361–8)
11. Quality First. Managing workload to deliver safe patient care 2015. British Medical Association, London. BMA 20150017
12. Roland M. The future of primary care: Creating teams for tomorrow. Primary Care Workforce Commission; 2015 Jul p. 1–62.
13. ICM Unlimited. British Medical Association National survey of GPs. The future of General Practice 2015 Full Report. London: British Medical Association; 2015 Feb.
14. Royal College of General Practitioners. 27m patients to wait a week or more to see GP in 2014. Available from:http://www.rcgp.org.uk/news/2013/december/27m-patients-to-wait-week-or-more-to-seegp-in-2014.aspx
15. Chartered Society of Physiotherapy (2016) http://www.csp.org.uk/professional-union/practice/your-business/evidence-base/physiotherapy-works/physiotherapyworks-prim [accessed January 2017]
16. Vos T, Y Flaxman AD, Naghavi M et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010 The Lancet 2013 , Volume 380 , Issue 9859 , 2163 - 2196
17. Health and Safety Executive Labour Force Survey (2016). http://www.hse.gov.uk/Statistics/causdis/musculoskeletal/ index.htm
18. Right Care (2011) The NHS Atlas of Variation in Healthcare.
19. Department of Work and Pensions Autumn statement 2016. Ref: ISBN 978-1-4741-3842-0, PU1983, Cm. 9362 https://www.gov.uk/government/publications/autumn-statement-2016-documents [Accessed august 2017]
20. Pawson R, Tilley N (2004). Realist evaluation. http://www.communitymatters.com.au/RE_chapter.pdf [Accessed August 2017]
21. Jagosh J. Introduction to Realist Evaluation and Synthesis. https://realistmethodology-cares.org/

22. Pawson R, Tilley N. (1997). Realistic Evaluation. Thousand Oaks, CA: Sage.
23. Jagosh J, Bush P, Salsberg J, Macaulay AC et al. A realist evaluation of community-based participatory research: partnership synergy, trust building and related ripple effects. BMC Public Health 201515:725 https://doi.org/10.1186/s12889-015-1949-1
24. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. BMC Medicine 201311:21 https://doi.org/10.1186/1741-7015-11-21
25. NHSE (2014). Five Year Forward View. https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf
26. CSP Case Studies repository. https://casestudies.csp.org.uk/ [Accessed January 2017]
27. CSP (2016). http://www.csp.org.uk/news/2016/04/26/gps-support-physios-first-point-contact-surgeries
28. NIHR 2015 Push the Pace. http://www.nihr.ac.uk/about-us/how-we-are-managed/boards-and-panels/push-the-pace.htm
29. Mallen CD, Thomas E, Belcher J, Rathod T, Croft P, Peat G.. Point-of-care prognosis for common musculoskeletal pain in older adults. JAMA Intern Med. 2013, vol. 173(12), 1119-1125.
30. Margham T. Musculoskeletal disorders: time for joint action in primary care British Journal of General Practice. 2011 Nov; 61(592): 657–658. Doi: 10.3399/bjgp11X601541
31. Goodwin RW, Hendrick P. Physiotherapy as a first point of contact in general practice: A solution to a growing problem? Primary Health Care Research and Development 2016, 6 (1). pp. 489-502. ISSN 1477-1128
32. Oakley C, Shacklady C. The Clinical Effectiveness of the Extended-Scope Physiotherapist Role in Musculoskeletal Triage: A Systematic Review. Musculoskeletal Care. 2015 Mar
33. Primary Care Workforce Commission. The future of primary care. Creating teams for tomorrow. Health Education England, July 2015. www.hee.nhs.uk/sites/default/files/documents/WES_The-future-of-primary-care.pdf
34. Rycroft-Malone J, McCormack B, Hutchinson SAM, Decorby K et al. Realist synthesis: illustrating the method for implementation research. Implementation Science 2012 7:33. https://doi.org/10.1186/1748-5908-7-33
35. Manzano A. The craft of interviewing in realist evaluation. Evaluation 2016; 22: 342-360. DOI: https://doi.org/10.1177/1356389016638615
36 Bishop A, Ogollah RO, Jowett S, Kigoz1 J et al. STEMS pilot trial: a pilot cluster randomised controlled trial to investigate the addition of patient direct access to physiotherapy to usual GP-led primary care for adults with musculoskeletal pain. BMJ Open 2017; 7: e012987. Doi: 10.1136/bmjopen-2016-012987
37. Ware JE, Kosinski M, Bjorner JB, et al. User's manual for the SF-36v2 Health Survey. 2nd edn. Lincoln, RI:QualityMetric Inc, 2007.
38. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of Life Research 2011; 20:1727–36.
39. Mead N, Bower P, Roland M. The general practice assessment questionnaire (GPAQ): development and psychometric characteristics. BMC Family Practice 2008; 9:13.
40. Knapp M. The economic evaluation of mental health care. Aldershot (UK): Arena; 1995.
41. Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, Valderas JM. Measuring Patient Safety in Primary Care: The Development and Validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC). Annals of Family Medicine 2016 May; 14(3):253-61 doi: 10.1370/afm.1935
42. Better Care Fund. How to... understand and measure impact. https://www.england.nhs.uk/wp-content/uploads/2015/06/bcf-user-guide-04.pdf.pdf [Accessed August 2017]
43. Rautenberg T, Hulme C, Edlin R. Methods to construct a step-by-step beginner's guide to decision analytic cost-effectiveness modeling. Clinicoeconomics Outcomes Res. 2016 Oct 11;8:573-581. eCollection 2016