Implementing the MSK-HQ to empower patients and improve services

The MSK-Tracker study

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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 trial in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

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

For and on behalf of the Study Sponsor:

Signature: Date:

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Name (please print):

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Position:

…….

Chief Investigator:

Signature: Date:

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Name (please print):

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LIST of CONTENTS

LIST OF ABBREVIATIONS

BMJ	British Medical Journal
BOA	British Orthopaedic Association
CATS	Clinical Assessment and Treatment Services
CI	Chief Investigator
CRF	Case Report Form
CSP	Chartered Society of Physiotherapy
CTU	Clinical Trials Unit
DoH	Department of Health
EBCD	Experience Based Co-Design
ELC	Experience Led Commissioning
e-PROM	electronic - Patient Reported Outcome Measure
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ISRCTN	International Standard Randomised Controlled Trials Number
MSK	Musculosketal
MSK-HQ	Musculoskeletal Health Questionnaire
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
PI	Principal Investigator
PPIE	Patient and Public Involvement and Engagement
PROM	Patient Reported Outcome Measure
QI	Quality Improvement
QiPP	Quality, Innovation, Productivity and Prevention programme
RCGP	Royal College of General Practitioners
RUG	Research User Group
SAE	Serious Adverse Event
SFTP	Secure File Transfer Protocol
SOP	Standard Operating Procedure
SSL	Secure Sockets Layer

KEY STUDY CONTACTS

Chief Investigator	Dr Jonathan Hill Research Institute for Primary Care and Health Sciences Keele University Staffordshire ST5 5BG UK +44 (0)1782 733900 Fax 01782 733911 Email: j.hill@keele.ac.uk
Principal Investigator	As above
Sponsor	Keele University Sponsor Representative: Dr Clark Crawford Head of Research Integrity, Directorate of Research, Innovation and Engagement, Innovation Centre 2, Keele University, Staffordshire, ST5 5NH Tel: 01782 733371 Email: research.governance@keele.ac.uk
Funder(s)	ARUK Health Services Research Award This Health Services Research Call is funded as a joint working programme between Arthritis Research UK and Pfizer Ltd, in partnership with the Chartered Society of Physiotherapy, the Chief Scientist's Office of the Scottish Government and NHS England.'
Study Management	Keele Clinical Trials Unit (CTU) David Weatherall Building Keele University, Staffordshire ST5 5BG Tel: 01782 732916 Email: ctu.operations@keele.ac.uk
Key Protocol Contributors	Steven Blackburn, Telephone: 01782 734846, Email: s.blackburn@keele.ac.uk Georgina Craig, Email: georgina@elcworks.co.uk Krysia Dziedzic, Telephone: 01782 733907, Email: k.s.dziedzic@keele.ac.uk Elizabeth Gibbons, Email: elizabeth.gibbons@dph.ox.ac.uk Elaine Hay, Email: e.m.hay@keele.ac.uk Gillian Lancaster, Telephone: 01782 732925, Email: g.lancaster@keele.ac.uk Ajit Menon, Telephone: 01782 673725 Email: ajit.menon@uhns.nhs.uk Andrew Price, Email: andrew.price@ndorms.ox.ac.uk, Joanne Protheroe, Telephone: 01782 734884, Email: j.protheroe@keele.ac.uk Kay Stevenson, Telephone: 1782 733967, Email: kay.stevenson@ssotp.nhs.uk Katie Tempest: Email: kjtempest@gmail.com

Lead Statistician	Professor Gillian Lancaster Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University Staffordshire, ST5 5BG Tel: 01782 732925 Fax: 01782 733911 Email: g.lancaster@keele.ac.uk
Committees	**The Trial Management Group** Dr Steven Blackburn, Tel: 01782 734846, Email: s.blackburn@keele.ac.uk Georgina Craig, Tel: 07879480005, Email: georgina@elcworks.co.uk Professor Krysia Dziedzic, Tel: 01782 733907, Email: k.s.dziedzic@keele.ac.uk Dr Elizabeth Gibbons, Tel: Email: elizabeth.gibbons@dph.ox.ac.uk Professor Elaine Hay, Tel: 01782 733904, Email: e.m.hay@keele.ac.uk Dr Jonathan Hill, Tel: 01782 733900, Email j.hill@keele.ac.uk Gail Sowden, Tel: 01782 734841, Email: g.sowden@keele.ac.uk Kay Stevenson, Tel: 1782 733967, Email: kay.stevenson@ssotp.nhs.uk The Trial Management Group will be supported by The Keele Clinical Trials Unit. **Key Industrial Partners** • Georgina Craig Managing Director of Experience Led Commissioning (ELC Works) and Georgina Craig Associates Limited, Email: georgina@elcworks.co.uk • Michael Phillips from PRO-MAPP, Email: michael.phillips@pro-mapp.com

STUDY SUMMARY

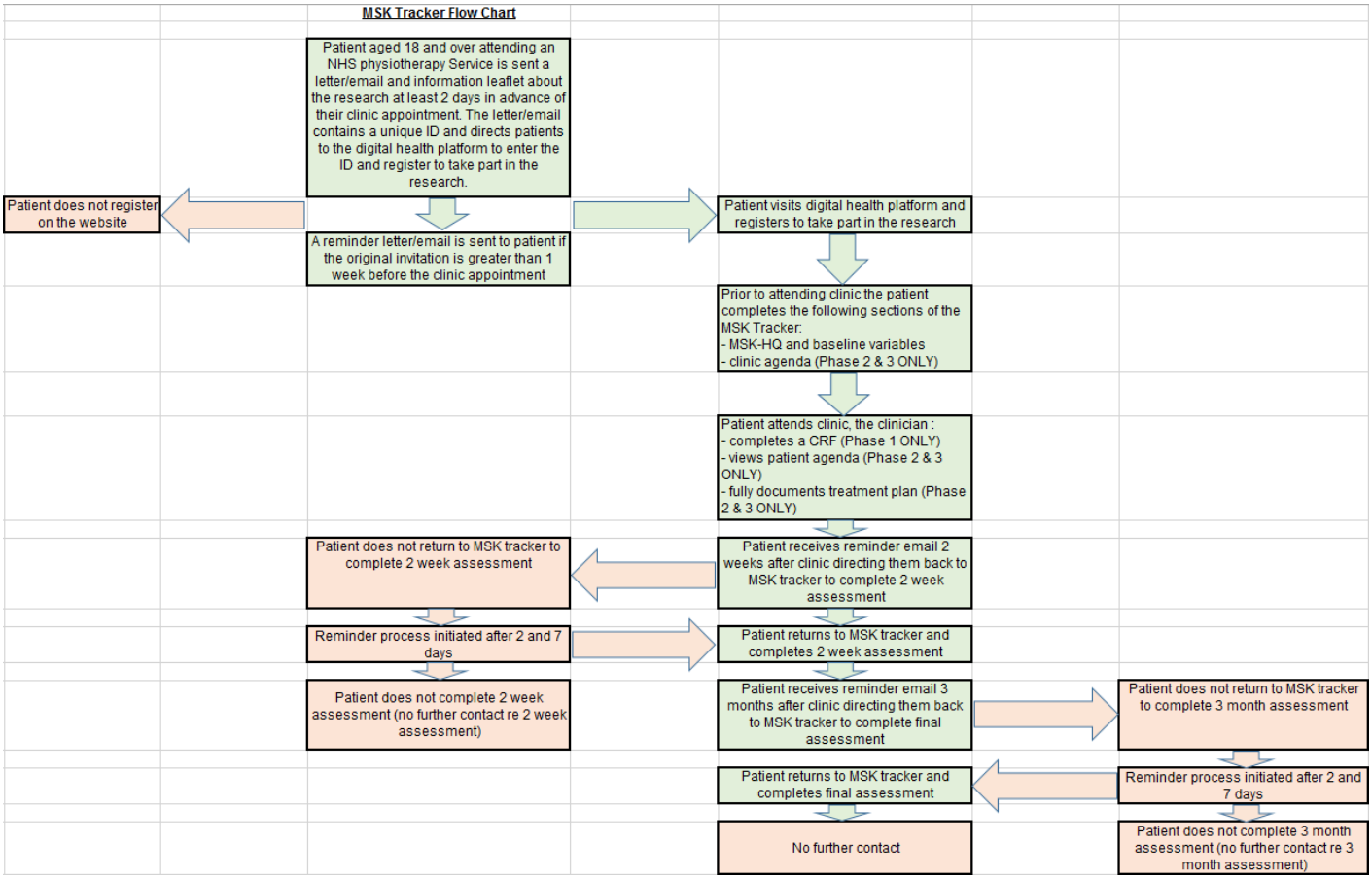
Study Title	Implementing the MSK-HQ to empower patients and improve services
Internal Ref. Number (or short title)	The MSK-Tracker study
Study Design	This study will co-design and test the feasibility and impact of implementing the Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) using an e-PROM (electronic Patient Reported Outcome Measure) delivered via a digital health platform, with innovative embedded components called the *MSK-Tracker*. The *MSK-Tracker* uses the MSK-HQ as a foundation to help patients with Musculoskeletal (MSK) pain to: • track the extent to which they are affected by their MSK condition across different aspects of their health, • prepare appropriately for their clinical encounters, and • take the right steps to making positive changes to improve their quality of life and manage their condition over the longer-term. **<u>The Study Aims</u>** to: 1. Test the ability of the MSK-Tracker to act as an empowerment tool and method of facilitating a person-centred care planning approach in routine MSK clinic consultations. 2. Assess the value of the MSK-Tracker in generating aggregated outputs that inform MSK service improvement. **<u>Study Design</u>** We will use a before and after design with the comparator between phases 1 and 3 across a range of outcomes. Phase 2 will focus on iterative testing of the MSK-Tracker. In addition, in phase 1 and 3 we will undertake qualitative research using the Experience Based Co-Design (EBCD) methodology to explore the impact of the MSK-Tracker and to inform further improvement and refinement of the tool and its use within the context of MSK services and clinical practice. The findings from the qualitative research will be triangulated with insights from the aggregated data of patient outcomes to enrich and help make sense of the study findings.
Study Intervention (where applicable)	The intervention is the use of the MSK-Tracker by patients and clinicians.
Study Participants	Patients aged 18 and over attending an MSK clinic with a range of different conditions at participating NHS Trusts
Planned Sample Size	The project is divided into 3 phases, each recruiting patients to both a quantitative prospective cohort and qualitative research (interviews and workshop) aspects. - Phase 1 will recruit approximately 200 patients to complete the quantitative online survey with up to 10 of these patients also interviewed about their experiences. In addition, up to 10 clinicians will also be

	recruited to take part in an interview about their current practice. - Phase 2 will recruit approximately 40 patients in up to 2 cycles of approximately 20 to complete the quantitative online survey, with up to 20 of these patients interviewed about their experiences (up to 2 cycles of approximately 10 patients). In addition, up to 10 clinicians will also be recruited to take part in a feedback workshop or individual interview about their experiences of the MSK-Tracker. - Phase 3 will recruit approximately 200 patients to complete the quantitative online survey with 10 of these patients also interviewed about their experiences. In addition, up to 10 clinicians will also be recruited to take part in a feedback workshop or individual interview about their experiences of the MSK-Tracker. In total the expected accrual figure for this project is approximately 440 patients consenting to take part in the MSK Tracker study with approximately 10 clinicians taking part in qualitative research.
Treatment duration	Patients will not receive any additional treatments in this study.
Follow up duration	In all three phases patients will complete the cohort follow-up surveys at 2 weeks and 3 months after their initial clinic consultation.
Planned Study Period	It is expected that recruitment for phase 1 will be staggered over the two NHS Trusts. The first Trust is expected to have completed phase 1 by Nov 2018, then to have a few months of Phase 2 and then to begin Phase 3 in spring 2019. At the second trust we expect to begin phase 1 in Jan 2019 and phase 3 around 2 months later. .

	Objectives	**Outcome Measures**
Primary	To improve patient self-reported measures of empowerment	A measure of patient empowerment - the patient enablement scale, will be the primary outcome in this study
Secondary	To impact on the nature of the conversations during the clinic consultation; focusing both parties on agreeing shared goals and actions and Improve patient self-reported quality of life.	Secondary outcome measures will include further clinical outcomes (see below), an evaluation of changes in the nature of the consultation conversation, and changes in clinician behaviours using case report form (CRF) information. **Clinical outcomes in the survey include:** • Musculoskeletal Health Questionnaire • Consumer Health Activation Index • Work Productivity & Activity Impairment Questionnaire • Valuing patients as individuals scale (short version) • Patient perceived global rating of change item (single item) • Patient experience using the friends and family test

		• Shared decision-making 3 questions • Ease of access, clinical environment, and reduction in healthcare usage The phase 2 and 3 surveys will also ask patients about the feasibility and acceptability of the MSK-Tracker, for example: • Did they find it useful? • Was it easy to use? • Did it help them think about issues related to their care? • Did it increase any stress associated with their appointment? Clinician behaviours such as the proportion of patients who are given information about their condition, specific advice about work issues, medication, injections, referrals to other services (e.g. to physiotherapy and secondary care specialists), and referrals for investigations (e.g. for radiographs, MRI/CT scans, blood tests) will be captured in all three phases using a clinician portal to house an electronic case report form (CRF).

STUDY FLOW CHART



1 BACKGROUND

Taken together, osteoarthritis, inflammatory disorders and common musculoskeletal conditions such as back, neck, shoulder, hip and knee pain now represent the single greatest cause of years lived with disability (1). Finding ways to prevent their impact on individuals' quality of life is a significant and important challenge (2). In the UK these conditions are mostly managed in primary care, with referral to secondary care for more complex management or specialist treatment and surgery such as Rheumatology or joint replacement. Effective and efficient management of long-term conditions is one of the core challenges facing health systems. There is consensus that meeting this challenge will require adoption of new models of care and ways of working that better reflect the individual needs of patients through improvements in self-management and care that is patient-centred, co-ordinated, and provides choice. In the last decade, the management of musculoskeletal conditions has been shifted away from secondary care towards multidisciplinary clinical assessment and treatment services (CATS) at the primary–secondary care interface, that provide a 'one-stop shop' for efficient, rapid assessment, diagnosis, and treatment of patients (3). One problem, however, is that many musculoskeletal (MSK) services are providing care within discrete silos, with little focus on supporting people to self-manage and cope with the long-term nature of their condition across the clinical pathway. Care planning supports people with long-term conditions to manage their health and well-being (4). It centres on a collaborative conversation between the individual who lives with an MSK condition and a healthcare professional. It involves the development of shared goals and actions, which are recorded. A recent report from Arthritis Research UK suggests that care planning approaches may enhance continuity of care across the MSK pathway (5). However, there is a lack of practical evaluation systems to support care planning or enable patients to track and manage their MSK condition over time.

2 RATIONALE

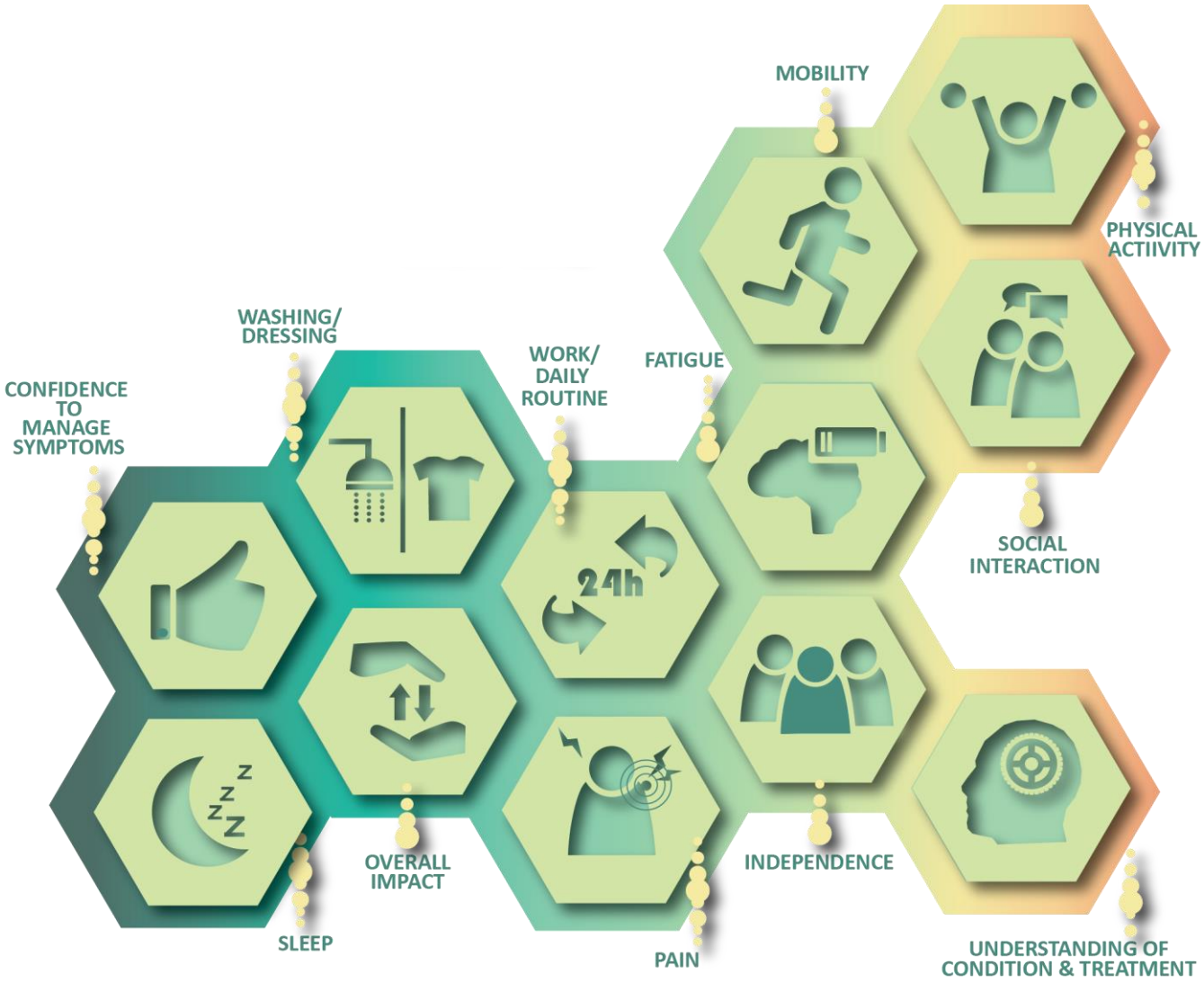
The Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) is a recently validated new MSK Patient Reported Outcome Measure (PROM) that has been co-produced with patients and clinicians to measure the holistic impact of an MSK condition on a person's health. It has been validated in both primary and secondary care populations and is appropriate for use by patients across the care pathway. It is designed for use in routine, busy, clinical practice. The MSK-HQ is freely available to the NHS, and consists of 14 health items that cover the domains that matter the most to MSK patients (6) and helps clinicians and patients to identify the areas of life where the condition is impacting most (see Figure 1). An electronic-PROM (e-PROM) version of the MSK-HQ is available and is being used by some early adopter MSK services to audit their clinical and patient outcome performance.

However, it is not yet known whether:

- Patients using the MSK-HQ routinely as part of their care planning, supports them to feel more involved and empowered in managing their health issues.
- Using the MSK-HQ can facilitate a more holistic care planning consultation, both in terms of the quality of patient interactions and communications with healthcare professionals.
- It is acceptable or feasible for both patients and clinicians to use the MSK-HQ as an e-PROM.

Enabling organisations to examine their aggregated MSK-HQ data at service level identifies unmet need, improvement opportunities and informs MSK service and organisational developments.

Figure 1: Health domains measured by the MSK-HQ



Outcomes are currently being used primarily as bookends to an episode of care (to justify the costs for treatment or to support a discharge decision) rather than to monitor patients' progress at regular intervals or to shape the consultation. Additionally, the act of documenting outcomes is often made unnecessarily burdensome, with lengthy paper based records that are frustratingly inefficient and are even seen as detrimental to the therapeutic alliance between therapists and patients. We believe there is an opportunity for change, as with some creativity, user-centred design approaches could be harnessed to create an electronic health record that facilitates outcomes collection through easy interfaces, and additionally generates information to guide the clinical interaction.

Given this clinical challenge, the MSK-HQ development and validation team (a Keele & Oxford collaboration) has partnered with an experienced electronic health record (e-PROM) provider (Pro-Mapp) (7) and a person-centred, co-design expert (Georgina Craig - Director of The ELC Programme) (8), to develop a technological solution and support package to facilitate the use of the MSK-HQ in clinical practice and inform the clinical interaction. Our new digital health platform will be designed to support patients to work in partnership with their clinical team to complete data gathering as part of a four stage care planning process. These stages include;

- the patient preparing for the consultation using the MSK-HQ and being prompted to identify the areas of their life where the condition is having the most impact that they want to discuss

- a clinical dashboard to facilitate a discussion of their current individual difficulties or concerns with the clinician
- documentation of agreed actions and the treatment plan going forward, and help with the setting of goals to motivate lifestyle changes (where needed)
- progress charts to track change in MSK health and condition impact over time.

This research will optimise implementation of the MSK-HQ using a digital health platform, and evaluate its impact on both clinicians and patients. In addition to investigating benefits at the individual level, we also hypothesise that the data generated by this innovation may provide substantial organisational level insight. We plan therefore to explore how MSK-HQ data can best be aggregated, made sense of and presented as actionable outputs that identify unmet need and service improvement opportunities.

This proposal is novel because of three specific developments;

i. The development of an IT innovation to support the implementation of the MSK-HQ within the individual consultation, which has the potential to bring many advantages to people with MSK conditions. The individual patient is often the only consistent connection between different service components. It therefore makes sense for patients to be able to own and access their care plan as they move between providers. For conditions such as osteoarthritis, many core treatments are initiated by patients themselves rather than by the doctor (12, 13) and the perspectives of patients may differ from the perspectives of healthcare professionals, with information recorded by professionals in the medical records not necessarily aligned to the patient's ideas about his or her treatment plan (14, 15).

ii. Making the MSK-HQ available to patients in advance as a prompt prior to their consultations, and testing if its application in this way facilitates a care planning approach. Patients want to be able to own and access their care plan as they move between providers, and the MSK-Tracker will enable them to do that. Patients can also find it difficult to raise important issues of concern in short, busy clinical interactions with different providers, which can lead to healthcare inconsistencies and inequalities in the support they receive. Although reports are limited, evidence from cancer research suggests that the use of consultation prompt lists can improve care (16-20) and augment consultations when they are used proactively by clinicians (21). Despite growing evidence that they can make the consultation more focused and time-efficient (22-24), prompt lists are infrequently used in NHS MSK consultations. Within the UK health community, there is a national debate about how to bring about more person-centred care "How can we get better at providing patient centred care?", and "No decision about me without me" (25, 26). Participants in the BMJ discussion agreed that a change in culture and better use of technology could benefit patients and doctors (27). The potential for the MSK-Tracker to influence the consultation and help patients keep track of their health status and in control of their care resonates with the 2014 Reith Lectures (28) by Atul Gawande, who highlighted the role of checklists and prompt questions as a stimulus for achieving better outcomes and service improvement (29). Problems with 'the system': the interactions between people and organisations that deliver healthcare were also highlighted. This debate is of growing relevance to the MSK community and new national policy from Arthritis Research UK is now focused on efforts to ensure that those living with arthritis and musculoskeletal conditions get the care and support they need to lead as healthy and active a life as possible in order to be "In control, independent and recognised" (30). It is clear that to empower patients to feel well supported, informed and able to manage the effects of their condition and

minimise its impact on their lives, they need to have equal voice and be at the heart of setting goals and planning their own care in partnership with their MSK clinical team. However, in order to deliver changes to the way care is delivered, innovative technological solutions such as this, are required.

iii. Identifying the best ways to present and format outputs of aggregated MSK-HQ data to generate insights that inform service development and improvement. The MSK-Tracker will be an exciting new development, which, if implemented through a scalable electronic solution, has substantial potential to drive forward large scale service changes. MSK-HQ is supported nationally by Arthritis Research UK, NHS England and professional bodies including the CSP (Chartered Society of Physiotherapy) and BOA (British Orthopaedic Association). The next important step is to find a feasible way to use this outcome measure within routine clinical practice as a stimulus to drive the whole system to focus on what matters to patients and improve the care provided.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The overall focus of this research is to co-design and test the feasibility and impact of implementing the MSK-HQ presented within an innovative online care planning package called the MSK-Tracker.

3.2 Secondary objectives

a) To optimise the acceptability and utility of the MSK-Tracker as a self-management support tool for patients to use to take control of their MSK health issues and facilitate personal goal setting during MSK clinical encounters

b) To assess the feasibility and utility of the MSK-Tracker in busy consultations; the impact on the nature of the consultation when the MSK-Tracker is used and whether it supports patient enablement (feeling more in control of their MSK condition).

c) To assess its value in generating aggregated outputs and insight to inform service improvement and organisational development of MSK interface services.

3.3 Primary endpoint/outcome

A measure of patient empowerment - the patient enablement scale (40), will be the primary outcome in this study and will be captured using an online e-PROM. The primary end-point will be the 2 week post-consultation measure, although the measure will also be included in the 3 month follow-up.

3.4 Secondary endpoints/outcomes

We will collect a range of patient self-report characteristics to be able to describe the patient population such as; age, gender, ethnicity, education level, work status, health literacy, MSK pain site/condition, and episode duration.

Secondary outcome measures will include further clinical outcomes (see Table 1 page 20), an evaluation of changes in the nature of the consultation conversation, and changes in clinician behaviours using CRF information. Clinical outcomes will be completed 2 weeks and 3 months after the patient's initial clinic date. This will be achieved by asking patients via an email with a text reminder (according to the patient's stated preference) to complete the online survey, including the following measures; the MSK-HQ, the patient enablement scale, the valuing patients as individuals scale (short 10-item version), psychological distress using a single item (0-10 NRS), the single global rating of change item, patient satisfaction with care (0-10 NRS), patient confidence in their ongoing treatment plan including any investigations, treatment referrals, medication changes, or ongoing self-management made during their consultation, and further MSK healthcare consultations received.

For those in the 'after' stage (phase 3) of the research they will also be asked feasibility questions to establish whether or not they found the MSK-Tracker useful, was it easy to use, did it help them think about issues related to their care, did it increase any stress associated with their appointment, and did it change the way the clinician dealt with them.

The nature of consultation conversations: To evaluate the impact of the MSK-Tracker on the consultation and the focus of what is discussed with the patient, we will use audio recordings of a purposive sample of approximately 20 consultations from phase 1 and again audio recordings of approximately 20 consultations from phase 3, where patients and clinicians provide consent, in order to: a) examine the content of what is discussed during the consultation, and b) examine the proportion of time spent in discussing different aspects such as the biomedical cause of the symptoms, treatment options, ways in which the patient can self-manage, specific concerns of the patient, and aspects of treatment beyond the immediate consultation. A descriptive content analysis will be conducted by a qualitative researcher to identify differences between phase 1 and phase 3.

Clinician behaviours using clinic CRF: A range of clinician level behaviours such as the proportion of patients who receive; opioid prescriptions, referrals to other services (e.g. to physiotherapy and secondary care specialists), referrals for investigations (e.g. for radiographs, MRI/CT scans, and blood tests) will be examined to test if there are significant differences in these behaviours between 'before' and 'after' stages. A similar case report form (CRF) was successfully used as part of the SAMBA study in this same MSK interface service (34). We also plan qualitative research (see section 7.6) to explore the experiences of patients, clinicians and service leads in relation to the impact of the MSK-Tracker and to inform its further improvement and refinement for the context of an MSK service and future clinical practice.

4 STUDY DESIGN

The study is using a 'before' and 'after' sequential comparison design with an iterative pilot and user testing phase in between. In addition, audio recordings of the consultation (in a sub-sample, n=40 (phase 1=20 & phase 3=20)), alongside individual clinician and patient interviews and a feedback workshop with clinicians and patients, will explore the feasibility, and impact of implementing the MSK-Tracker within routine consultations and the experiences of those who have used it.

Phase 1 ('Before' stage). Patients (approx. n=200) who meet the eligibility criteria for having long-term MSK pain and an appointment at participating clinical sites, will be consented and recruited to complete the e-PROM survey and demographic information shortly before their consultation. This phase will seek to collect patient information via the online digital health platform without using the new innovative 'MSK-Tracker' components, in order to give a baseline of what changes are observed before the MSK-Tracker intervention is used. Patients will complete data online before clinic, and then 2 weeks and 3 months after clinic and their change scores examined. Clinicians will complete a case report form (CRF) using the clinician portal to record clinical behaviours within the consultation. Audio recordings of approximately 20 patient consultations will examine consultation conversations and their content.

Phase 2. ('Pilot stage'). The MSK-Tracker will be developed and optimised through an iterative user testing framework with patients, clinicians, software provider, and experts. The MSK-Tracker will have a number of key 'care planning' components including, pre-clinic preparation, clinic dashboard, summary action plan, personal goal setting and follow-up and progress charts.

Early pilot testing of the MSK-Tracker will mirror the processes used in phase 3, with a limited number of patients and clinicians using the Tracker. We will aim to recruit approximately 40 patients (in up to 2 cycles of 20) to use the MSK-Tracker. During this phase we will invite all patients and clinicians to take part in an interview about their experiences to identify further potential improvements that can be

made to the Tracker before commencing phase 3. We aim to interview up to 10 patients in each of up to 2 cycles.

Phase 3 ('After' stage). Identical to phase 1, patients (n=200) who meet the eligibility criteria for having long-term MSK pain and an appointment at participating clinical sites, will complete an e-PROM shortly before their consultation and again 2 weeks and 3 months after their consultation. During phase 3 the MSK-Tracker components will be used alongside the e-PROM to support the new innovative 'care planning' approach and clinicians will be trained to use the MSK-Tracker within their clinical encounters. As in phase 1 audio recordings of approximately 20 patient consultations will examine consultation conversations and their content. A descriptive content analysis will be conducted to identify differences before and after the introduction of the MSK-Tracker in clinic.

In addition, we will undertake qualitative research using the Experience Based Co-Design (EBCD) methodology in both phase 1 and 3. This will involve interviews with approximately 10 patients and up to 10 clinicians to explore the impact of the MSK-Tracker and to inform further improvement and refinement of the tool and its use within the context of an MSK service and clinical practice. The findings from this qualitative research will be triangulated with insights from the aggregated data of patient outcomes to enrich and help make sense of the study findings.

4.1 Interventions/Treatments

The intervention is not a treatment per se, but involves patients and clinicians engaging with the MSK-Tracker software. It is envisaged that the MSK-Tracker will facilitate a new care planning approach with the following distinct components:

- **Pre-clinic preparation**. Prior to a consultation, the MSK-Tracker will help patients to set their clinic agenda by asking them to think about the ways in which their long-term MSK condition is impacting on their lives.
- **Clinic dashboard**. During the consultation it will enable the clinician to see the patient's health impact from their MSK condition (using MSK-HQ), and present the patient's clinic agenda to inform the consultation focus and ensure the individual's specific needs are addressed.
- **Summary action plan**. The Tracker will be used to record the agreed action plan from the consultation, including advice, information, referrals and investigations, which the patient can access when they want to as a reminder of what was agreed.
- **Personal goal setting**. To help the patient focus on what they personally seek to change (e.g. to get more fit and active) in relation to the impact of the MSK condition on their life and to help them reflect on what things are helping/hindering them to achieve goals to reduce this impact a goal setting module will be available to patients within the Tracker.
- **Follow-up and monitoring.** The Tracker will enable the patient to re-take the MSK-HQ at 2 weeks and 3 months and then have the opportunity to look at tracker charts that show their progress on the MSK-HQ overall score and individual domains.

4.2 Study Training

Clinicians involved in the study will undergo training in the use of the online e-PROM and full MSK-Tracker functionality (depending on the study phase). They will also have time to discuss the benefits of involving the patient's agenda within the consultation, and to practice ways that are built into the digital health platform to empower patients to better manage their symptoms. Training will take place prior to commencement of each phase of the study to ensure clinicians are appropriately prepared for each phase.

5 STUDY SETTING

The study will take place in participating NHS MSK clinical sites.

These services assess patients over the age of 18 with non-inflammatory and non-surgical musculoskeletal disease. They accept referrals from general practitioners and physiotherapists. They assess and diagnose a patient's musculoskeletal problem and agree a management plan in conjunction with the patient.

The types of conditions seen within these clinical services are patients aged 18 years and above with any muscle or joint problems. This can include conditions such as early to late osteoarthritis and soft tissue tendinopathies as well as back or neck pain.

6 ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Patients aged 18 years and above with an appointment at one of the participating services for an MSK pain problem will be invited to take part.

6.2 Exclusion criteria

Patients unable to use or access the internet will be unable to take part in this research as well as patients who do not provide informed consent for study participation and data collection. The online system will only be available in English.

7 STUDY PROCEDURES

7.1 Recruitment

Patients will be recruited at participating NHS MSK clinical sites.

7.1.1 Patient identification

Patients with an upcoming appointment to attend for an MSK pain problem at a participating site will be sent an invitation letter and patient information leaflet (either by email or post) informing them of the research at least 48 hours before their appointment date. The letter sent will contain an online web-address and a unique passcode for the patient to access the online e-PROM (phase 1) and additional embedded MSK-Tracker components (in phase 2 and 3). If the invitation is sent to participants via the post a reminder will be sent a few days later as this is a simple process for clinic administrators. However, if the invitation is sent via email, then there will not be a reminder process.

7.2 Consent

Consent - main study

Consent will be taken online through the e-PROM platform. If after reading the invitation letter and patient information leaflet the patient wishes to take part in the research, they will visit the website and enter the unique study ID provided in the invitation letter. The patient will be provided with information on screen about the research and how the data they provide will be handled before they enter any data. After completion of the pre-clinic e-PROM survey patients will see a screen asking them to provide consent to:

- take part in the study
- share their information with the researchers and clinicians
- to be invited to complete follow-up at 2 weeks and 3 months
- and agree for their anonymised data to be used in future research studies

If the patient declines to take part in the research at this stage a screen will appear thanking them for considering taking part in the research and confirming that any information they have provided so far will be destroyed. There will be the option to 'Finish', or 'Go Back' if they have changed their mind or clicked on 'decline' by mistake. It is not possible to save data entered by the patient if consent is not given. In the case where data entry is started but does not reach participant consent, additional security is provided through the links used to access the survey data to ensure an individual's data is protected. Any data entered will perish after 4 days if consent is not provided. At the end of the study details of patients who took part in the study will be held within the local investigator site file and will be securely archived in line with the Sponsor's procedures for a minimum of 10 years after the publication of the study findings.

Members of the clinic team will ask patients at the start of the consultation if they have consented to take part in the MSK Tracker study, before searching via a clinician portal for the relevant patient record. A poster will be displayed in the waiting area reminding patients about the study and asking patients to let their clinician know if they are taking part in the MSK Tracker study. Where possible, computer tablets will also be available in the clinic waiting room for patients to take part in the study if they wish to do so. The clinicians at the participating sites will only be able to see details of patients that have provided consent through the Tracker attending their own service.

Consent - consultation recording
The patient information leaflet sent to patients with the invitation letter asking them if they would like to take part in the study will provide information on the optional audio recording of their consultation. On attending clinic, patients taking part will be asked by their clinician if they are willing to have their consultation audio recorded. A button within the MSK-Tracker will be used to record consent and start the recording for those patients who agree. Verbal patient consent will also be recorded on the audio file and will be reconfirmed at the end of the recording. If at the end of the recording either the patient or the clinician does not want the recording to be saved it will be deleted and not used in the research.

Consent - interviews
Patients taking part in the quantitative survey may be given the option of also consenting for an invitation to take part in an interview. This additional consent option will be switched off when enough patients for interview have been identified. When patients complete their 2 week follow-up they will be asked if they are interested in taking part in additional related research. A patient information leaflet about the additional research will be available to view online. The patient will then be presented with a consent form to complete if they decide to take part. The patient will consent to taking part in the interview and sharing their name and telephone number with the researcher to arrange the interview by clicking on the consent button on screen and entering their name, telephone number and best time to be contacted.

7.3 Baseline data

During all phases of the study, patients will complete a baseline assessment within the electronic survey prior to attending clinic. The assessment consists of the MSK-HQ, Consumer Health Activation Index, and demographic information including age, gender, work status, site of main presenting MSK problem, level of education, pain related days off work over the past three months, pain episode duration and how many times they have attended healthcare for an MSK problem in the past year. The full list of data is provided in Table 1 (page 20).

7.4 Follow up data at 2 weeks

Patients will complete an assessment using the e-PROM/MSK-Tracker 2 weeks after their clinic appointment. See Table 1 (page 20) for details of the assessment questions.

7.5 Follow up data at 3 months

Patients will complete a further and final assessment 3 months after their clinic appointment. See Table 1 below for details of the assessment questions.

Table 1: Patient survey variables

Variable name	**Frequency (Baseline / 2 Weeks / 3 Months)**
Pain site and diagnosis (Please indicate on this body chart where the particular health problem(s) for which you have sought treatment from this service is located. You may select more than one)	**Baseline**
At follow-up a pain site reminder is given to patients (the software displays the body manikin picture with lit-up areas in colour that the patient selected in their pre-clinic survey)	**2 Weeks / 3 Months**
Demographic and additional items	
Episode duration (1 Item)	**Baseline**
Age (1 Item)	**Baseline**
Gender (1 Item)	**Baseline**
Previous physio treatment for this problem (1 Item)	**Baseline**
Previous Surgery (1Item)	**Baseline**
Referrer (1 Item)	**Baseline**
Use of medication at intake (1 Item)	**Baseline**
Comorbidities (1 Item)	**Baseline**
Index of Multiple Deprivation (1 Item)	**Baseline**
Ethnicity (1 Item)	**Baseline**
Health Literacy single-item literacy screener (1 Item)	**Baseline**
Assisted at Q1 (Baseline Q) (1 Item)	**Baseline**
Carer status (1 Item)	**Baseline**
Patient reported outcome measures	
MSK-HQ (14 Items)	**Baseline / 2 Weeks / 3 Months**
Work Productivity Activity Index questionnaire (6 Items)	**Baseline / 3 Months**
The Consumer Health Activation Index (10 Items)	**Baseline / 2 Weeks / 3 Months**
The patient enablement instrument (PEI) (6 Items)	**2 Weeks / 3 Months**
Global change (1 Item)	**2 Weeks / 3 Months**

Patient reported experience measures	
Treated with Care & Respect, and Understanding & Engagement (using the Valuing Patients as Individuals Scale) (6 Items)	**2 Weeks**
Friends and family test Experience of accessibility of service Experience of the environment of service As a result of your visit are you accessing less or more NHS care?	**2 Weeks** **2 Weeks** **2 Weeks** **2 Weeks and 3 months**
NHS England's three shared decision making questions (3 Items)	**2 Weeks**
Phase 2 and 3 only: For phase 2 and 3: patients will be asked about a few additional questions to capture their feedback on the feasibility of the online MSK-Tracker system within the 3 month questionnaire.	
MSK-Tracker feasibility (4 Items) (phase 2 and 3 only)	**3 Months**

7.6 Qualitative assessments – Nested studies

There are four different sections of qualitative research within the study:

1. To contribute directly to the iterative user testing in phase 2
2. To explore how the MSK-Tracker changes the nature of consultation conversations
3. To interview patients and clinicians about their experiences of using the MSK-Tracker
4. To explore how MSK-Tracker aggregated data informs service quality improvement

Each of these are now outlined in further detail below.

There is also some PPIE activity described below which forms an integral part of the iterative user testing in phase 2 in section 7.6.1.

7.6.1 To contribute directly to the iterative user testing in Phase 2

During phase 2 of the project we aim to optimise the MSK-Tracker through an iterative user testing process with patients, clinicians, software provider, and experts. The purpose of this phase is to identify specific difficulties people have with using the system and solutions to how these could be improved. This is different from the interviews in phase 3 where the purpose will be to explore how MSK-Tracker impacted on the care of patients. The optimisation of the MSK Tracker will be achieved using:

a) Informal assessment of usability, including ongoing feedback and co-design with members of the study patient advisory group (non-research activity)

b) Interviews to assess user experiences of patients who have interacted with the MSK-Tracker as part of the clinical care

c) Interviews to assess user experiences of the clinicians who have interacted with MSK-Tracker as part of patient consultation

The interviews will be conducted within the context of early pilot testing by mirroring the processes patients and clinicians will use in phase 3. For the usability assessment we will seek to work with the study existing patient advisory group members. For the qualitative assessment of user experiences, we aim to recruit sufficient numbers of patients to interview up to 20 patients (in up to 2 cycles of 10 patients) and interview approximately 10 clinicians who have used the MSK-Tracker in clinic. Patients and clinicians will consent to be interviewed about their experiences of using the MSK-Tracker with the aim of identifying further improvements that can be made to the product. Phase 2 will consist of up to two cycles of user testing with up to two periods of system redesign and refinement to ensure iterative development of the MSK-Tracker:

- Cycle 1: Usability and user experience testing (patients and clinicians) of first full version of the MSK-Tracker
- System redesign and refinement based on feedback from Cycle 1
- Cycle 2: Usability and user experience testing (patients and clinicians) of the second full version of the MSK-Tracker (focussing on the refined aspects)
- System redesign and refinement based on feedback from Cycle 2

Recruitment during Phase 2 (at first clinical site only)

PPIE: We will invite existing members of our study patient advisory group plus additional members of the Keele Research User Group who have musculoskeletal conditions to attend a stakeholder meeting at the Research Institute at Keele University for the informal assessment of usability.

Patient recruitment: During phase 2 of the MSK-Tracker study patients will be recruited to the MSK Tracker study as in phase 1, however they may also be invited to take part in an interview when they complete their 2 week follow-up questionnaire online. Patients will be asked if they are interested in taking part in an interview about their experiences of using the MSK-Tracker. A patient information leaflet will be available for patients to read before deciding if they wish to take part. Consent will be taken online and patients who consent to take part will be asked to provide a telephone number and preferred day/time for the researcher to ring to arrange an interview. Interviews will take place at a time and date convenient to the patient and will be conducted via Skype or telephone with a member of the research team.

At the start of the interview patients will be asked about their attitudes towards technology and previous use of technology. They will also be asked to complete the System Usability Scale (Brooke, 1996) which provides a global view of subjective assessment of usability.

Clinician recruitment: Clinicians involved in treating the patients recruited to the MSK Tracker study will be invited by email or telephone to attend a Skype or telephone interview with a researcher. They will be provided with a participant information leaflet outlining the purpose of the interview and their role in it, and an informed consent form to sign and return to the research team.

[Brooke, John. "SUS-A quick and dirty usability scale." *Usability evaluation in industry* 189.194 (1996): 4-7.]

Method

Cycle 1

Informal assessment of usability: At the PPIE stakeholder workshop, the room will be set up with a laptop for use by each participant. They will be asked to use the MSK-Tracker to complete a series of 5-8 predefined tasks. As PPIE members undertake a task, they will be encouraged to talk about how easy or difficult the task is to complete. Each task will relate to one of the six main components of the MSK-Tracker (Registration, Pre-clinic preparation, Clinic dashboard, Summary action plan, Personal goal setting, Follow-up and monitoring). The nature of each task (along with the task start point and success criteria) will depend on the final design of the MSK-Tracker but will likely include:

- Using the website URL, they will be required to access and complete the registration page
- Complete the MSK-HQ questionnaire and additional baseline data
- Complete their clinic agenda (choose the items they wish to discuss in their consultation)
- View the clinician dashboard (to ensure clarity and transparency to the patient)
- Access and view their summary action plan, and access some of the information links provided
- Access the personal goal setting page and add one personal goal
- Access and view MSK-HQ scores on the Tracker Charts

When all tasks are completed, PPIE members will discuss with the researchers as a group any difficulties encountered and be encouraged to talk about how the MSK-Tracker could be improved. Outcomes of the meeting will be documented on flipcharts and notes and collated with feedback from patient and clinician interviews to inform refinement of the MSK-Tracker. At the end of Cycle 1, PPIE members will be sent feedback about how they have informed the refinement of the MSK-Tracker.

Patient feedback interviews: Up to ten patients will be recruited to attend a Skype or telephone interview with a researcher to discuss their experiences of using the MSK-Tracker. The purpose of the interview is to identify and focus on specific difficulties people had with using the system over a period of time and how these could be improved. The format of the interview will broadly be as follows:

1. Welcome and introductions
2. Confirming of informed consent forms
3. Patients will be asked to complete the short questionnaire (attitudes towards technology, previous use of technology, System Usability Scale)
4. General discussion of patients experiences of using the MSK-Tracker
5. A researcher will discuss each of the six components of the MSK-Tracker with the patient. The patient will be asked to discuss any difficulties they had using each component. Our PPIE group will help inform the discussion topic guide but prompts will focus on ease of organisation of items on the screen, adequate use of information, intuitiveness and ease of navigation, ease of reading, consistent use and placement of similar information/graphics, quality and adequacy of feedback.

6. The patient will be asked to discuss about the general layout of the MSK-Tracker interface, including the use of colour, graphics/images, text size and readability of the text, and the MSK-Tracker brand name and logo
7. Patients will be asked to discuss and suggest any improvements to the MSK-Tracker not already highlighted in the earlier discussions.
8. Summary, thank you and closure

Notes will be taken by the researcher throughout the interview and will be used to inform refinement of the MSK-Tracker.

Table of feasibility questions: Items included on the short questionnaire provided to patients at the start of the interview

Item	Response options
In general, I enjoy using technology like computers, tablets and smart phones?	Strongly agree, Agree, Neither agree or disagree, Disagree, Strongly disagree
How often do you use technology to: • Research health information such as conditions, treatments, or drugs on a web site • Take part in online shopping or auctions (e.g. Amazon, eBay) • Play games with others on the Internet • Pay bills through a website	Never, Once a month, Once a week, Daily, Several times a day:
10-item System Usability Scale (SUS): • I think that I would like to use this system frequently. • I found the system unnecessarily complex. • I thought the system was easy to use. • I think that I would need the support of a technical person to be able to use this system. • I found the various functions in this system were well integrated. • I thought there was too much inconsistency in this system. • I would imagine that most people would learn to use this system very quickly. • I found the system very cumbersome to use. • I felt very confident using the system. • I needed to learn a lot of things before I could get going with this system.	Strongly agree, Agree, Neither agree or disagree, Disagree, Strongly disagree

Interviews with clinicians via Skype or over the telephone: The researcher will contact the clinician via telephone or email to arrange a convenient time for the interview. Prior to the interview, clinicians will be sent an email confirming the details of the interview, a copy of the participant information leaflet and consent form.

The interview will start with a general discussion of the clinician's views of using the MSK-Tracker in clinic. The researcher will then talk through each of the clinician-facing components of the MSK-Tracker i.e. the Clinician Dashboard and Summary Action plan. Clinicians will be asked to discuss any difficulties they have experienced using each component. Discussion prompts will focus on ease of use, organisation of items on the screen, compatibility and interaction with other clinical systems, items on the screen, adequate use of information, intuitiveness and ease of navigation, ease of reading, consistent use and placement of similar information/graphics, quality and adequacy of feedback. The System Usability Scale (Brooke, 1996) will form part of the interview.

Clinicians will be asked to discuss about the general layout of the MSK-Tracker interface, including the use of colour, graphics/images, text size and readability of the text, and the MSK-Tracker brand name and logo

Clinicians will be asked to discuss and suggest any improvements to the MSK-Tracker not already highlighted in the earlier discussions.

MSK-Tracker system redesign and refinement: Based on the feedback from users and PPIE members in Cycle 1, the design team (including clinicians, patient representative and experts) will amend the System Specification Document to instruct the developers to refine the MSK-Tracker accordingly.

Cycle 2 (if required): After the developers have revised and refined the MSK-Tracker, a further cycle of usability and user experience testing may take place, following a similar format to Cycle 1, depending on a decision made by the team on the need for a further round of iterative changes. The main purpose of an additional meeting will be to focus on any further refinements required for the MSK-Tracker.

Informal assessment of usability: A second stakeholder workshop of the PPIE member will be convened. As before, the room will be set up with a laptop for use by each PPIE member. They will be asked to use the MSK-Tracker to complete a series of predefined tasks. As PPIE members undertake a task, they will be encouraged to talk about how easy or difficult the task is to complete. The number and nature of the tasks (along with the task start point) will depend on the changes made to the MSK-Tracker.
When all tasks are completed, PPIE members will discuss with the researchers as a group any further difficulties encountered and be encouraged to talk about how the MSK-Tracker could be improved. Outcomes of the meeting will be documented on flipcharts and notes. At the end of Cycle 2, PPIE members will be sent feedback about how their contributions have informed the further refinement of the MSK-Tracker.

Patient feedback interviews: Up to 20 new patients will be recruited into the MSK Tracker study after the refinements to the MSK-Tracker following Cycle 1 have been made. Participants will be invited to attend a telephone or Skype interview with a researcher to discuss their experiences of using the MSK-Tracker, with the expectation of achieving up to 10 patient interviews. The purpose of the interview will be to identify specific difficulties people had with using the system over a period of time and how these could be improved. **Specific focus will be made on the components that were refined following Cycle 1**. Patients will be invited and recruited in the same way as Cycle 1. The format of the interview will also be the same as described in Cycle 1.

Clinician feedback interview: Clinicians involved in treating these patients will be invited to attend a second interview via telephone or Skype (if preferred) with a researcher to discuss their experiences of using the MSK-Tracker during clinic. It is anticipated that this will be a much shorter interview than in Cycle 1. The purpose of the interview will be to identify specific difficulties people had with using the system over a period of time and how these could be improved. **Specific focus will be made on the components that were refined following Cycle 1**. Clinicians will be invited and recruited in the same way as Cycle 1. The format of the interview will also be the same as described in Cycle 1.

MSK-Tracker system redesign and refinement: Based on the feedback from users and PPIE members in Cycle 2, the design team (including clinicians, patient representative and experts) will amend the System Specification Document to instruct the developers to refine the MSK-Tracker accordingly.

Analysis

As the purpose of the user testing phase is to identify specific problems with and improvement to the MSK-Tracker, the analysis of qualitative data in phase 2 will be focussed. This information will be used to refine and improve the MSK-Tracker. A deductive framework analysis methodology (Ritchie, J & Spencer, L 1994, 'Qualitative data analysis for applied policy research', in B Bryman & R Burgess (eds.), Analyzing qualitative data, Routledge, London and New York, pp. 173–94) will be applied using a priori issues relating to the usability of the MSK-Tracker along with relevant themes that emerge from the data. The a priori issues will consist of:

- ease of use
- organisation of items on the screen
- adequate use of information
- intuitiveness and ease of navigation
- ease of reading and inappropriate use of terminology/jargon
- consistent use and placement of similar information/graphics throughout the system
- quality and adequacy of feedback
- compatibility and interaction with other clinical systems
- use of colour
- use of graphics/images
- adequacy of text size and readability of the text
- engagement (logo, branding)

7.6.2. To explore how the MSK-Tracker changes the nature of consultation conversations

To evaluate the impact of the MSK-Tracker on the consultation in respect to the focus of what is discussed with the patient, we will use audio recordings of a purposive sample of approximately 20 consultations from Stage 1 and again approximately 20 consultations from Stage 3, where patients and clinicians provide consent, in order to examine the content of what is discussed during the consultation. In particular we will examine the proportion of time in both phases spent in discussing;

the biomedical cause of the symptoms, the patient's treatment options, ways in which the patient can self-manage, return to work or support at work issues, specific concerns identified by the patient, and aspects of long-term management beyond the immediate consultation. A descriptive content analysis will be conducted by a qualitative researcher to identify differences between phase 1 and phase 3.

Recruitment and consent – for the consultation recording: The study patient information leaflet sent to patients at the start of the study will alert patient to the fact that they may be asked if their consultation can be audio recorded. On attending clinic, patients taking part in the study will be asked by their clinician if they consent to the audio recording of their consultation. Consent will be recorded on the Tracker and consent will be checked with the patient again at the end of the recording ensuring patients can change their mind easily.

7.6.3. Individual interviews with patients and clinicians to explore experiences of the MSK-Tracker

Baseline patient interviews in phase 1 will establish a baseline and map current experiences of clinic consultations and patient empowerment through supported self-management. The experience based co design (EBCD) (reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2565809/) will be applied. Patient recruitment: Following completion of their 2-week follow-up questionnaire online, patients will be asked if they are willing to take part in additional related research. A link to an online patient information leaflet will be available providing detailed information relating to the interview (see section 7.2 for full details of consent). We will seek to interview approximately 10 patients. Patients will be asked if they are able to be interviewed over the telephone or via Skype about their clinic experiences.

Baseline clinician interviews at the end of Phase 1 and prior to the beginning of the phase 2 clinician interviews will be used to establish a baseline and map current experiences of clinicians' views of consulting with MSK patients and empowering patients through supported self-management and better healthcare planning. Individual clinicians taking part in the MSK-Tracker study will be provided with a participant information leaflet and consent form and will be asked to return the consent form to the research team informing them when would be convenient to contact them for their interview over the telephone/via Skype. The EBCD approach will again be applied (approximately 10 clinicians). Building on existing insight into the aspects of consultations that matter to patients and clinicians, this baseline will establish clinicians' experiences of consultations without the MSK-Tracker being available.

There will be 10 touchpoints covered. The clinician and patient interviews will cover the same or extremely similar touchpoints so that we have a 360 degree perspective on the conversation.

The full list of touchpoints is given below. Supported by our regular PPIE involvement in the study and our clinician expert advisors, this full list will be shortlisted to 10 touchpoints:

1. Establishing rapport and setting the clinic agenda; exploring and understanding what matters to me (patients)
2. Getting "must do" work done (clinicians only)
3. Getting to the bottom of the story
4. (Educating and providing information) being educated; getting information I need
5. (Supporting) improving self-management

6. (Explaining) understanding test results, clinical measures and terms in simple words
7. (Explaining) understanding the options; making choices
8. Sharing decisions; making changes
9. Setting goals and personal outcomes
10. Getting to know each other; feeling understood i.e. relationships between patients and clinicians
11. Learning from one another; experiencing “lightbulb moments”
12. Working with technology and IT in clinic
13. Documenting treatments and actions (clinician only)
14. Reflections after the appointment
15. Professional fulfilment (clinician only)
16. Satisfaction with the quality of the clinic conversation
17. Progressing towards personal goals and outcomes

The discovery process applied with both groups around these touchpoints will enable personal reflection and discussion, and will focus heavily on how each party feels (including negative emotions and fears as well as positive emotions like hope, inspiration and trust). It will also capture perceptions of the clinic conversation process and any contextual factors that people perceive impact on the nature of the clinic conversation and what happens after.

In addition, clinicians will be asked the following open questions:

- What is the best thing about your current clinic conversations with patients?
- What is the worst thing about your current clinic conversations with patients?
- What helps you have person centred conversations?
- What hinders you having person centred conversations?
- What is the one thing you would change so you can have more person centred conversations?

In addition, patients will be asked the following open questions:

- What is the best thing about your current clinic conversations?
- What is the worst thing about your current clinic conversations?
- What helps you share what matters to you in clinic appointments?
- What hinders you sharing what matters to you in clinic appointments?
- What is the one thing you would change so you and your clinician focus more on what matters to you?

Follow up interviews in Phase 3

Patients and clinicians will also be interviewed during phase 3 to establish whether and how the introduction of MSK-Tracker has altered their perceived experience of clinic conversations and patients’ ability to take control of their health issues. Patient and clinician recruitment will mirror the processes used in phase 1. The follow up questions will mirror the same shortlisted 10 touchpoints,

agreed at baseline, so comparison is possible, only adding their views about the influence of the MSK-Tracker on their MSK consultations. The following guide will be used:

With clinicians:

- What is the best thing about using MSK-Tracker in clinic conversations with patients?
- What is the worst thing about using MSK-Tracker in clinic conversations with patients?
- How does MSK-Tracker help you focus on and have more person-centred conversations?
- What gets in the way of MSK-Tracker supporting person-centred conversations?
- What is the one thing you would change about MSK-Tracker so that it supports you to have even more person-centred conversations?

With patients:

- What is the best thing about using MSK-Tracker in clinic conversations?
- What is the worst thing about using MSK-Tracker in clinic conversations?
- How does MSK-Tracker help you focus on and share what matters to you in clinic conversations?
- What gets in the way of MSK-Tracker supporting you to share what matters to you in clinic appointments?
- What is the one thing you would change about MSK-Tracker so that you and your clinician focus even more on what matters to you?

With both parties and where individuals are interested in exploring these questions, researchers will also capture:

- What surprised people about how MSK-Tracker changed things
- What resonated with peoples' previous experiences
- What people learnt from using the tool
- What people will stop, start and continue to do
- Advice to researchers and others around scaling up MSK-Tracker (including identification of particularly appropriate or inappropriate patient groups to use the Tracker).

7.6.4. To explore how MSK-Tracker aggregated data informs service quality improvement

It is anticipated that the MSK-Tracker, as well as empowering patients, will be useful for generating aggregated feedback about what matters to patients that MSK Service providers (and potentially commissioners) can use to support continuous quality improvement.

For the purposes of this study, anonymised data generated from MSK-Tracker will be combined with insights generated from the EBCD research programme as this mirrors what would be possible in the real world.

The research team has already conducted a Stakeholder Workshop with service provider leads, commissioners and PPIE group representatives and explored what matters to them in relation to great Quality Improvement (QI) insight.

The key findings were the MSK-Tracker QI data set should immediately:

1. Be designed for three end users, with data presented in formats that are easy to use for each group:
    - The individual person and their support circle
    - The provider and their front line clinical teams
    - Commissioners and others who manage the whole system at a clinical site level
2. Include an equal balance of qualitative and quantitative data
3. Focus on what matters to patients, most especially their emotional journey and supporting the enablers that help them to improve their lives

The research team have responded to these three immediate recommendations.

The group also recommended that in time in the future (beyond the life of this study), the MSK-Tracker QI data set should aim to:

- Enable MSK-Tracker QI data to be triangulated with National Health Service (NHS) service use data and/or patients' self-reported service use data so that the whole system impacts of introducing MSK-Tracker can be measured as part of routine/real time business intelligence
- Explore the potential for MSK-Tracker to generate feedback from staff to support reflective practice at the end of clinic conversations
- Look at how partners, spouses or other family carers who are an important source of support for patients can access the tool with permission from patient
- Ensure data collection can continue beyond 3 months.

Building on the findings from the Stakeholder Workshop we have already held with service provider leads, commissioners and PPIE group representatives, this EBCD programme will have two phases using two workshops;

1. The Experience Led Commissioning (ELC) Programme (www.elcworks.co.uk) – experts in quality improvement and in interpreting and translating patient and staff feedback into actionable improvement insights - will run a joint workshop with a co-design team of PPIE members and end user clinicians and managers, including organisational and clinical leads from the MSK interface service and present a 'mock up' presentation of QI insight, aimed at the three end users. The MSK-Tracker development team and the software provider will also attend the workshop so that they can hear discussions first hand.

Our co-design team of experts by experience will positively challenge and improve the presentation of the QI data, feeding back what they like about it and what they would like to see change and improve. They will also reflect on what they might stop, start and continue to do when they have business intelligence of this kind available to them.

2. Towards the end of phase 3, researchers will analyse anonymised data and combine insights generated (downloaded) from MSK-Tracker (including PROMs, process and activity data) with insights gained from the qualitative EBCD insights generated from frontline clinicians and patients' experience of clinic conversations with and without MSK-Tracker.

Building on the feedback from the initial co-design workshop, The ELC Programme will present the QI data for the three end user groups as actionable insights so that those leading delivery and improvement of the local MSK service can use this information for quality improvement purposes.

This will happen at a QI Challenge Workshop with local service leaders, clinicians and patients at each participating site. All stakeholders will have the opportunity to work with their QI data, and respond with key improvement actions. In a safe space for reflection and exploration, workshop participants will discuss whether the findings are in line with their expectations; their perceptions of what might underpin and explain their performance, and whether and how they can use the feedback to influence quality improvement going forward.

They will also feed back to the research team and the ELC Programme their thoughts about the trustworthiness, credibility, value, usability and utility of the QI insights and how their presentation and utility can be further improved. This will in turn inform the design of the MSK-Tracker and recommendations around how it can be harnessed to support quality improvement at personal, service provider and whole system levels. Following this workshop, where data is already available, the final QI report will be improved so that the team's understanding about what such a report should contain for maxim utility is not lost.

7.7 Withdrawal criteria

Patients can withdraw at any time. Withdrawal will mean no further reminders or emails to complete online questionnaires will be sent. Any information provided up to the point they withdraw will be used unless the patients asks for their data to be destroyed.

7.8 End of study

The study end point is either when the last participant recruited in phase 3 completes their 3 month follow up, or the final qualitative interview or workshop is completed (whichever is last).

8 STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

The primary outcome of this trial is the patient enablement instrument (PEI) at 2 week follow up. As patients are asked to retrospectively rate the level of enablement, at the 2-week follow up, as a result of their visit to the Staffordshire Musculoskeletal Interface Service we only have a score at a single time point (and not a change score) for each group of patients in Phase 1 and Phase 3. The Patient Enablement Instrument consists of six items graded on three-point scales. It is scored between 0 and 12 and a high score represents more enablement. The sample size was generated based on that required for an independent groups two-sample t-test with a two tailed 5% significance level at 80% power. As no Minimally Clinically Important Difference (MCID) relevant to the specific context could be found for the PEI, the study is powered to find a 0.40 effect size – representative of a small to medium effect. The expected SD for the population is 3.86 thus, the implied MCID between the groups would be a score of 1.55 scale points. Accordingly, the required sample is 100 in each arm. If we account for 50% dropout and missingness, the target recruitment is 200 in both phases 1 and 3.

8.2 Planned recruitment rate

The target recruitment will be 200 participants (in both phase 1 and phase 3.

8.3 Statistical analysis plan

Initially, descriptive data will characterise the study sample. A descriptive statistical analysis will provide estimates of the extent to which, between phase 1 and phase 3, the use of the MSK-Tracker changed the content and time spent on topics of patient concern in the clinic consultations. A formal hypothesis testing of the effectiveness of the MSK-Tracker to empower patients using the patient

enablement scale will be conducted. Estimates of mean differences will be calculated between phase 1 and phase 3 with 95% confidence intervals (and with adjustment for any important differences between phase 1 and phase 3 participants, if appropriate). Additionally, by calculating between-group effect sizes on a range of clinical outcomes, the analysis will seek to identify on which outcomes the MSK-Tracker implementation has had impact. If a clinically meaningful difference on an outcome lies within the confidence interval, this will support evidence of an effect of the MSK-Tracker. Changes in clinician behaviours reported on the case report forms will be examined to test if there are significant differences in these behaviours between 'before' and 'after' phases i.e. phase 1 and phase 3.

Feasibility will be determined if greater than 50% of both patients and clinicians agree that the MSK-Tracker is acceptable and useful in routine clinical care based on items in the 3 month follow-up questionnaire to patients, and the interviews with patients and clinicians in phase 3.

9 DATA HANDLING

9.1 Data within the MSK-Tracker is to be captured through secure online forms ensuring that all regulatory requirements are met, including the new General Data Protection Regulation (GDPR), NHS Information Governance, and GCP. The secure servers will be operated using SSL secure environments and all based and managed in the UK, with Keele University being the 'data controller' and the software company operating as the 'data processor'. The software company hold a Level 2 IG Toolkit awarded by NHS Digital England. The consenting process will be clearly outlined and the patient/potential participant will have to agree to the study and what information is being shared (and with whom) at the end of the baseline pre MSK-Tracker/MSK-Tracker to allow the patient to be 100% clear on exactly what information they are consenting to share. Consent is contained within the survey itself, ensuring that it is not possible to save data if consent is not given. In the case where data entry is started but does not reach participant consent, additional security is provided through the links used to access the survey data to ensure an individual's data is not reusable and perishes after 4 days. As part of the baseline pre MSK-Tracker/MSK-Tracker, a minimal set of participant identifiable data will be collected in order to ensure an individual is correctly identified at subsequent login to the MSK-Tracker and that the right participant is identifiable for follow-up survey completion. At the end of each phase of the study and once the study is completed, Keele University researchers will be provided with quantitative data sets that are anonymized (have all participant identifiable data removed). Qualitative data will also be transferred from PROMAPP to Keele University after each phase of the study, however due to the nature of this data e.g. recording of consultations, it may potentially contain identifiable data. Transfer of all data between the data processor and data controller will be managed using industry standard encryption and transfer methods - Secure File Transfer Protocol (SFTP), which enables the secure movement of files from one computer to another using encrypted communications to properly authenticate and establish secure links between hosts over the Internet. The SFTP Client will be used by the Trial Manager/Study Coordinator to allow them to transfer the anonymised data returned from the MSK-Tracker to the study master file. When the study is complete and data securely transferred, the software company will delete all data they hold relating to participants in this study.

If a patient consents to take part in the additional qualitative research, a notification will be sent via secure email from the online digital health platform to the study's NHS.net account. This email will contain the following data which the patient has provided and consented to share with the researchers at Keele University; study ID number, full name, telephone number, best time to contact. Authorised individuals from the research team will have access and be able to process this data. These details will be held in a password-protected spreadsheet stored on the secure network until the interviews have been completed.

Participant details will be stored in the local investigator site file. The site will maintain a record of all patients invited into the study along with an ID allocated to each at the time of invitation mailing. At the

end of the study the site will be notified of the ID of each patient consenting to take part in order to maintain a full list of all consenters for the investigator site file.

9.2 Data Sharing Agreements

Keele (Clinical Trials Unit) CTU is committed to sharing access to our anonymised research databases derived from our population, consultation, clinical, and RCT cohorts. Any requests for access to the anonymised data from anyone outside of the study team (e.g. collaboration, joint publication, data sharing requests from publishers) will be reviewed. The full statement on data sharing can be found at www.keele.ac.uk/pchs/datasharing. All information will be held securely and in strict confidence. Each person in this study will be given a study ID so that data from the study will not have any identifiable information, such as names and addresses. On this basis, these anonymised data will be kept electronically and may be used in other research studies.

9.3 Data Archiving

At the end of the study, data will be securely archived in line with the Sponsor's procedures for a minimum of 10 years after the publication of the study findings. A record of consent will be held in the local investigator site file. All other data will be held by Keele CTU and will be archived in the designated Keele CTU archive facility. Following authorisation from the Sponsor, arrangements for the destruction of all confidential data will be made.

10 MONITORING & AUDIT

10.1 Study Management

The study will be managed by Keele Clinical Trials Unit (CTU) adhering to its Standard Operating Procedures. The trial manager will convene a Study Management Group consisting of the study lead (Hill), all the co-applicants including the PPIE member, those from Oxford and the external partners. Monthly study management meetings will forward plan and review progress against timelines, ensure sufficient staffing support and planning, delivery and analyses within all phases of the study. Based on the specified research plans, an IT specification has been developed and a linked formal contract with the software provider to ensure feasible delivery plans. Each work phase will convene monthly team meetings to plan and deliver research plans. Our experience demonstrates that this combination of detailed plans with regular study team meetings, and Study Management group meetings ensures successful delivery. Good communication across the study will be facilitated by commonly shared study specific and protected drives on the University's network.

10.2 Safety Reporting

The NHS Health Research Authority (HRA) definition of a Serious Adverse Event (SAE) is an untoward occurrence during the conduct of the study that:

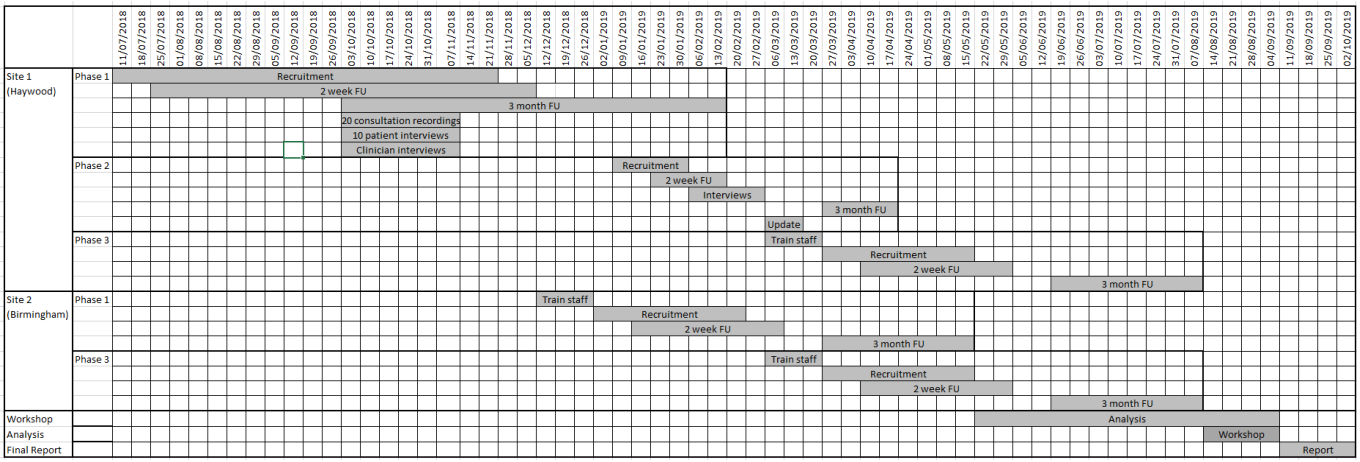
- results in death;
- is life-threatening;
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- consists of a congenital anomaly or birth defect, or
- is otherwise considered medically significant by the investigator(s).

An SAE occurring to a research participant must be reported to the Research Ethics Committee (REC) where in the opinion of the Chief Investigator the event was: "Related" that is, it resulted from administration of any of the research procedures, and "Unexpected" that is, the type of event is not an expected occurrence as a result of the intervention provided.

The potential harms of this study on patient safety are considered to be minimal as treatment is not affected, the MSK-Tracker is an additional tool to empower patients to manage their own MSK condition within a usual care environment. Information given to patients through use of the MSK Tracker are considered not only to be evidence-based but also have strong clinical community endorsement and credibility.

Reporting procedures will be made clear during the protocol study training and will be contained in site files for all clinicians involved in the study. If Keele CTU become aware of any SAE's these will be dealt with according to Keele University SOP 20 (Safety Reporting and Pharmacovigilance). Adverse events will not be investigated.

10.3 Trial timeline



11 ETHICAL AND REGULATORY CONSIDERATIONS

This study will be submitted for approval by an appropriate NHS Research Ethics Committee and to the Health Research Authority (HRA). It will also be submitted for inclusion within the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio.

Patient data (in an electronic format) will be acquired, anonymised, transferred and stored according to the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679); the Confidentiality—NHS Code of Practice (46); and the Caldicott principles (47).

11.2 Peer review

An external scientific panel reviewed the study funding proposal on behalf of the Arthritis Research UK, Health Service Research award panel. As a result the study has had extensive peer review as part of that 2-stage application process. For example, we were asked to strengthen the justification for our choice of the MSK-HQ over other measures, and to acknowledge that this was not a definitive randomised controlled trial of the MSK-HQ effectiveness as an intervention.

11.3 Public and Patient Involvement

The Research Institute for Primary Care & Health Sciences at Keele University has a strong Patient and Public involvement and Engagement (PPIE) infrastructure, supported by Arthritis Research UK Centre of Excellence funding, which includes a large Research User Group (RUG) advising on all studies within this institute. For this study, a group of patient representatives have been invited from the current RUG members to form a patient advisory group to contribute to the consensus workshops with stakeholders, interpretation of results, and development of evidence summaries and other information materials. Steven Blackburn leads this group. His role will focus on providing coordination

and support to ensure strong and appropriate PPIE during the design and delivery of the proposed study, ensuring effective working relationships between members of the patient advisory group and the study team, one member of the group is a study co-applicant.

PPIE has already contributed to the research design by:

- Stressing the importance that patients “have a voice” during the stakeholder workshops and throughout the study process to ensure that it remains patient-centred.
- Advising on how patients can play an active and meaningful role during the iterative development of the MSK-Tracker and the delivery of the study.
- Confirming that patients would prefer to complete the consultation prompt of the MSK-Tracker prior to attending the consultation.
- Suggesting that patients would find it useful and acceptable to complete the MSK-Tracker on a touchscreen device.
- Confirming that the proposed outcome measures were important from a patient perspective, particularly feelings of empowerment in shared-decision making process. The PPIE group also made suggestions to capture how the MSK-Tracker changes the relationship between the patients and MSK practitioner and how patients engage in their own care planning. Therefore, we have included a secondary outcome measure to examine the changes in the nature of the consultation conversation.

Ongoing PPIE

RUG members have agreed to be involved during the study as part of a patient advisory group. The RUG members’ input has helped to shape the development of the MSK-Tracker and the delivery of the study, ensuring that it remains focussed on patients’ needs. One member of the RUG has joined as a member of the study team and will continue to provide advice based on their lived experience of having a chronic painful musculoskeletal condition. Their key role will include:

1. To contribute to and review participant facing study documents used in the study
2. To provide the patient perspective on the design of the MSK-Tracker as part of the co-design team.
3. To contribute to and review the dissemination strategy and publications, such as materials or talks with patient forums and practitioners

In regular meetings of the patient advisory group with the research team, members of the group will:

1. Contribute to and review patient information leaflets and interview topic guides;
2. Give feedback on the MSK-Tracker prototypes
3. Help interpret the findings of the iterative user testing and the comparison study (phase 2 & 3) from a patient perspective;
4. Give advice and input to other areas of the study process.
5. Informing and contributing to how the findings of the study are shared with other patients and the wider public.

PPIE is supported by co-applicant Blackburn, along with a dedicated PPIE Co-ordinator and User Support Worker, both patients themselves. The PPIE team hold regular support and training sessions for RUG members at Keele, funded by our ARUK Centre of Excellence grant, and work with the RUG to ensure the type and level of involvement is appropriate. PPIE is organised and funded according to our PPIE Reward and Recognition Policy, in line with INVOLVE's Budgeting for Involvement guideline. This support infrastructure will ensure strong and appropriate PPIE during the development and delivery of the proposed research, and help to build relationships and trust to create effective working relationships between members of the public and researchers.

11.4 Regulatory Compliance

Data within the MSK-Tracker is to be captured through secure online forms that meet NHS Information Governance requirements. Patient data (in an electronic format) will be acquired, anonymised, transferred and stored according to the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679); the Confidentiality—NHS Code of Practice (46); and the Caldicott principles (47).

11.5 Protocol compliance

Deviations from study protocols and Good Clinical Practice (GCP) occur commonly in health and social care research. The majority of these instances are technical non-compliances that do not result in harm to the trial subjects, do not compromise data integrity, or significantly affect the scientific value of the reported results of the study. These technical deviations will be documented and processed according to the sponsors standard operating procedures.

11.6 Data protection and patient confidentiality

See section 9.1 for details of how data is protected and patient confidentiality maintained throughout this study.

11.7 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall study management

Professor Andrew Price (co-applicant on this grant) is the Chief Executive of PRO-MAPP and is remunerated for his directorship.

11.8 Access to the final study dataset

See section 9.2

12 DISSEMINATION POLICY

12.1 Dissemination policy

Findings of this study will be disseminated through patient forums, health partners, academic health sciences networks, commissioners and healthcare providers, national associations, appropriate groups within NHS England, and international organisations. A summary of the findings will be available on the Keele University website. Adoption widely across MSK centres in the UK will involve national training days and locality specific support. Funding will be sought for wider rollout through speciality associations and other agencies.

The hallmark of this proposal will be the integration of knowledge mobilisation methods (KD, KS) with research to accelerate knowledge exchange and implementation. The applicants will produce short reports (e.g. in Musculoskeletal Matters) which are available via the Keele University web-site and will be disseminated via the local Clinical Commissioning Groups (CCGs) and Arthritis Research UK's and Royal College of General Practitioners (RCGP) communication systems, to provide easily accessible, relevant information for primary care and policy-makers on musculoskeletal problems in older adults. At a local level, the applicants will produce regular updates to the CATS service, and through update meetings with MSK leads to influence local quality improvement and provide support for identifying outputs most relevant to the health needs of the local community. The importance of capturing and incorporating key messages from research within educational material for health care professionals is recognised and training and educational packages will be prepared for the Royal Colleges, professional bodies and medical charities. Additional knowledge mobilisation activities will be undertaken within the Research Institute for Primary Care & Health Sciences' Impact Framework where it will be embedded within the research strategy and operational structures (Dziedzic, Duffy, Stevenson) in order to facilitate local service improvements and

best practice. Dissemination is supported by the Primary Care Consortium Board where outputs of high quality research e.g. STarT Back (Lancet; Hill et al, 2011), are disseminated to key stakeholders e.g. DoH; QiPP Guidelines; Any Qualified Provider documentation; commissioning online toolkits; Clinical Guidelines (NICE); Arthritis Research UK/BMJ e-learning modules; RCGP curriculum modules and clinical Best Practice days. In summary, success in disseminating research findings and achieving impact is underpinned by a systematic approach to developing research that can make a real difference to patients, healthcare providers and policy makers, coupled with a strategic approach to securing collaborations and partnerships which can support rapid roll-out and translation of the research findings.

12.2 Authorship eligibility guidelines

Criteria for the authorship of scientific papers have been developed by the International Committee of Medical Journal Editors (ICMJE), and to be designated as an author on a paper an individual must fulfil all four of the following criteria:

1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2) Drafting the work or revising it critically for important intellectual content; AND

3) Final approval of the version to be published; AND

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

No-one who fulfils the four criteria in the box above should be excluded from authorship credit and, of equal importance, no-one who fails to fulfil the four criteria should receive authorship credit. This includes academic staff and students as well as CTU, administrative, informatics, IT and nursing staff where they fulfil all four criteria above. However, individuals have the right to choose not to be an author on a particular paper.

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