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Complete List of Authors:	Noblet, Timothy; University of Birmingham, ; Macquarie University Faculty of Medicine and Health Sciences, Marriott, John; University of Birmingham Rushton, Alison; niversity of Birmingham, School of Health and Population Sciences, College of Medical and Dental Sciences
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Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: protocol for a feasibility trial with an embedded qualitative component

Noblet TD, Marriot JF, Rushton AB

Mr Timothy Noblet
Centre of Precision Rehabilitation for Spinal Pain (CPR Spine)
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK
Tel: +447740360178
Email: timnoblet@hotmail.com

Professor John Marriott
Institute of Clinical Sciences
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK

Dr Alison Rushton
Centre of Precision Rehabilitation for Spinal Pain (CPR Spine)
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK

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Abstract

Introduction: Low back pain (LBP) is the most prevalent musculoskeletal-condition in the UK. Guidelines advocate a multimodal approach, including prescription of medications. Advanced Physiotherapy Practitioners (APPs) are well placed to provide this care in primary care. Physiotherapist independent prescribing remains novel, with the first prescribers qualifying in 2013. This feasibility trial aims to evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care, to inform the design of a future definitive stepped-wedged cluster trial.

Method and Analysis: 1. Trial component. An APP (registered prescriber) will complete the initial participant consultation. If prescription drugs are required within the multi-modal physiotherapeutic context, these will be prescribed. Patient reported outcome measures will be completed prior to initial assessment and at 6 and 12 weeks to assess feasibility of follow-up and data collection procedures. Accelerometers will be fitted for 7 days to assess physical activity, sedentary behavior and feasibility of use. 2. Embedded qualitative component. A Focus group and semi-structured interviews will be used to evaluate the views and experiences of the participants and APPs respectively, about the feasibility, suitability and acceptability of the proposed full trial. A CONSORT diagram will be used to analyse feasible eligibility, recruitment and follow up rates. Descriptive analysis of the data will be completed to evaluate procedures. Thematic analysis will be used to analyse and synthesise the qualitative data.

Ethics and dissemination: This feasibility trial is approved by the Health Research Authority (HRA) ethical approval was sought and granted via the Integrated Research Application System (IRAS) ID 250734.
Data will be disseminated via publication in peer reviewed journal and conference presentation. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or re-design of the essential full RCT.
Registration: ISRCTN database, Ref ISRCTN15516596

Strengths and Limitations of this Study

- First rigorous investigation aiming to evaluate the methods required to assess the clinical and cost-effectiveness of independent prescribing by advanced physiotherapists for patients with low back pain in primary care.
- The design of this feasibility trial was developed by clinicians, academics, methodological experts, health care service managers, professional leaders and the public/ patients.
- The methods will be tested across a range of cities, towns and villages in varying geographical areas across England.

BACK GROUND

Low back pain (LBP) is the most prevalent musculoskeletal condition in the UK, with 58-84% of the population experiencing LBP in their lifetime.(1-3) At any time, 28.5% of adults over 25 are experiencing LBP.(2) Data indicates that 3.2 million work days are lost per year in the UK, with an average of 16.5 days lost per case .(4) Approximately 20% of those with LBP seek care from their general practitioner (GP),(1) with 7% of all GP consultations being due to LBP.(3, 5)

Despite increased funding for treatments and a growing understanding of the complex biopsychosocial nature of LBP leading to improvements in assessment and management of the condition, up to 7% of the general population in the UK have chronic LBP associated with significant disability (1, 2) and the health and function of this demographic continues to decline.(6) In an attempt to address this, novel approaches have been adopted to inform shared decision-making and stratification tools are being utilised to improve outcomes through recognising clinical heterogeneity, ensuring that all biopsychosocial risk factors are addressed, improving patient management and reducing the overall cost of health care.(6-8) Early assessment, diagnosis and treatment of LBP has been seen to reduce chronicity.(1) However, the complex and multidimensional nature of LBP combined with a current deficit in the availability of GPs in the UK,(9, 10) has prompted the redesign of out-dated traditional LBP clinical-pathways, and the introduction of new treatment models designed to maximise clinical and cost-effectiveness, whilst readying the health services for the future.(10-12)

Physiotherapists are experts in the assessment, diagnosis and treatment of musculoskeletal disorders.(13) For more than 30 years, physiotherapists have been working in advanced practice roles across the country, utilising their scope of practice to optimise patient care, providing support in health services where the availability of medical practitioners does not meet the demands of a local community.(13, 14) Advanced musculoskeletal physiotherapists have been shown to be clinically and cost-effective in a variety of settings including orthopaedic and emergency care departments as well as in primary care in musculoskeletal interface-services.(14-16) Recently, the success and experience of these practitioners, alongside changes in demographics and predictions that GP numbers will further reduce by 2020, have prompted successful pilot studies investigating the effectiveness of first contact advanced physiotherapy practitioners (FCPs) in primary care.(11, 17) As a result, Health Education England (HEE), in collaboration with NHS England, the Royal College of General Practitioners (RCGP), the British Medical Association (BMA) and the Chartered Society of Physiotherapy (CSP) have committed to introducing these roles across England.(17-19)

Recently published guidelines from the National Institute for Health and Care Excellence (NICE) (8) for LBP and sciatica, advocate for a holistic, multimodal approach to assessment and management (3). Advanced physiotherapists are well placed to provide this care owing to their competency in physical therapies including manual and exercise therapy; knowledge and skills associated with the management of psychosocial factors; and ability to appropriately refer for blood tests, imaging, spinal injections, denervation and surgery.(20, 21) Further, the NICE guidelines recommend the use of drugs that are helpful and minimise harm.(3, 8) It is therefore envisaged that independent physiotherapist prescribing will be a key competency required for the successful implementation of first contact advanced physiotherapists working in primary care.

Independent physiotherapist prescribing remains relatively new, with the first prescribers qualifying in 2013. A recent mixed-methods systematic review of investigating the barriers and facilitators of non-medical prescribing (NMP) concludes that the successful implementation and utilisation of NMP is dependent upon adequate preparation and organisation of a range of factors.(22) Considerations such as the use of advanced physiotherapists in primary care were seen to facilitate successful

implementation of NMP as long as clinical governance, policy development and service practicalities and logistics are adequately developed and established prior to implementing NMP. To ensure longevity and future growth, education, support and financial factors alongside the management of personal and professional considerations were also deemed paramount.(22)

For clinical-services to be successful they must deliver positive clinical outcomes in a safe and economically sound manner.(23) Our recent rigorous systematic review investigating the clinical and cost-effectiveness of NMP across all professions and clinical settings, identified limited evidence with unclear risk of bias.(24) We concluded that quantifiable benefits of NMP remain unknown and called for adequately powered, low risk of bias randomised controlled trials (RCTs) in specific patient groups, professions and clinical settings.(24) Owing to the contemporary nature of independent physiotherapist prescribing, no trial has examined the clinical or cost-effectiveness of this intervention in the complex context of LBP. Trial design required careful consideration particularly as independent physiotherapy prescribing is within the process of implementation across private health services and NHS Trusts. A feasibility study is therefore required to inform a multi-centre RCT investigating physiotherapist independent prescribing by advanced physiotherapists for patients with LBP, in primary care. The project will aim to evaluate the feasibility, suitability and acceptability of procedures and outcomes for use in the full trial, also assessing the commitment and burden on participants, clinicians and researchers as well as infrastructure and technological requirements.

Aim:

To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners (APPs) for patients with LBP in primary care to inform the design of a future definitive stepped-wedged cluster trial.

Objectives:

General Objectives

- To assess the feasibility, suitability and acceptability of the proposed full trial (25) including:
  - Eligibility criteria (26-28)
  - Recruitment strategy (26-28)
  - Data collection methods (26-28)
  - Follow up procedures (26, 27)

Specific Objectives:

Feasibility:

- To evaluate participant recruitment rates.(25-27)
- To evaluate the ease of fitting participants with accelerometers and ease of data collection.(26, 27)
- To evaluate the capacity (time and effort) of clinicians and researchers to complete trial related tasks.(26, 27)
- To evaluate the necessary training requirements required by clinicians to successfully implement a full trial.(26, 27)

Suitability:

- To evaluate the range of participants' scores on the Roland and Morris Disability Questionnaire (RMDQ), assessing for floor effects and therefore the appropriateness of outcome measure for use in a full trial.(25-28)
- To evaluate participant compliance with wearing the accelerometer device.(26, 27)
- To evaluate the time required to conduct each stage of the protocol.(26, 27)
- To evaluate the appropriateness and availability of services and infrastructure such as access to national and institutional communication and information technologies required to undertake a full trial.(26, 27)

Acceptability:

- To evaluate the acceptability of the intervention to patients and the public.(25-28)

METHODS

To ensure transparency and reproducibility this feasibility trial protocol has been registered on the ISRCTN database (ISRCTN15516596) and is reported in line with the CONSORT 2010 statement: extension to randomised pilot and feasibility trials,(29-31) with all patient and public involvement (PPI) reported in line with the GRIPP2 short form reporting check list.(32, 33)

The feasibility trial will utilise a mixed-methods research approach, comprising of:

- a quantitative one-armed feasibility trial
- qualitative semi-structured interviews and patient focus groups, using thematic analysis.

Mixed methods designs are recognised to enable a richer synthesis, generating data which will facilitate appropriate change.(34-36)

Design

RCTs are considered the gold standard for evaluating the effectiveness of an intervention.(37) Cluster RCTs (cRCTs) allowing for randomisation by group have been developed to overcome practical issues in clinical settings, where individual randomisation is not convenient or feasible.(37-39) When evaluating contemporary interventions, parallel deigns requiring the new intervention to be simultaneously provided to multiple clusters of participants are often too costly or not practical owing to the necessary clinician training required to deliver the intervention safely.(37, 38) A stepped-wedge cluster randomised controlled trial (SWcRCT) design will therefore be used to evaluate the clinical and cost-effectiveness of physiotherapist prescribing for LBP in the future. This design is valuable when evaluating innovative clinical interventions where there is a strong ethical belief that the intervention will benefit patients.(38, 40, 41) SWcRCTs allow each experimental cluster to begin in the control arm then cross over to the experimental arm at specified time points (Finger 1).(40) As the implementation of independent physiotherapy prescribing and the utilisation of APPs working as FCPs are both relatively contemporary innovations, there are limited numbers of clinicians currently working in these innovative roles who are registered to prescribe. This research design allows for the use of fewer clinicians than those required for a parallel design and is therefore more reflective of current practice.(38-41)

Currently no clear framework exists describing the requirements for best practice when completing feasibility trials in preparation for SWcRCTs.(42) Two-arm feasibility trials that have aimed to calculate intra-cluster correlation coefficients (ICCs) required for sample size calculations in preparation for full cRCTs have demonstrated insufficient accuracy, unless the feasibility trial is equal in size to the proposed full trial.(42) Therefore, a single-arm feasibility design will be employed to test specific aspects of the trial protocol in terms of feasibility, suitability and acceptability on the experimental arm of the future SWcRCT, without sample size estimation.(26, 43, 44)

Trial Component

A prospective, mixed-methods, single-group feasibility trial will be utilised to evaluate the trial objectives.(28, 43) Participant consent forms (Supplementary File 1) and patient reported outcome measures (Supplementary File 2) will be completed digitally via an online survey at initial assessment (baseline) and at 6 and 12 weeks (12 weeks is the planned primary endpoint of the definitive trial)

following a prescription being issued, to evaluate the feasibility of follow-up data collection procedure.(44, 45) Follow-up time points have been selected in line with the prognostic literature showing that 40% of patients presenting to primary care with LBP will be pain free 6 weeks post onset, with 58% pain free by 12 weeks.(46-48) The online outcome measures survey will be built using REDCap (Research Electronic Data Capture) software (hosted in the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK), enabling data to be captured and stored in real-time, on a range of electronic devices.(49) Baseline measurements will be completed by the participants within the clinical setting. A link to the online outcome measures survey with instructions will be emailed to participants for completion at 6 and 12 weeks. If participants forget to complete the outcome questionnaire on the required day, a reminder to complete will be sent at 24hrs and 48hrs after the deadline to facilitate compliance.(44, 50) To evaluate the feasibility of fitting participants with accelerometers in clinic, the ease of data collection and participant compliance with wearing the accelerometer device,(26, 27) n=10 participants at one research site, will be fitted with an accelerometer to wear for 7 days immediately following completion of patient reported outcome measures at the first consultation. Participants will be provided with stamped/addressed envelopes in which to return the devices after use.

Participants

Potential participants will be identified by the APPs at each clinical site, by using the STarT Back Tool at initial assessment, to stratify all patients presenting with LBP.(7) Patients stratified into the medium risk group by the STarT Back Tool will be eligible for recruitment if they meet the inclusion criteria following assessment. This group of patients have been recognised as predominant cohort presenting for assessment and treatment of LBP in primary care; exhibiting both physical and psychosocial prognostic factors and may require physiotherapist prescribing to optimise their multimodal physiotherapeutic treatment.(7, 51-53) Convenience sampling will be adopted, as this method has the advantages of fluid recruitment and follow-up required by feasibility trials, with good retention of participants where time is limited.(27, 44, 45, 54) Patients that are interested in participating will be provided with a participant information sheet (Supplementary File 3) explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants. The physiotherapist will answer any questions and if the patient wishes to participate, consent will be obtained using an online consent form. Contact details for the research team will be provided to give the participants the opportunity to have any further questions answered. Contact details for an independent advisory service (PALS at each site) will also be provided in case external advice is desired by participants. Participants will be free to withdraw at any time, without any impact on their care.(44, 45)

Box 1: Participant Eligibility Criteria

Inclusion Criteria
• Male and female patients, aged >18 years. • Non-specific LBP +/- leg pain requiring medication advice and drug prescription on assessment • Classified as Moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment(7)) • Able to read/communicate in English (owing to funding restrictions for interpreters and translators) • Capable of following the demands inherent of the study
Exclusion Criteria
• Signs of lumbar nerve root compression(55) • Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy(55) • Spinal stenosis(56) • Suspicion of or confirmed corda equine syndrome(57) • Does not have capacity to consent(58)

Interventions

As the control arm of the definitive trial will be "current normal practice", the intervention designed for the experimental arm of the definitive trial will be utilised to evaluate the feasibility trial objectives.(25-28) As per "current normal practice", an APP acting as a FCP will complete the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP will have the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required within the multi-modal physiotherapeutic context, these will be prescribed/de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation.

Outcomes

The literature reports that the use of a core outcome set assessing pain intensity, health related quality of life and physical function is required for the assessment of non-specific LBP.(59) However, no consensus exists with regards to the instruments most suitable to measure these domains.(59) The outcome measures selected for use within the trial were informed by a team of subject-experts including physiotherapists, pharmacists, medical practitioners, academics and health-service managers and deemed most appropriate to evaluate the studies objectives whilst attempting to minimise the burden on participants. Two primary outcome measures (detailed below) were selected as they jointly evaluate the core outcome set requirements.(59) Detail of the secondary outcome measures and rationale for selection are found in Table 2.

Primary Outcome Measures

- Overall Pain, Numerical Rating Scale (NRS): The NRS is a unidimensional 11-point scale (0-10) used to measure pain intensity, where 0 represents no pain and 10 represents maximum pain (e.g. the worse pain you can possibly imagine).(60) Patients with pain have been shown to prefer the NRS over other pain measure including the pain Visual Analogue Scale (VAS) owing to simplicity and clarity.(60, 61) The NRS has demonstrated good reliability, validity and responsiveness and has been used extensively in pain research.(62-64) A reduction of 2.5 points on the NRS has been shown to be clinically important for chronic LBP.(63-65) Participants will score pain in 3 categories: “worst pain over the last two weeks”, “least pain over the last two weeks” and “average pain level today”.

- Roland Morris Disability Questionnaire (RMDQ): The RMDQ is one of the most widely used outcome measures for LBP, with well-established good levels of validity and reliability.(66) The RMDQ has been selected over its counterparts owing to its superior measurement properties in patients reporting moderate disability demonstrated by those stratified into the medium risk group by the STarT Back Tool.(7, 65, 66) The 24-item questionnaire takes approximately 5 minutes to complete and includes items assessing: physical activity, sleep, psychosocial factors, activities of daily living, appetite and pain.(67) Scores range from 0 (no disability) to 24 (maximum disability), with a change of 3.5 points deemed clinically significant.(65)

Table 1: Secondary Outcome Measures and their Rationale

Outcome	Measure	Rationale
Health Related Quality of Life (QALY)	EQ-5D 5L	The EQ-5D 5L is used to measure health related quality of life demonstrating good reliability and validity through psychometric testing.(68) If feasibility is found this measure will inform cost-utility is a full RCT.
Pain Related Fear of Movement	The Tampa Scale for Kinesiophobia (TSK)	The Tampa Scale for Kinesiophobia (TSK) is a 17-item tool which was developed to measure a person's fear of movement owing to LBP. Ongoing fear of movement has been linked to the development of long term persistent pain.(69) This outcome measure has been found to show good validity and reliability when measuring pain related fear of movement.(70)
Physical activity and	ActivPal 3 Accelerometer	Anecdotal evidence suggests that decreasing sedentary behaviour in people with LBP may have significant health benefits,(52) reducing risks of obesity, metabolic syndrome, type two diabetes and mortality.(71) Systematic reviews have revealed that physical activity of people with LBP is lower or equal to the healthy population,(72-74) however there appears to be differing patterns of physical behaviour, with the back-pain population engaging in shorter bouts of physical activity which are not long enough to incur health benefits (>10 minutes).(74, 75) An accelerometer will be used to collect data including: steps count and sedentary periods.(76) To date no individual brand/model of accelerometer has been identified as gold standard. The ActivPal 3 has been selected for use in this feasibility trial as it has been seen to be more precise and sensitive than other accelerometers.(76, 77)
Sleep	ActivPal 3 Accelerometer	50-60% of people experiencing with either acute or persistent low back pain experience high levels of sleep disturbance.(78) Poor sleep over long periods of time may lead to depression, obesity, diabetes and cardiovascular disease.(78, 79) Patients with LBP suffering with sleep disturbance have been reported as twice as likely to be hospitalised.(80) Improved sleep has been seen to modulate pain intensity,(81) with poor quality sleep associated with increased pain intensity, fatigue, decreased function and psychological stress. An accelerometer will be used to collect sleep duration data alongside physical activity and sedentary behaviour.(82)
Time to return to work and nature of return to work (e.g. full time, part time, light duties)	Days	Work absence owing to sick leave for work disability is a key issue clinically, socially and economically. The MCIC for time return to work has not been defined due to the specific measurement (days on sick leave) being widely accepted and recognition of the measure's value in social and economic issues rather than an indicator of morbidity.(65) This measure would therefore be useful when conducting economic evaluation of physiotherapist prescribing.
Prescription Utilisation, Participant	Days	Time requiring drugs for the treatment of non-specific LBP discussed/prescribed by the advanced physiotherapists will be monitored to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.
Number of appointments with other healthcare professionals about this episode of LBP	Number of appointments with each type of healthcare professional	The number of appointments with other healthcare professionals about this specific episode of LBP being studied will be recorded via a question in the outcome questionnaire to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.

Sample Size

As the number of FCP physiotherapists that are registered to prescribe is currently limited(83), three first contact Advanced Physiotherapy Practitioners (APPs) (n=3), across 3 primary care sites representative of English geography (x1 capitol city, x1 regional city, x1 rural town), will recruit, assess and treat n=10 participants per APP, to enable the evaluation of recruitment rates across clinicians and the feasibility of the trial methods in both metropolitan and rural healthcare services.(26, 42, 43) This feasibility trial does not aim to estimate the sample size required for the full trial as feasibility trials for cRCTs have been shown not to adequately predict sample size, therefore large numbers of participants are not required.(42, 84) A total sample of n=30 patients will be recruited as a sample size of n>20 is regarded as adequate when testing feasibility objectives for cRCTs.(26, 27, 42, 43) This allows for some loss to follow up of participants.

Data Analysis

A CONSORT diagram will be used to describe the flow of participants and lost to follow up rates. This will be used to analyse feasible eligibility, recruitment and follow up rates.(29) Only data from fully completed outcome questionnaires will be included in the data analysis, however the number of partly completed outcome questionnaires will be noted and reasons for this explored in the embedded qualitative component of the trial. Data will be tabulated, and primary descriptive analysis of the data will be completed to test procedure.(26, 44, 45) Causality will not be statistically analysed as this is not within the scope of this feasibility trial.(44, 45) The distribution of the scores on the RMDQ will be evaluated at baseline, 6 and 12 weeks following initial intervention. The percentage of scores equalling 0/24 at 12 weeks will be used to measure a potential floor effect.(85)

Embedded Qualitative Component

Design

An embedded qualitative component will be utilised as recommended by current guidance, to address trial objectives and to refine and adapt the proposed full trial design following evaluation.(86, 87) The methodology was designed and is reported using the Consolidated Criteria for Reporting Qualitative Health Research (COREQ)(88)

Advanced Physiotherapy Practitioners

Semi-structured in-depth face to face interviews with all of the APPs (n=3) will be used to evaluate their views and experiences about the feasibility, suitability and acceptability of the trial, specifically evaluating trials objectives.(25-28, 89, 90) Interviews will be undertaken by one researcher (TN) following completion of participant data collection, to evaluate the research objectives and to gather qualitative data regarding the participants' views, perceptions and experiences about taking part, future risks and how the trial might be improved.(26, 27) Question design was informed by the methodological literature and developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology.(44, 54) A patient and public involvement group reviewed the questions for appropriateness and clarity.(91) Prior to completing the interviews, the APP participants will be provided with an information sheet and will have the opportunity to ask the researcher any questions about the interview process. Consent to taking part will be gained using a consent form. Interviews will be recorded and transcribed verbatim. Transcripts will be returned to

participants for inspection, comments and corrections prior to analysis, to ensure all views and thoughts are captured.(89)

Patients

A focus group of patients will take place following the 12 week assessment point, specifically to evaluate the research objectives.(26, 92) Focus groups are recognised to produce data on collective views, generating a rich understanding of participants' experiences.(93) A purposive sample of 6-8 patients, representative of ages and sexes will be used; this sample size is reported in the literature as the optimum.(92) The focus group will meet in the qualitative laboratory within the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK, ensuring confidentiality. The focus group will be conducted by two researchers (facilitator and observer) using a predetermined topic guide designed to assess the research objectives, developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.(44, 54) The topic guide has been reviewed by a patient and public involvement group to ensure appropriateness and clarity.(91) Consent to participate in the focus group will be taken prior to the focus group commencing. The participants will receive an information leaflet and have the opportunity to have any questions answered by the researchers. The focus group will be recorded and transcribed verbatim. Transcripts will be returned to participants for comments/correction to ensure all views are represented. (88)

Analysis and Findings

To fulfil the trial objectives a thematic analysis approach will be used to analyse and synthesise the qualitative data.(44, 94, 95) This systematic, inductive and interactive method is recognised to be useful in identifying the key thoughts and views of the population being studied. The method is useful
where there are likely to be both similarities and diversity of opinion and where the intervention is novel, often providing explanations alluding to how the concerns may be resolved or processed in preparation for a full trial.(94-97) Focus group and Interview transcripts will be coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and be verified by a second researcher (AR).(45, 95, 96) Rigorous comparative analysis will be completed by one researcher (TN) to identify similarities and differences within the data, informing the development of descriptive categories which will be linked, merged or split to synthesise a conceptual understanding of the data.(95, 96) To avoid single researcher bias, a second researcher (AR) will re- interrogate the data to validate or contradict findings.(95) Outcomes will then be discussed with a panel of experts for confirmation and agreement.(94, 95, 97)

Integration: Feasibility, Suitability and Acceptability

Following data analysis of the trial and embedded qualitative components, the quantitative and qualitative data will be assessed against a success criterion outlined *a priori* (Table 2). The predetermined success criteria were developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.(44, 54, 98) Trial objectives will be considered successful if the success criteria are satisfied following the integration of the quantitative and qualitative findings.(98)

Table 2: Success Criteria

General Objectives	**Success Criteria**
Eligibility criteria	A favourable number of patients fit the eligibility criteria to enable the stipulated recruitment rate
	APPs agreed with the eligibility criteria
Recruitment strategy	Participants were recruited within the time constraints of the local clinical environment
	Patients and APPs report that they were happy with the recruitment strategy
Data collection methods	Data were collected with ease via RedCap and no complications were experienced
	Data completeness of ≥ 80 %
	Patients and APPs report that they were happy with the data collection methods
Follow up procedures	100% of participants were contacted for follow up
	≥80% completion of follow up outcome measures
	Patients and APPs report that they were happy with follow up procedures
Specific Objectives	**Success Criteria**
Feasibility	
Participant recruitment rates	Recruitment target of n=10 per clinician met in the time available (3 months)
Ease of fitting accelerometers	Accelerometers were fitted within the allocated clinical time allowed with the FCP APP
	Patients and APPs report that accelerometers were fitted with no issues

Accelerometer data collection	RedCap was able to capture the data from the accelerometers with no errors or data loss
	Patients report that they were happy with data collection using accelerometers/ burden within subjectively appropriate limits
Capacity (time and effort) of clinicians' complete trial related tasks	APPs report that adequate time was allowed to complete all tasks required by them during the trail
Training requirements required by clinicians	APPs report that they had a adequate training to be able to complete the tasks required by them during the trial
Suitability	
Outcome measures	Data completeness of ≥ 80 %
	Patients and APPs report that the outcome measures were appropriate and self-explanatory
Compliance with wearing the accelerometers	Data collected ≥ 80 % of the requested time (16hrs/day for 7 days)
Time required to conduct each stage of the protocol	APPs report having adequate time to complete each stage of the protocol
Service infrastructure	Recruitment targets met Data completeness of ≥ 80 %
	APPs report that adequate service infrastructure is in place to allow for a full trial to be completed
Acceptability	
Intervention	Patients and APPs report that the intervention was appropriate/ satisfactory

Patient and Public Involvement (PPI)

Patients with LBP are part of our research team / co-investigators to ensure the patient perspective is central. There is a PPI representative on both the Trial Management Group and Trial Steering Group to ensure that patients and the public are involved at all steps in the research process.

Patients have contributed to the development of the interview / focus group questions, participant information sheet, consent form; and importantly to the processes of data analysis and interpretation and producing a lay summary of findings. They have reviewed this protocol and have helped to ensure that their involvement is fully considered.

Data Storage

All data will be electronic and stored in password protected computer files that can be accessed only by study investigators at the University of Birmingham. Participants who choose to disclose personal details will be additionally protected via coding on data files. This coding will be kept in a password protected computer file on the University of Birmingham server, only accessible to the research team ensuring confidentiality.(44, 99) These personal data and participant contact details (stored during study to arrange focus groups and interviews) will be securely destroyed at the end of the study. No participants will be identifiable in data presentation or dissemination. The confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators by maintaining the de-personalised data format and ensuring that no data are traceable to an individual participant. The password-protected files will be retained for 10 years, in a confidential, locked storage unit, satisfying university code of practice.

Ethics and Dissemination

Ethical Considerations

The feasibility trial will be conducted in accordance with the principles of the Research Governance Framework for Health and Social Care. To ensure that the study is conducted in an ethical manner within best research practice, Health Research Authority (HRA) ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734.(44, 99) Approval was granted on 30th October 2018. Participants' inclusion within the study will be entirely voluntary, with no incentives offered to participants to minimise bias.(44, 45) Participant consent will be gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants.(44, 99) Participants will be free to withdraw at any time.(44, 45)

Dissemination of Findings

The study's findings will be disseminated via study reports, publication in academic peer-reviewed journals and conference presentations.(44, 45) The results will be communicated to participants as a summary report written in lay language including key findings and plans for future research.

DISCUSSION

The results from this prospective, mixed-methods, single group feasibility trial with an embedded qualitative component, will serve to inform researchers about the feasibility, suitability and

acceptability of the specific methods evaluated, in preparation for a full RCT to assess the clinical and cost effectiveness of physiotherapist prescribing for LBP in primary care. Evidence is required by researchers, policy makers and health service managers to inform decisions regarding the selection of appropriate, rigorous, clinically safe and economically sound design of a robust, high quality full RCT with low risk of bias. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or re-design of the essential full RCT.

Declarations

Ethics Approval and Consent to Participate

This trial is approved by the Health Research Authority (HRA) ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734

Availability of Data and Materials: Not applicable

Data Sharing Statement

There is no unpublished data available.

Contributors

TN is a clinical advanced practice physiotherapist and PhD candidate at the University of Birmingham (UK). AR is a Reader in Musculoskeletal Rehabilitation Sciences and lead supervisor. JM is a Professor of Clinical Pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. All authors have contributed to the content of this article. TN wrote the first draft of this article and has worked with all authors to develop subsequent drafts. All authors prior to publication gave final approval. Patients and the general public were involved in the design of this study via PPI evaluation groups.

Competing Interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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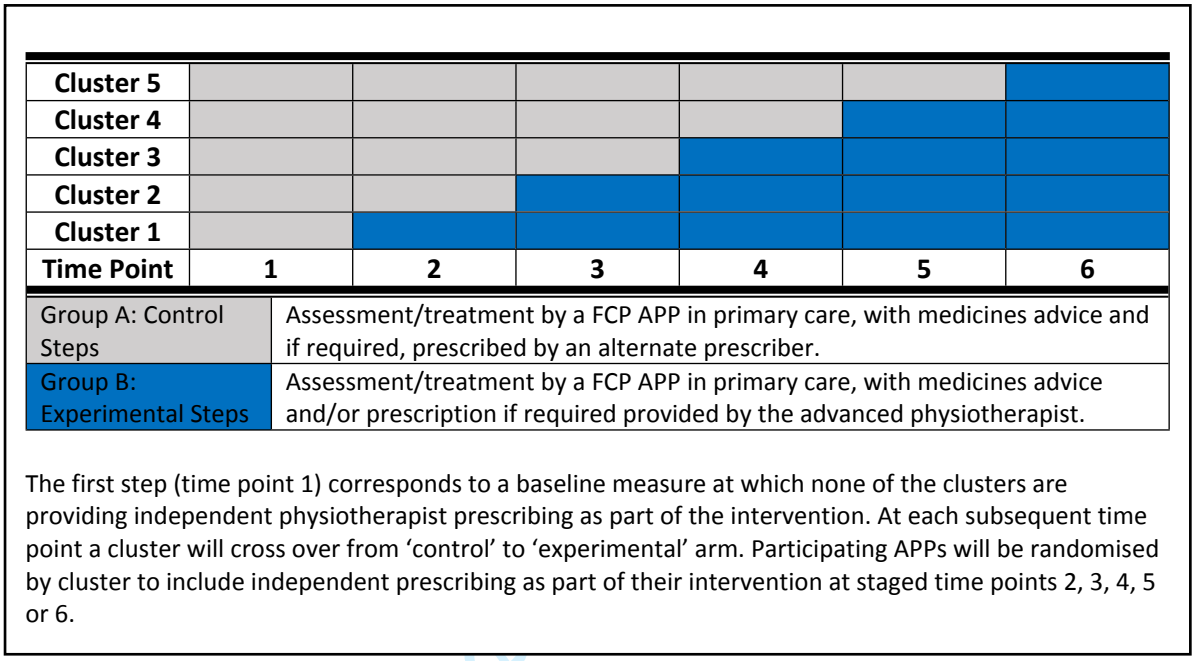
Figure 1: The stepped-wedge cRCT design for potential use in a full trial



The first step (time point 1) corresponds to a baseline measure at which none of the clusters are providing independent physiotherapist prescribing as part of the intervention. At each subsequent time point a cluster will cross over from 'control' to 'experimental' arm. Participating APPs will be randomised by cluster to include independent prescribing as part of their intervention at staged time points 2, 3, 4, 5 or 6.

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Supplementary File 1: Participant consent form

CONSENT FORM: Person with Back Pain

Title of Project: Prescribing medications for low back pain by physiotherapists

Name of Participant: ……

Please initial box

1. I confirm that I have read and understand the information sheet, for the above study. I have had the opportunity to consider the information, to ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that all data will be confidential and securely stored for a period of 10 years. I understand that if I withdraw from the study my data up to the point of my withdrawal will be used in the analysis ☐
4. I agree to take part in the above study ☐
5. I agree to be contacted to take part in the focus group ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

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Supplementary File 2: Outcome Measures Questionnaire

Outcome Measures Questionnaire

Participant Questionnaire

Q1 What is your gender?

- ❍ Male
- ❍ Female
- ❍ Other

Q2 What is your age?

- ❍ 17-29
- ❍ 30-39
- ❍ 40-49
- ❍ 50-59
- ❍ 60 or older

The Keele STarT Back Screening Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible and it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

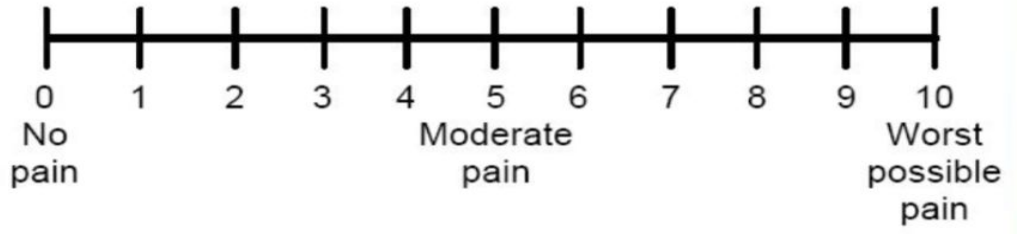
9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

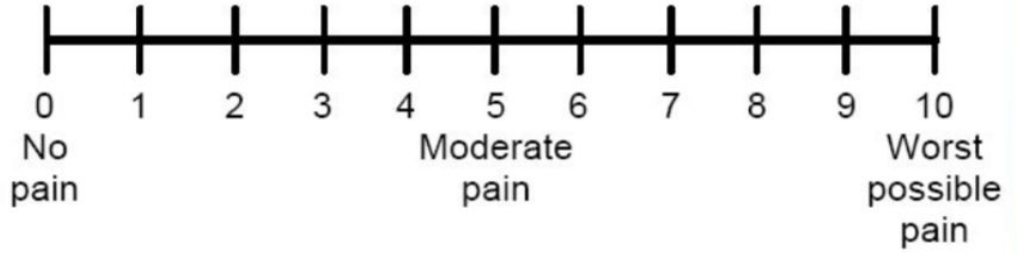
Funded by Arthritis Research UK

On the scales below (0-10), please mark the amount of back pain that you have experienced:

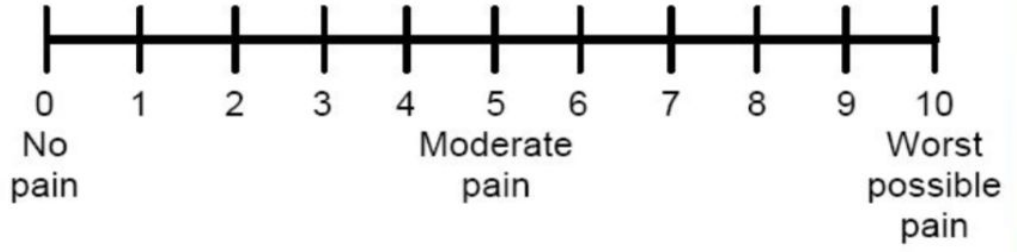
Worst pain over the last two weeks



Least pain over the last two weeks



Average pain level today



The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.

13. My back is painful almost all the time.

14. I find it difficult to turn over in bed because of my back.

15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or stockings) because of the pain in my back.

17. I only walk short distances because of my back.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Tampa Scale:

Please mark how much you agree or disagree with the following statements:
1= Strongly disagree
2= Disagree
3= Agree
4= Strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Since receiving your prescription from the physiotherapist, how many days have you taken the medication to date?

Have you seen any other healthcare professionals for your back pain since your initial assessment?	Yes		No	

If YES, which type of health professional(s) have you seen, and on how many occasions?	Number of occasions

Have you had to take any time off work due to your back pain?	Yes		No	

If YES, how many days have you had to take off work due to your back pain?

Thank you for completing this questionnaire

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Supplementary File 3: Participant Information Sheet

Participant Information Sheet: Person with Back Pain

Study title: Prescribing medications for low back pain by physiotherapists

We would like to invite you to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. The study is part of a larger PhD being completed by Tim Noblet (Researcher). Someone in our research team will go through the information sheet with you and will answer any questions that you have. Please ask if anything is not clear or if you would like more information.

What is the purpose of the study?

1 in 5 people with Low Back Pain (LBP) see their General Practitioner (GP) and this makes up almost 1 in 10 GP Consultations. Each year in the UK over 3 million working days are lost because almost 1 in 3 adults experience LBP at any one time. Early assessment and management of LBP is important to reduce long term problems.

The NHS is committed to providing the best services for all its patients, and due to the growing demand on health services, new and innovative ideas are being trialled to maximise quality care. A range of organisations including the British Medical Association and the Chartered Society of Physiotherapy have committed to enabling patients with LBP to be able to book appointments directly with the NHS physiotherapists in their local health centre without having to see a GP first. In addition to the normal treatment, physiotherapists are now able to prescribe medicines such as pain killers which patients usually need to get from their GP. To do this the physiotherapists complete a programme of education the same as your doctor or dentist.

Patients being able to access physiotherapists who can prescribed medicines directly is a new system in England. This study is intended to help decide how we will best assess what and what does not work, to enable provision of the best healthcare for people in England. This will be undertaken by asking approximately 30 people to complete questionnaires. A small number of people may also be asked to wear monitoring equipment (like 'fitbits') for a week, which assesses how active they are during each day, and 6-8 people will also be invited to participate in a focus group where they will be asked to share their opinions on how the study was conducted and how we could improve the evaluation process for the future. Physiotherapists will also have an opportunity to voice their opinions and experiences in a 1:1 interview. The results will be used to plan a large clinical trial to access how well the new services work for patients.

Why have I been invited?

You have been invited to take part because you have attended an appointment with the physiotherapist for your LBP and require a prescription to support your treatment. We aim to recruit 30 people across England.

Do I have to take part?

It is up to you to decide whether or not to take part. Feel free to ask any questions. After you have asked any questions, if you agree to take part, the researcher will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the normal treatment that you would receive.

What will happen to me if I take part?

If you choose to take part in the study, you will be asked to fill out a short questionnaire on a tablet computer at your appointment with the physiotherapist. You will be asked to complete the same questionnaire 6 weeks later and 12 weeks later- these can either be sent to you by email or hard copies provided with stamped addressed envelopes so that you can return the questionnaires by post.

Some patients will also be asked to wear a small monitoring device like a 'fitbit' on their belt for 7 days. The monitoring devices measure the amount of time people spend moving and being still as well as your sleep pattern.

6-8 patients will be invited to attend a focus group at a local venue, and again it is up to you whether you choose to attend or not.

What will I have to do?

The questionnaire will take approximately 15 minutes to complete, asking you for your contact details and for information about how your back pain is affecting your everyday life at that point in time. For the 6 & 12 week questionnaire you will be able to choose either a paper (postal) or email version for you to complete. Support from your physiotherapist will always be available to you to help in completing the questionnaire.

What are the possible disadvantages of taking part?

It is possible that when talking about your back pain or filling in the questionnaire we may ask you to relive events which are emotional for you. However, we will make every effort to ensure that you are comfortable at all times. The only cost to you is the time needed to complete the questionnaire and (for some people) attend a focus group.

What are the possible benefits of taking part?

We are not able to make any promises on the benefits at this stage until we have analysed the information you provide, which may help you and other patients in the future. It will not change the treatment that you receive for your back pain.

What will happen when the research stops?

When the research is complete, your future treatment will not be affected in any way. Decisions about your future care will be in-line with standard procedures at the GP practice/health centre that you have been attending.

What will happen if I don't want to carry on with the study?

If you do not wish to carry on with the study, you are free to withdraw at any time, without having to give a reason. Your decision to withdraw will not influence your current or future health care. It is important for us that information collected up to the point of your withdrawal is included in the analysis.

What if there is a problem?

It is unlikely that there will be any problems during the study. If you have a concern about any aspect of the way that you have been approached or treated during the course of this study, you can speak to Mr. Tim Noblet (researcher) or Dr Alison Rushton (Chief Investigator) who will answer any questions you have. If you remain unhappy and wish to complain formally, you can do this by following the

National Health Service complaints procedure. You can get advice from the Patient Services Teams at your GP practice/ health centre (all contact details below).

In the unlikely event that you are harmed whilst participating in this study, there are no special compensation arrangements, but if this is due to someone's negligence then you may have grounds for legal action. The normal National Health Service complaints mechanism will still be available to you. You may obtain advice from the Patient Services Teams at your GP practice/ health centre (contact details at the end of this information sheet).

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of the study will be kept confidential. Your name or contact details will not appear on any data and you will not be identifiable from any report or publication of the findings. Your contact details will be held on a computer database so that questionnaires can be sent to you and the focus groups can be organised. This will be password protected and only accessible by the researchers. Passwords will not be used by or given to anyone outside the research team. Contact details will be destroyed at the end of the study. All information from the questionnaires that you complete and the 'fitbits' (if you wear one) will be kept securely by University of Birmingham for ten years following the study. After that period, all information will be disposed of in a secure manner through confidential waste.

What will happen to the results of the study?

Results from this study will be used to develop a clinical trial that will evaluate the use of physiotherapists who can prescribe medications in GP practices and health centres. This trial will aim to improve the patient experience and their outcomes.

The results will be published in scientific journals and through presentation at research conferences. You will not be identifiable in any report, publication or presentation. If you are interested in the results of this investigation you can obtain a summary of the results by contacting Mr. Tim Noblet or Dr Alison Rushton (contact details below).

Who is organising and funding this study?

The research is sponsored by the University of Birmingham and funded by Health Education England and the Private Physiotherapy Educational Fund. The research will be conducted by physiotherapists at Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust or Windemere/ Ambleside Health.

Who has reviewed the study?

All research in the NHS is reviewed by the Research Ethics Committee, engaged to protect your interests and those of the researchers. This study has been reviewed and given favourable opinion by the XXX and the Research and Development Directorates, Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust and Windemere Health Centre.

The role of the University of Birmingham

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham securely keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your physiotherapists will collect information from you for this research study in accordance with our instructions. The NHS site will keep your name and contact details confidential. If you consent to be approached to participate in a focus group, the University of Birmingham will have access to your name and contact details to arrange the focus group. The researchers who analyse the information collected will not be able to identify you and will not be able to find out your name or contact details.

The NHS site will keep identifiable information about you from this study 10 years after the study has finished.

You can find out more about how we use your information by contacting Legal Services at dataprotection@legalservices.contacts.ac.uk.

Contact for further information or any questions about this study:

Tim Noblet (researcher)
Tel: 07740360178
Email: TDN818@student.bham.ac.uk

Dr Alison Rushton (Chief Investigator / supervisor)
Tel: 0121 415 8597
Email: a.b.rushton@bham.ac.uk

Centre of Precision Rehabilitation Spinal Pain, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT

Site PALS Information:

One Medical Group-Windermere Health Centre & Ambleside Health Centre
Telephone No:015394 45159
Email Address: tess.shaw@onemedicalgroup.co.uk

Sheffield Teaching Hospital NHS Foundation Trust
Telephone No: 0114 271 2400
Email Address: PST@sth.nhs.uk

Guy's and St Thomas' NHS Foundation Trust
Telephone No: 020 7188 8801
Email Address: pals@gstt.nhs.uk

Thank you for taking the time to read this information sheet.

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Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: protocol for a feasibility trial with an embedded qualitative component

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Independent Prescribing by Advanced Physiotherapists for Patients with Low Back Pain in Primary Care: protocol for a feasibility trial with an embedded qualitative component

Noblet TD, Marriot JF, Rushton AB

Mr Timothy Noblet
Centre of Precision Rehabilitation for Spinal Pain (CPR Spine)
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK
Tel: +447740360178
Email: timnoblet@hotmail.com

Professor John Marriott
Institute of Clinical Sciences
College of Medical and Dental Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK

Dr Alison Rushton
Centre of Precision Rehabilitation for Spinal Pain (CPR Spine)
School of Sport, Exercise and Rehabilitation Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT, UK

Corresponding Author: Timothy Noblet, timnoblet@hotmail.com

Keywords: Non-medical Prescribing, Physiotherapist Prescribing, Low Back Pain, Advanced Physiotherapy Practitioners, Primary Care

Abstract

Introduction: Low back pain (LBP) is the most prevalent musculoskeletal-condition in the UK. Guidelines advocate a multimodal approach, including prescription of medications. Advanced Physiotherapy Practitioners (APPs) are well placed to provide this care in primary care. Physiotherapist independent prescribing remains novel, with the first prescribers qualifying in 2013. This feasibility trial aims to evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by APPs for patients with LBP in primary care, to inform the design of a future definitive stepped-wedged cluster trial.

Method and Analysis: 1. Trial component. An APP (registered prescriber) will complete the initial participant consultation. If prescription drugs are required within the multi-modal physiotherapeutic context, these will be prescribed. Patient reported outcome measures will be completed prior to initial assessment and at 6 and 12 weeks to assess feasibility of follow-up and data collection procedures. Accelerometers will be fitted for 7 days to assess physical activity, sedentary behavior and feasibility of use. 2. Embedded qualitative component. A Focus group and semi-structured interviews will be used to evaluate the views and experiences of the participants and APPs respectively, about the feasibility, suitability and acceptability of the proposed full trial. A CONSORT diagram will be used to analyse feasible eligibility, recruitment and follow up rates. Descriptive analysis of the data will be completed to evaluate procedures. Thematic analysis will be used to analyse and synthesise the qualitative data.

Ethics and dissemination: This feasibility trial is approved by the Health Research Authority (HRA) ethical approval was sought and granted via the Integrated Research Application System (IRAS) ID 250734.
Data will be disseminated via publication in peer reviewed journal and conference presentation. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or re-design of the essential full RCT.
Registration: ISRCTN database, Ref ISRCTN15516596

Strengths and Limitations of this Study

- First rigorous investigation aiming to evaluate the methods required to assess the clinical and cost-effectiveness of independent prescribing by advanced physiotherapists for patients with low back pain in primary care.
- The design of this feasibility trial was developed by clinicians, academics, methodological experts, health care service managers, professional leaders and the public/ patients.
- The methods will be tested across a range of cities, towns and villages in varying geographical areas across England.

BACK GROUND

Low back pain (LBP) is the most prevalent musculoskeletal condition in the UK, with 58-84% of the population experiencing LBP in their lifetime.[1-3] At any time, 28.5% of adults over 25 are experiencing LBP.[2] Data indicates that 3.2 million work days are lost per year in the UK, with an average of 16.5 days lost per case .[4] Approximately 20% of those with LBP seek care from their general practitioner (GP),[1] with 7% of all GP consultations being due to LBP.[3 5]

Despite increased funding for treatments and a growing understanding of the complex biopsychosocial nature of LBP leading to improvements in assessment and management of the condition, up to 7% of the general population in the UK have chronic LBP associated with significant disability [1 2] and the health and function of this demographic continues to decline.[6] In an attempt to address this, novel approaches have been adopted to inform shared decision-making and stratification tools are being utilised to improve outcomes through recognising clinical heterogeneity, ensuring that all biopsychosocial risk factors are addressed, improving patient management and reducing the overall cost of health care.[6-8] Early assessment, diagnosis and treatment of LBP has been seen to reduce chronicity.[1] However, the complex and multidimensional nature of LBP combined with a current deficit in the availability of GPs in the UK,[9 10] has prompted the redesign of out-dated traditional LBP clinical-pathways, and the introduction of new treatment models designed to maximise clinical and cost-effectiveness, whilst readying the health services for the future.[10-12]

Physiotherapists are experts in the assessment, diagnosis and treatment of musculoskeletal disorders.[13] For more than 30 years, physiotherapists have been working in advanced practice roles across the country, utilising their scope of practice to optimise patient care, providing support in health services where the availability of medical practitioners does not meet the demands of a local community.[13 14] Advanced musculoskeletal physiotherapists have been shown to be clinically and cost-effective in a variety of settings including orthopaedic and emergency care departments as well as in primary care in musculoskeletal interface-services.[14-16] Recently, the success and experience of these practitioners, alongside changes in demographics and predictions that GP numbers will further reduce by 2020, have prompted successful pilot studies investigating the effectiveness of first contact advanced physiotherapy practitioners (FCPs) in primary care.[11 17] As a result, Health Education England (HEE), in collaboration with NHS England, the Royal College of General Practitioners (RCGP), the British Medical Association (BMA) and the Chartered Society of Physiotherapy (CSP) have committed to introducing these roles across England.[17-19]

Recently published guidelines from the National Institute for Health and Care Excellence (NICE) [8] for LBP and sciatica, advocate for a holistic, multimodal approach to assessment and management [3]. Advanced physiotherapists are well placed to provide this care owing to their competency in physical therapies including manual and exercise therapy; knowledge and skills associated with the management of psychosocial factors; and ability to appropriately refer for blood tests, imaging, spinal injections, denervation and surgery.[20 21] Further, the NICE guidelines recommend the use of drugs that are helpful and minimise harm.[3 8] It is therefore envisaged that independent physiotherapist prescribing will be a key competency required for the successful implementation of first contact advanced physiotherapists working in primary care.

Independent physiotherapist prescribing remains relatively new, with the first prescribers qualifying in 2014. Evaluation of physiotherapist and podiatrist independent prescribing has shown good acceptance by patients and a good safety record to date. [22] A recent mixed-methods systematic review of investigating the barriers and facilitators of non-medical prescribing (NMP) concludes that the successful implementation and utilisation of NMP is dependent upon adequate preparation and

organisation of a range of factors.[23] Considerations such as the use of advanced physiotherapists in primary care were seen to facilitate successful implementation of NMP as long as clinical governance, policy development and service practicalities and logistics are adequately developed and established prior to implementing NMP. To ensure longevity and future growth, education, support and financial factors alongside the management of personal and professional considerations were also deemed paramount.[23]

For clinical-services to be successful they must deliver positive clinical outcomes in a safe and economically sound manner.[24] Our recent rigorous systematic review investigating the clinical and cost-effectiveness of NMP across all professions and clinical settings, identified limited evidence with unclear risk of bias.[25] We concluded that quantifiable benefits of NMP remain unknown and called for adequately powered, low risk of bias randomised controlled trials (RCTs) in specific patient groups, professions and clinical settings.[25] Owing to the contemporary nature of independent physiotherapist prescribing, no trial has examined the clinical or cost-effectiveness of this intervention in the complex context of LBP. Trial design required careful consideration particularly as independent physiotherapy prescribing is within the process of implementation across private health services and NHS Trusts. A feasibility study is therefore required to inform a multi-centre RCT investigating physiotherapist independent prescribing by advanced physiotherapists for patients with LBP, in primary care. The project will aim to evaluate the feasibility, suitability and acceptability of procedures and outcomes for use in the full trial, also assessing the commitment and burden on participants, clinicians and researchers as well as infrastructure and technological requirements.

Aim:

To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners (APPs) for patients with LBP in primary care to inform the design of a future definitive stepped-wedged cluster trial.

Objectives:

General Objectives

- To assess the feasibility, suitability and acceptability of the proposed full trial [26] including:
  - Eligibility criteria [27-29]
  - Recruitment strategy [27-29]
  - Data collection methods [27-29]
  - Follow up procedures [27 28]

Specific Objectives:

Feasibility:

- To evaluate participant recruitment rates.[26-28]
- To evaluate the ease of fitting participants with accelerometers and ease of data collection.[27 28]
- To evaluate the capacity (time and effort) of clinicians and researchers to complete trial related tasks.[27 28]
- To evaluate the necessary training requirements required by clinicians to successfully implement a full trial.[27 28]

Suitability:

- To evaluate the range of participants' scores on the Roland and Morris Disability Questionnaire (RMDQ), assessing for floor effects and therefore the appropriateness of outcome measure for use in a full trial.[26-29]
- To evaluate participant compliance with wearing the accelerometer device.[27 28]
- To evaluate the time required to conduct each stage of the protocol.[27 28]
- To evaluate the appropriateness and availability of services and infrastructure such as access to national and institutional communication and information technologies required to undertake a full trial.[27 28]

Acceptability:

- To evaluate the acceptability of the intervention to patients and the public.[26-29]

METHODS

To ensure transparency and reproducibility this feasibility trial protocol has been registered on the ISRCTN database (ISRCTN15516596) and is reported in line with the CONSORT 2010 statement: extension to randomised pilot and feasibility trials,[30-32] with all patient and public involvement (PPI) reported in line with the GRIPP2 short form reporting check list.[33 34]

The feasibility trial will utilise a mixed-methods research approach, comprising of:

- a quantitative one-armed feasibility trial
- qualitative semi-structured interviews and patient focus groups, using thematic analysis.

Mixed methods designs are recognised to enable a richer synthesis, generating data which will facilitate appropriate change.[35-37]

Design

RCTs are considered the gold standard for evaluating the effectiveness of an intervention.[38] Cluster RCTs (cRCTs) allowing for randomisation by group have been developed to overcome practical issues in clinical settings, where individual randomisation is not convenient or feasible.[38-40] When evaluating contemporary interventions, parallel deigns requiring the new intervention to be simultaneously provided to multiple clusters of participants are often too costly or not practical owing to the necessary clinician training required to deliver the intervention safely.[38 39] A stepped-wedge cluster randomised controlled trial (SWcRCT) design will therefore be used to evaluate the clinical and cost-effectiveness of physiotherapist prescribing for LBP in the future. This design is valuable when evaluating innovative clinical interventions where there is a strong ethical belief that the intervention will benefit patients.[39 41 42] SWcRCTs allow each experimental cluster to begin in the control arm then cross over to the experimental arm at specified time points (Figure 1).[41] As the implementation of independent physiotherapy prescribing and the utilisation of APPs working as FCPs are both relatively contemporary innovations, there are limited numbers of clinicians currently working in these innovative roles who are registered to prescribe. This research design allows for the use of fewer clinicians than those required for a parallel design and is therefore more reflective of current practice. APPs who are not prescribers will start in the control group and cross to the experimental group following registration as an independent prescriber. APP who are not prescribers start in the control group and cross to the experimental group.[39-42]

Currently no clear framework exists describing the requirements for best practice when completing feasibility trials in preparation for SWcRCTs.[43] Two-arm feasibility trials that have aimed to calculate intra-cluster correlation coefficients (ICCs) required for sample size calculations in preparation for full cRCTs have demonstrated insufficient accuracy, unless the feasibility trial is equal in size to the proposed full trial.[43] Therefore, a single-arm feasibility design will be employed to test specific aspects of the trial protocol in terms of feasibility, suitability and acceptability on the experimental arm of the future SWcRCT, without sample size estimation.[27 44 45]

Trial Component

A prospective, mixed-methods, single-group feasibility trial will be utilised to evaluate the trial objectives.[29 44] Participant consent forms (Supplementary File 1) and patient reported outcome

measures (Supplementary File 2) will be completed digitally via an online survey at initial assessment (baseline) and at 6 and 12 weeks (12 weeks is the planned primary endpoint of the definitive trial) following a prescription being issued, to evaluate the feasibility of follow-up data collection procedure.[45 46] Follow-up time points have been selected in line with the prognostic literature showing that 40% of patients presenting to primary care with LBP will be pain free 6 weeks post onset, with 58% pain free by 12 weeks.[47-49] The online outcome measures survey will be built using REDCap (Research Electronic Data Capture) software (hosted in the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK), enabling data to be captured and stored in real-time, on a range of electronic devices.[50] Baseline measurements will be completed by the participants within the clinical setting. A link to the online outcome measures survey with instructions will be emailed to participants for completion at 6 and 12 weeks. If participants forget to complete the outcome questionnaire on the required day, a reminder to complete will be sent at 24hrs and 48hrs after the deadline to facilitate compliance.[45 51] To evaluate the feasibility of fitting participants with accelerometers in clinic, the ease of data collection and participant compliance with wearing the accelerometer device,[27 28] n=10 participants at one research site, will be fitted with an accelerometer to wear for 7 days immediately following completion of patient reported outcome measures at the first consultation. Participants will be provided with stamped/addressed envelopes in which to return the devices after use.

Participants

Potential participants will be identified by the APPs at each clinical site, by using the STarT Back Tool at initial assessment, to stratify all patients presenting with LBP.[7] Patients stratified into the medium risk group by the STarT Back Tool will be eligible for recruitment if they meet the inclusion criteria following assessment (Box 1). This group of patients have been recognised as predominant cohort presenting for assessment and treatment of LBP in primary care; exhibiting both physical and psychosocial prognostic factors and may require physiotherapist prescribing to optimise their multimodal physiotherapeutic treatment.[7 52-54] Convenience sampling will be adopted, as this method has the advantages of fluid recruitment and follow-up required by feasibility trials, with good retention of participants where time is limited.[28 45 46 55] Patients that are interested in participating will be provided with a participant information sheet (Supplementary File 3) explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants. The physiotherapist will answer any questions and if the patient wishes to participate, consent will be obtained using an online consent form. Contact details for the research team will be provided to give the participants the opportunity to have any further questions answered. Contact details for an independent advisory service (PALS at each site) will also be provided in case external advice is desired by participants. Participants will be free to withdraw at any time, without any impact on their care.[45 46]

Box 1: Participant Eligibility Criteria

Inclusion Criteria
• Male and female patients, aged >18 years. • Non-specific LBP +/- leg pain requiring medication advice and drug prescription on assessment • Classified as Moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment[7]) • Able to read/communicate in English (owing to funding restrictions for interpreters and translators) • Capable of following the demands inherent of the study
Exclusion Criteria
• Signs of lumbar nerve root compression[56] • Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy[56] • Spinal stenosis[57] • Suspicion of or confirmed corda equine syndrome[58] • Does not have capacity to consent[59] • Unable to receive email and/or complete online questionnaires

Interventions

As the control arm of the definitive trial will be "current normal practice", the intervention designed for the experimental arm of the definitive trial will be utilised to evaluate the feasibility trial objectives.[26-29] As per "current normal practice", an APP acting as a FCP will complete the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP will have the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required within the multi-modal physiotherapeutic context, these will be prescribed/de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation.

Outcomes

The literature reports that the use of a core outcome set assessing pain intensity, health related quality of life and physical function is required for the assessment of non-specific LBP.[60] However, no consensus exists with regards to the instruments most suitable to measure these domains.[60] The outcome measures selected for use within the trial were informed by a team of subject-experts including physiotherapists, pharmacists, medical practitioners, academics and health-service managers and deemed most appropriate to evaluate the studies objectives whilst attempting to minimise the burden on participants. Two primary outcome measures (detailed below) were selected as they jointly evaluate the core outcome set requirements.[60] Detail of the secondary outcome measures and rationale for selection are found in Table 1.

Primary Outcome Measures

- Overall Pain, Numerical Rating Scale (NRS): The NRS is a unidimensional 11-point scale (0-10) used to measure pain intensity, where 0 represents no pain and 10 represents maximum pain (e.g. the worse pain you can possibly imagine).[61] Patients with pain have been shown to prefer the NRS over other pain measure including the pain Visual Analogue Scale (VAS) owing to simplicity and clarity.[61 62] The NRS has demonstrated good reliability, validity and responsiveness and has been used extensively in pain research.[63-65] A reduction of 2.5 points on the NRS has been shown to be clinically important for chronic LBP.[64-66] Participants will score pain in 3 categories: “worst pain over the last two weeks”, “least pain over the last two weeks” and “average pain level today”.

- Roland Morris Disability Questionnaire (RMDQ): The RMDQ is one of the most widely used outcome measures for LBP, with well-established good levels of validity and reliability.[67] The RMDQ has been selected over its counterparts owing to its superior measurement properties in patients reporting moderate disability demonstrated by those stratified into the medium risk group by the STarT Back Tool.[7 66 67] The 24-item questionnaire takes approximately 5 minutes to complete and includes items assessing: physical activity, sleep, psychosocial factors, activities of daily living, appetite and pain.[68] Scores range from 0 (no disability) to 24 (maximum disability), with a change of 3.5 points deemed clinically significant.[66]

Table 1: Secondary Outcome Measures and their Rationale

Outcome	Measure	Rationale
Health Related Quality of Life (QALY)	EQ-5D 5L	The EQ-5D 5L is used to measure health related quality of life demonstrating good reliability and validity through psychometric testing.[69] If feasibility is found this measure will inform cost utility is a full RCT.
Pain Related Fear of Movement	The Tampa Scale for Kinesiophobia (TSK)	The Tampa Scale for Kinesiophobia (TSK) is a 17-item tool which was developed to measure a person's fear of movement owing to LBP. Ongoing fear of movement has been linked to the development of long term persistent pain.[70] This outcome measure has been found to show good validity and reliability when measuring pain related fear of movement.[71]
Physical activity and	ActivPal 3 Accelerometer	Anecdotal evidence suggests that decreasing sedentary behaviour in people with LBP may have significant health benefits,[53] reducing risks of obesity, metabolic syndrome, type two diabetes and mortality.[72] Systematic reviews have revealed that physical activity of people with LBP is lower or equal to the healthy population,[73-75] however there appears to be differing patterns of physical behaviour, with the back pain population engaging in shorter bouts of physical activity which are not long enough to incur health benefits (>10 minutes).[75 76] An accelerometer will be used to collect data including: steps count and sedentary periods.[77] To date no individual brand/model of accelerometer has been identified as gold standard. The ActivPal 3 has been selected for use in this feasibility trial as it has been seen to be more precise and sensitive than other accelerometers.[77 78]
Sleep	ActivPal 3 Accelerometer	50-60% of people experiencing with either acute or persistent low back pain experience high levels of sleep disturbance.[79] Poor sleep over long periods of time may lead to depression, obesity, diabetes and cardiovascular disease.[79 80] Patients with LBP suffering with sleep disturbance have been reported as twice as likely to be hospitalised.[81] Improved sleep has been seen to modulate pain intensity,[82] with poor quality sleep associated with increased pain intensity, fatigue, decreased function and psychological stress. An accelerometer will be used to collect sleep duration data alongside physical activity and sedentary behaviour.[83]
Time to return to work and nature of return to work (e.g. full time, part time, light duties)	Days	Work absence owing to sick leave for work disability is a key issue clinically, socially and economically. The MCIC for time return to work has not been defined due to the specific measurement (days on sick leave) being widely accepted and recognition of the measure's value in social and economic issues rather than an indicator of morbidity.[66] This measure would therefore be useful when conducting economic evaluation of physiotherapist prescribing.
Prescription Utilisation, Participant	Days	Time requiring drugs for the treatment of non-specific LBP discussed/prescribed by the advanced physiotherapists will be monitored to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.
Number of appointments with other healthcare professionals about this episode of LBP	Number of appointments with each type of healthcare professional	The number of appointments with other healthcare professionals about this specific episode of LBP being studied will be recorded via a question in the outcome questionnaire to evaluate the necessity of this measure for future cost-effectiveness analysis within a full trial.

Sample Size

As the number of FCP physiotherapists that are registered to prescribe is currently limited[84], three first contact Advanced Physiotherapy Practitioners (APPs) (n=3), across 3 primary care sites representative of English geography (x1 capitol city, x1 regional city, x1 rural town), will recruit, assess and treat n=10 participants per APP, to enable the evaluation of recruitment rates across clinicians and the feasibility of the trial methods in both metropolitan and rural healthcare services.[27 43 44] This feasibility trial does not aim to estimate the sample size required for the full trial as feasibility trials for cRCTs have been shown not to adequately predict sample size, therefore large numbers of participants are not required.[43 85] A total sample of n=30 patients will be recruited as a sample size of n>20 is regarded as adequate when testing feasibility objectives for cRCTs.[27 28 43 44] This allows for some loss to follow up of participants.

Data Analysis

A CONSORT diagram will be used to describe the flow of participants and lost to follow up rates. This will be used to analyse feasible eligibility, recruitment and follow up rates.[30] Only data from fully completed outcome questionnaires will be included in the data analysis, however the number of partly completed outcome questionnaires will be noted and reasons for this explored in the embedded qualitative component of the trial. Data will be tabulated, and primary descriptive analysis of the data will be completed to test procedure.[27 45 46] Causality will not be statistically analysed as this is not within the scope of this feasibility trial.[45 46] The distribution of the scores on the RMDQ will be evaluated at baseline, 6 and 12 weeks following initial intervention. The percentage of scores equalling 0/24 at 12 weeks will be used to measure a potential floor effect.[86]

Embedded Qualitative Component

Design

An embedded qualitative component will be utilised as recommended by current guidance, to address trial objectives and to refine and adapt the proposed full trial design following evaluation.[87 88] The methodology was designed and is reported using the Consolidated Criteria for Reporting Qualitative Health Research (COREQ)[89]

Advanced Physiotherapy Practitioners

Semi-structured in-depth face to face interviews with all of the APPs (n=3) will be used to evaluate their views and experiences about the feasibility, suitability and acceptability of the trial, specifically evaluating trials objectives.[26-29 90 91] Interviews will be undertaken by one researcher (TN) following completion of participant data collection, to evaluate the research objectives and to gather qualitative data regarding the participants' views, perceptions and experiences about taking part, future risks and how the trial might be improved.[27 28] Question design was informed by the methodological literature and developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology.[45 55] A patient and public involvement group reviewed the questions for appropriateness and clarity.[92] Prior to completing the interviews, the APP participants will be provided with an information sheet and will have the opportunity to ask the researcher any questions about the interview process. Consent to taking part will be gained using a consent form. Interviews will be recorded and transcribed verbatim. Transcripts will be returned to

participants for inspection, comments and corrections prior to analysis, to ensure all views and thoughts are captured.[90]

Patients

A focus group of patients will take place following the 12 week assessment point, specifically to evaluate the research objectives.[27 93] Focus groups are recognised to produce data on collective views, generating a rich understanding of participants' experiences.[94] A purposive sample of 6-8 patients, representative of ages and sexes will be used; this sample size is reported in the literature as the optimum.[93] The focus group will meet in the qualitative laboratory within the Centre for Precision Rehabilitation for Spinal Pain (CPR Spine) at the University of Birmingham, UK, ensuring confidentiality. The focus group will be conducted by two researchers (facilitator and observer) using a predetermined topic guide designed to assess the research objectives, developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.[45 55] The topic guide has been reviewed by a patient and public involvement group to ensure appropriateness and clarity.[92] Consent to participate in the focus group will be taken prior to the focus group commencing. The participants will receive an information leaflet and have the opportunity to have any questions answered by the researchers. The focus group will be recorded and transcribed verbatim. Transcripts will be returned to participants for comments/correction to ensure all views are represented. [89]

Analysis and Findings

To fulfil the trial objectives a thematic analysis approach will be used to analyse and synthesise the qualitative data.[45 95 96] This systematic, inductive and interactive method is recognised to be useful in identifying the key thoughts and views of the population being studied. The method is useful where there are likely to be both similarities and diversity of opinion and where the intervention is novel, often providing explanations alluding to how the concerns may be resolved or processed in preparation for a full trial.[95-98] Focus group and Interview transcripts will be coded line-by-line using NVivo 11 software (QSR International, Melbourne, Australia) by one researcher (TN) and be verified by a second researcher (AR).[46 96 97] Rigorous comparative analysis will be completed by one researcher (TN) to identify similarities and differences within the data, informing the development of descriptive categories which will be linked, merged or split to synthesise a conceptual understanding of the data.[96 97] To avoid single researcher bias, a second researcher (AR) will re-interrogate the data to validate or contradict findings.[96] Outcomes will then be discussed with a panel of experts for confirmation and agreement.[95 96 98]

Integration: Feasibility, Suitability and Acceptability

Following data analysis of the trial and embedded qualitative components, the quantitative and qualitative data will be assessed against a success criterion outlined *a priori* (Table 2). The predetermined success criteria were developed by a team of experts in the fields of physiotherapy, primary care, NMP, health policy and trial methodology and informed by the methodological literature.[45 55 99] Trial objectives will be considered successful if the success criteria are satisfied following the integration of the quantitative and qualitative findings.[99]

Table 2: Success Criteria

General Objectives	**Success Criteria**
Eligibility criteria	A favourable number of patients fit the eligibility criteria to enable the stipulated recruitment rate
	APPs agreed with the eligibility criteria
Recruitment strategy	Participants were recruited within the time constraints of the local clinical environment
	Patients and APPs report that they were happy with the recruitment strategy
Data collection methods	Data were collected with ease via RedCap and no complications were experienced
	Data completeness of ≥ 80 %
	Patients and APPs report that they were happy with the data collection methods
Follow up procedures	100% of participants were contacted for follow up
	≥80% completion of follow up outcome measures
	Patients and APPs report that they were happy with follow up procedures
Specific Objectives	**Success Criteria**
Feasibility	
Participant recruitment rates	Recruitment target of n=10 per clinician met in the time available (3 months)
Ease of fitting accelerometers	Accelerometers were fitted within the allocated clinical time allowed with the FCP APP
	Patients and APPs report that accelerometers were fitted with no issues

Accelerometer data collection	RedCap was able to capture the data from the accelerometers with no errors or data loss
	Patients report that they were happy with data collection using accelerometers/ burden within subjectively appropriate limits
Capacity (time and effort) of clinicians' complete trial related tasks	APPs report that adequate time was allowed to complete all tasks required by them during the trail
Training requirements required by clinicians	APPs report that they had a adequate training to be able to complete the tasks required by them during the trial
Suitability	
Outcome measures	Data completeness of ≥ 80 %
	Patients and APPs report that the outcome measures were appropriate and self-explanatory
Compliance with wearing the accelerometers	Data collected ≥ 80 % of the requested time (16hrs/day for 7 days)
Time required to conduct each stage of the protocol	APPs report having adequate time to complete each stage of the protocol
Service infrastructure	Recruitment targets met Data completeness of ≥ 80 %
	APPs report that adequate service infrastructure is in place to allow for a full trial to be completed
Acceptability	
Intervention	Patients and APPs report that the intervention was appropriate/ satisfactory

Patient and Public Involvement (PPI)

Patients with LBP are part of our research team / co-investigators to ensure the patient perspective is central. There is a PPI representative on both the Trial Management Group and Trial Steering Group to ensure that patients and the public are involved at all steps in the research process.

Patients have contributed to the development of the interview / focus group questions, participant information sheet, consent form; and importantly to the processes of data analysis and interpretation and producing a lay summary of findings. They have reviewed this protocol and have helped to ensure that their involvement is fully considered.

Data Storage

All data will be electronic and stored in password protected computer files that can be accessed only by study investigators at the University of Birmingham. Participants who choose to disclose personal details will be additionally protected via coding on data files. This coding will be kept in a password protected computer file on the University of Birmingham server, only accessible to the research team ensuring confidentiality.[45 100] These personal data and participant contact details (stored during study to arrange focus groups and interviews) will be securely destroyed at the end of the study. No participants will be identifiable in data presentation or dissemination. The confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators by maintaining the de-personalised data format and ensuring that no data are traceable to an individual participant. The password-protected files will be retained for 10 years, in a confidential, locked storage unit, satisfying university code of practice.

Ethics and Dissemination

Ethical Considerations

The feasibility trial will be conducted in accordance with the principles of the Research Governance Framework for Health and Social Care. To ensure that the study is conducted in an ethical manner within best research practice, Health Research Authority (HRA) ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734.[45 100] Approval was granted on 30th October 2018. Participants' inclusion within the study will be entirely voluntary, with no incentives offered to participants to minimise bias.[45 46] Participant consent will be gained using an online consent form following the provision of information explaining the rationale, content and research dissemination plans to ensure ethical recruitment of participants.[45 100] Participants will be free to withdraw at any time.[45 46]

Dissemination of Findings

The study's findings will be disseminated via study reports, publication in academic peer-reviewed journals and conference presentations.[45 46] The results will be communicated to participants as a summary report written in lay language including key findings and plans for future research.

DISCUSSION

The results from this prospective, mixed-methods, single group feasibility trial with an embedded qualitative component, will serve to inform researchers about the feasibility, suitability and

acceptability of the specific methods evaluated, in preparation for a full RCT to assess the clinical and cost effectiveness of physiotherapist prescribing for LBP in primary care. Evidence is required by researchers, policy makers and health service managers to inform decisions regarding the selection of appropriate, rigorous, clinically safe and economically sound design of a robust, high quality full RCT with low risk of bias. It is anticipated that the results of this study will be used in conjunction with ethical evaluation, economic and risk analyses, as well as consultation with key stakeholders including the British health consumer when contemplating change, enhancement or re-design of the essential full RCT.

Declarations

Ethics Approval and Consent to Participate

This trial is approved by the Health Research Authority (HRA) ethical approval was sought via the Integrated Research Application System (IRAS) ID 250734

Availability of Data and Materials: Not applicable

Data Sharing Statement

There is no unpublished data available.

Contributors

TN is a clinical advanced practice physiotherapist and PhD candidate at the University of Birmingham (UK). AR is a Reader in Musculoskeletal Rehabilitation Sciences and lead supervisor. JM is a Professor of Clinical Pharmacy and co-supervisor. Both supervisors ensured the rigour of methods and analyses. All authors have contributed to the content of this article. TN wrote the first draft of this article and has worked with all authors to develop subsequent drafts. All authors prior to publication gave final approval. Patients and the general public were involved in the design of this study via PPI evaluation groups.

Competing Interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Health Education England (HEE) funding has allowed for the procurement of accelerometers and the associated IT programmes to ensure that innovative physical measures can be evaluated alongside patient reported outcome measures. The Private Physiotherapy Educational Fund has allowed for the procurement of x3 tablet computers for use in data collection and 7.5hrs per week of the principal Investigators time for 18 months.

The funders have no direct role in study design, conduct, data analysis and interpretation, manuscript writing and dissemination of findings. There were no conditions attached to funding.

Identification of the study funders provides transparency and accountability.

Figure Legends:

Figure 1: The stepped-wedge cRCT design for potential use in a full trial

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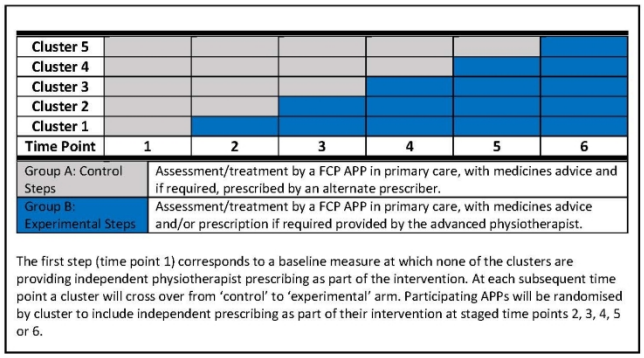
Figure 1: The stepped-wedge cRCT design for potential use in a full trial



209x297mm (200 x 200 DPI)

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Supplementary File 1: Participant consent form

CONSENT FORM: Person with Back Pain

Title of Project: Prescribing medications for low back pain by physiotherapists

Name of Participant: ……

Please initial box

1. I confirm that I have read and understand the information sheet, for the above study. I have had the opportunity to consider the information, to ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that all data will be confidential and securely stored for a period of 10 years. I understand that if I withdraw from the study my data up to the point of my withdrawal will be used in the analysis ☐
4. I agree to take part in the above study ☐
5. I agree to be contacted to take part in the focus group ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

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Supplementary File 2: Outcome Measures Questionnaire

Outcome Measures Questionnaire

Participant Questionnaire

Q1 What is your gender?

- ❍ Male
- ❍ Female
- ❍ Other

Q2 What is your age?

- ❍ 17-29
- ❍ 30-39
- ❍ 40-49
- ❍ 50-59
- ❍ 60 or older

The Keele STarT Back Screening Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible and it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

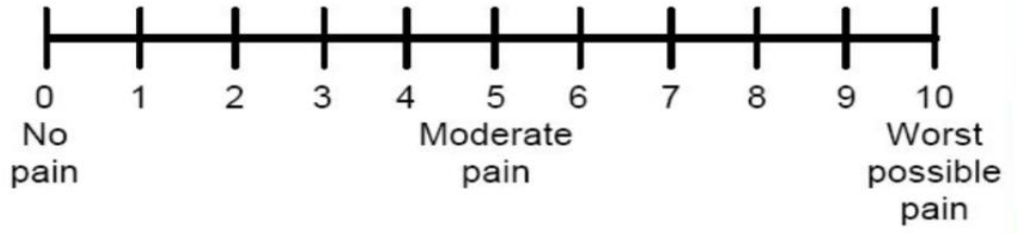
9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

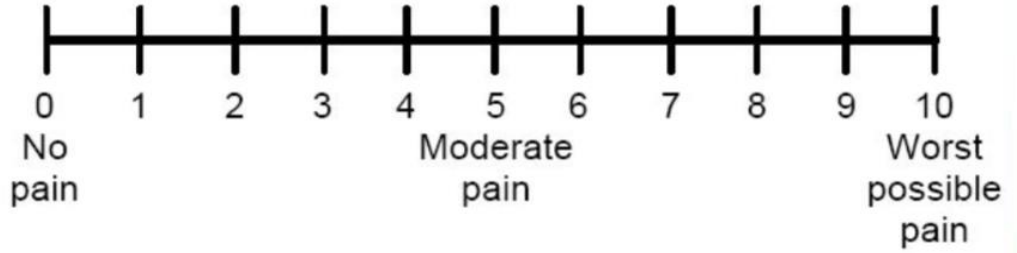
Funded by Arthritis Research UK

On the scales below (0-10), please mark the amount of back pain that you have experienced:

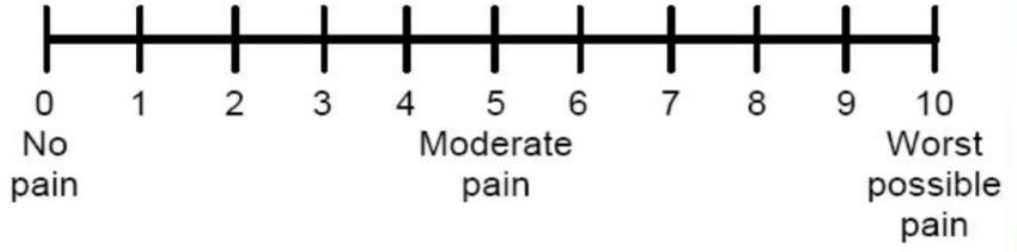
Worst pain over the last two weeks



Least pain over the last two weeks



Average pain level today



The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.

13. My back is painful almost all the time.

14. I find it difficult to turn over in bed because of my back.

15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or stockings) because of the pain in my back.

17. I only walk short distances because of my back.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Tampa Scale:

Please mark how much you agree or disagree with the following statements:
1= Strongly disagree
2= Disagree
3= Agree
4= Strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Since receiving your prescription from the physiotherapist, how many days have you taken the medication to date?

Have you seen any other healthcare professionals for your back pain since your initial assessment?	Yes		No	

If YES, which type of health professional(s) have you seen, and on how many occasions?	Number of occasions

Have you had to take any time off work due to your back pain?	Yes		No	

If YES, how many days have you had to take off work due to your back pain?

Thank you for completing this questionnaire

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Supplementary File 3: Participant Information Sheet

Participant Information Sheet: Person with Back Pain

Study title: Prescribing medications for low back pain by physiotherapists

We would like to invite you to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. The study is part of a larger PhD being completed by Tim Noblet (Researcher). Someone in our research team will go through the information sheet with you and will answer any questions that you have. Please ask if anything is not clear or if you would like more information.

What is the purpose of the study?

1 in 5 people with Low Back Pain (LBP) see their General Practitioner (GP) and this makes up almost 1 in 10 GP Consultations. Each year in the UK over 3 million working days are lost because almost 1 in 3 adults experience LBP at any one time. Early assessment and management of LBP is important to reduce long term problems.

The NHS is committed to providing the best services for all its patients, and due to the growing demand on health services, new and innovative ideas are being trialled to maximise quality care. A range of organisations including the British Medical Association and the Chartered Society of Physiotherapy have committed to enabling patients with LBP to be able to book appointments directly with the NHS physiotherapists in their local health centre without having to see a GP first. In addition to the normal treatment, physiotherapists are now able to prescribe medicines such as pain killers which patients usually need to get from their GP. To do this the physiotherapists complete a programme of education the same as your doctor or dentist.

Patients being able to access physiotherapists who can prescribed medicines directly is a new system in England. This study is intended to help decide how we will best assess what and what does not work, to enable provision of the best healthcare for people in England. This will be undertaken by asking approximately 30 people to complete questionnaires. A small number of people may also be asked to wear monitoring equipment (like 'fitbits') for a week, which assesses how active they are during each day, and 6-8 people will also be invited to participate in a focus group where they will be asked to share their opinions on how the study was conducted and how we could improve the evaluation process for the future. Physiotherapists will also have an opportunity to voice their opinions and experiences in a 1:1 interview. The results will be used to plan a large clinical trial to access how well the new services work for patients.

Why have I been invited?

You have been invited to take part because you have attended an appointment with the physiotherapist for your LBP and require a prescription to support your treatment. We aim to recruit 30 people across England.

Do I have to take part?

It is up to you to decide whether or not to take part. Feel free to ask any questions. After you have asked any questions, if you agree to take part, the researcher will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the normal treatment that you would receive.

What will happen to me if I take part?

If you choose to take part in the study, you will be asked to fill out a short questionnaire on a tablet computer at your appointment with the physiotherapist. You will be asked to complete the same questionnaire 6 weeks later and 12 weeks later- these can either be sent to you by email or hard copies provided with stamped addressed envelopes so that you can return the questionnaires by post.

Some patients will also be asked to wear a small monitoring device like a 'fitbit' on their belt for 7 days. The monitoring devices measure the amount of time people spend moving and being still as well as your sleep pattern.

6-8 patients will be invited to attend a focus group at a local venue, and again it is up to you whether you choose to attend or not.

What will I have to do?

The questionnaire will take approximately 15 minutes to complete, asking you for your contact details and for information about how your back pain is affecting your everyday life at that point in time. For the 6 & 12 week questionnaire you will be able to choose either a paper (postal) or email version for you to complete. Support from your physiotherapist will always be available to you to help in completing the questionnaire.

What are the possible disadvantages of taking part?

It is possible that when talking about your back pain or filling in the questionnaire we may ask you to relive events which are emotional for you. However, we will make every effort to ensure that you are comfortable at all times. The only cost to you is the time needed to complete the questionnaire and (for some people) attend a focus group.

What are the possible benefits of taking part?

We are not able to make any promises on the benefits at this stage until we have analysed the information you provide, which may help you and other patients in the future. It will not change the treatment that you receive for your back pain.

What will happen when the research stops?

When the research is complete, your future treatment will not be affected in any way. Decisions about your future care will be in-line with standard procedures at the GP practice/health centre that you have been attending.

What will happen if I don't want to carry on with the study?

If you do not wish to carry on with the study, you are free to withdraw at any time, without having to give a reason. Your decision to withdraw will not influence your current or future health care. It is important for us that information collected up to the point of your withdrawal is included in the analysis.

What if there is a problem?

It is unlikely that there will be any problems during the study. If you have a concern about any aspect of the way that you have been approached or treated during the course of this study, you can speak to Mr. Tim Noblet (researcher) or Dr Alison Rushton (Chief Investigator) who will answer any questions you have. If you remain unhappy and wish to complain formally, you can do this by following the

National Health Service complaints procedure. You can get advice from the Patient Services Teams at your GP practice/ health centre (all contact details below).

In the unlikely event that you are harmed whilst participating in this study, there are no special compensation arrangements, but if this is due to someone's negligence then you may have grounds for legal action. The normal National Health Service complaints mechanism will still be available to you. You may obtain advice from the Patient Services Teams at your GP practice/ health centre (contact details at the end of this information sheet).

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of the study will be kept confidential. Your name or contact details will not appear on any data and you will not be identifiable from any report or publication of the findings. Your contact details will be held on a computer database so that questionnaires can be sent to you and the focus groups can be organised. This will be password protected and only accessible by the researchers. Passwords will not be used by or given to anyone outside the research team. Contact details will be destroyed at the end of the study. All information from the questionnaires that you complete and the 'fitbits' (if you wear one) will be kept securely by University of Birmingham for ten years following the study. After that period, all information will be disposed of in a secure manner through confidential waste.

What will happen to the results of the study?

Results from this study will be used to develop a clinical trial that will evaluate the use of physiotherapists who can prescribe medications in GP practices and health centres. This trial will aim to improve the patient experience and their outcomes.

The results will be published in scientific journals and through presentation at research conferences. You will not be identifiable in any report, publication or presentation. If you are interested in the results of this investigation you can obtain a summary of the results by contacting Mr. Tim Noblet or Dr Alison Rushton (contact details below).

Who is organising and funding this study?

The research is sponsored by the University of Birmingham and funded by Health Education England and the Private Physiotherapy Educational Fund. The research will be conducted by physiotherapists at Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust or Windemere/ Ambleside Health.

Who has reviewed the study?

All research in the NHS is reviewed by the Research Ethics Committee, engaged to protect your interests and those of the researchers. This study has been reviewed and given favourable opinion by the IRAS and the Research and Development Directorates, Guys and St Thomas' NHS Foundation Trust, the Sheffield Teaching Hospitals NHS Foundation Trust and Windemere Health Centre.

The role of the University of Birmingham

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham securely keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your physiotherapists will collect information from you for this research study in accordance with our instructions. The NHS site will keep your name and contact details confidential. If you consent to be approached to participate in a focus group, the University of Birmingham will have access to your name and contact details to arrange the focus group. The researchers who analyse the information collected will not be able to identify you and will not be able to find out your name or contact details.

The NHS site will keep identifiable information about you from this study 10 years after the study has finished.

You can find out more about how we use your information by contacting Legal Services at dataprotection@legalservices.contacts.ac.uk.

Contact for further information or any questions about this study:

Tim Noblet (researcher)
Tel: 07740360178
Email: TDN818@student.bham.ac.uk

Dr Alison Rushton (Chief Investigator / supervisor)
Tel: 0121 415 8597
Email: a.b.rushton@bham.ac.uk

Centre of Precision Rehabilitation Spinal Pain, School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT

Site PALS Information:

One Medical Group-Windermere Health Centre & Ambleside Health Centre
Telephone No:015394 45159
Email Address: tess.shaw@onemedicalgroup.co.uk

Sheffield Teaching Hospital NHS Foundation Trust
Telephone No: 0114 271 2400
Email Address: PST@sth.nhs.uk

Guy's and St Thomas' NHS Foundation Trust
Telephone No: 020 7188 8801
Email Address: pals@gstt.nhs.uk

Thank you for taking the time to read this information sheet.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	11
	4c	How participants were identified and consented	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	9-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	13-14
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12

NB: Results, discussion and conclusion components N/A for protocol papers.

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.