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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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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 2014. 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 multimodal 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 behaviour and feasibility of use. (2) Embedded qualitative component. A focus group and semistructured 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 Consolidated Standards of Reporting Trials 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 redesign of the essential full randomised controlled trial.

Trial registration number ISRCTN15516596, Pre-results.

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, healthcare 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.

BACKGROUND

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 >25 years are experiencing LBP.[2] Data indicate 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 used to improve outcomes through recognising clinical heterogeneity, ensuring that

all biopsychosocial risk factors are addressed, improving patient management and reducing the overall cost of healthcare.[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 outdated traditional LBP clinical pathways, and the introduction of new treatment models designed to maximise clinical and cost-effectiveness, while readying the health services for the future.[10–12]

Physiotherapists are experts in the assessment, diagnosis and treatment of musculoskeletal disorders.[13] For >30 years, physiotherapists have been working in advanced practice roles across the country, using 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 when working 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, in collaboration with NHS England, the Royal College of General Practitioners (RCGP), the British Medical Association and the Chartered Society of Physiotherapy 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 on 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 multicentre 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 the following:
  - 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 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 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 checklist.[33 34]

The feasibility trial will use a mixed-methods research approach, comprising the following:

- A quantitative one-armed feasibility trial.
- Qualitative semistructured interviews and patient focus groups, using thematic analysis.

Mixed-methods designs are recognised to enable a richer synthesis, generating data that 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. APPs who are not prescribers start in the control group and cross to the experimental group.[39–42]

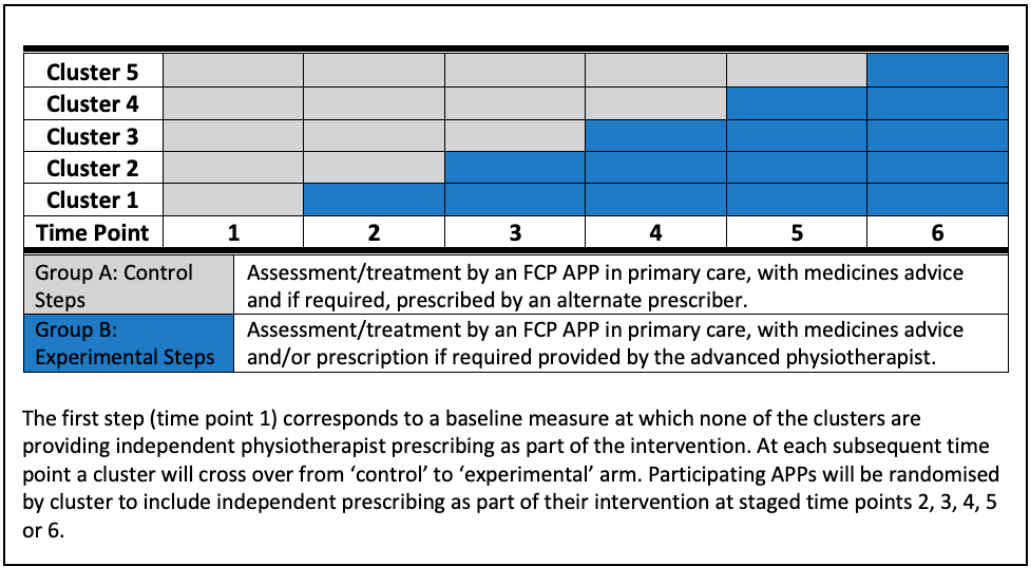

Figure 1 The SWcRCT design for potential use in a full trial. APP, advanced physiotherapy practitioner; FCP, first contact advanced physiotherapy practitioner; SWcRCT, stepped-wedge cluster randomised controlled trial.

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 intracluster correlation coefficients 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 used to evaluate the trial objectives.[29 44] Participant consent forms (online supplementary file 1) and patient-reported outcome measures (online 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 end point 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 it will be sent at 24 and 48 hours 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 who are interested in participating will be provided with a participant information sheet (online 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 with or without 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.[82]
- Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy.[82]
- Spinal stenosis.[83]
- Suspicion of or confirmed cauda equina syndrome.[84]
- Does not have capacity to consent.[85]
- Unable to receive email and/or complete online questionnaires.

LBP, low back pain.LBP, low back pain.

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 used to evaluate the feasibility trial objectives.[26–29] As per 'current normal practice', an APP acting as an 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

Table 1 Secondary outcome measures and their rationale

Outcome	Measure	Rationale
Health-related quality of life (QALY)	EQ-5D 5 L	The EQ-5D 5 L is used to measure health-related quality of life demonstrating good reliability and validity through psychometric testing.[86] If feasibility is found, this measure will inform cost utility in a full RCT.
Pain-related fear of movement	The TSK	The TSK is a 17-item tool that 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.[87] This outcome measure has been found to show good validity and reliability when measuring pain-related fear of movement.[88]
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 2 diabetes and mortality.[89] Systematic reviews have revealed that physical activity of people with LBP is lower or equal to the healthy population[90–92]; however, there appears to be differing patterns of physical behaviour, with the back-pain population engaging in shorter bouts of physical activity that are not long enough to incur health benefits (>10 min).[92 93] An accelerometer will be used to collect data including steps count and sedentary periods.[94] 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.[94 95]
Sleep	ActivPal 3 Accelerometer	50%–60% of people experiencing either acute or persistent LBP experience high levels of sleep disturbance.[96] Poor sleep over long periods of time may lead to depression, obesity, diabetes and cardiovascular disease.[96 97]Patients with LBP suffering with sleep disturbance have been reported as twice as likely to be hospitalised.[98] Improved sleep has been seen to modulate pain intensity,[99] 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.[100]
Time to return to work and nature of return to work (eg, full time, part time and light duties)	Days	Work absence owing to sick leave for work disability is a key issue clinically, socially and economically. The minimally clinically important change (MCIC) for time to 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.[62] 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 the 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.

within the multimodal 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.[56] However, no consensus exists with regards to the instruments most suitable to measure these domains.[56] 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 study's objectives while attempting to minimise the burden on participants. Two primary outcome measures (detailed below) were selected as they jointly evaluate the core outcome set requirements.[56] Details 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 (eg, the worse pain you can possibly imagine).[57]Patients with pain have been shown to prefer the NRS over other pain measure including the pain Visual Analogue Scale owing to simplicity and clarity.[57 58] The NRS has demonstrated good reliability, validity and responsiveness and has been used extensively in pain research.[59–61] A reduction of 2.5 points on the NRS has been shown to be clinically important for chronic LBP.[60–62] Participants will score pain in three categories: 'worst pain over the last 2 weeks', 'least pain over the last 2 weeks' and 'average pain level today'.
- RMDQ: The RMDQ is one of the most widely used outcome measures for LBP, with well-established good levels of validity and reliability.[63] 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 62 63] The 24-item questionnaire takes approximately 5 min to complete and includes items assessing physical activity, sleep, psychosocial factors, activities of daily living, appetite and pain.[64] Scores range from 0 (no disability) to 24 (maximum disability), with a change of 3.5 points deemed clinically significant.[62]

Sample size

As the number of FCP physiotherapists that are registered to prescribe is currently limited,[65] three first contact APPs (n=3), across three 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 66] 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.[67]

EMBEDDED QUALITATIVE COMPONENT

Design

An embedded qualitative component will be used as recommended by current guidance, to address trial objectives and to refine and adapt the proposed full trial design following evaluation.[68 69] The methodology was designed and is reported using the Consolidated Criteria for Reporting Qualitative Health Research.[70]

Advanced physiotherapy practitioners

Semistructured 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 71 72] 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.[73] 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.[71]

Patients

A focus group of patients will take place following the 12 weeks assessment point, specifically to evaluate the research objectives.[27 74] Focus groups are recognised to produce data on collective views, generating a rich understanding of participants' experiences.[75] A purposive sample of six to eight patients, representative of ages and sexes will be used; this sample size is reported in the literature as the optimum.[74] The focus group will meet in the qualitative laboratory within the 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.[73] 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.[70]

Analysis and findings

To fulfil the trial objectives, a thematic analysis approach will be used to analyse and synthesise the qualitative data.[45 76 77] 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.[76–79] 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 77 78] 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.[77 78] To avoid single researcher bias, a second researcher (AR) will re-interrogate the data to validate or contradict findings.[77] Outcomes will then be discussed with a panel of experts for confirmation and agreement.[76 77 79]

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 80] Trial objectives will be considered successful if the success criteria are satisfied following the integration of the quantitative and qualitative findings.[80]

Patient and public involvement

Patients with LBP are part of our research team/co-investigators to ensure that 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 81] These personal data and participant contact details (stored during study to arrange focus groups and interviews) will be securely

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 required by clinicians	APPs report that they had 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 (16 hours/day for 7 days)

Continued

Table 2 Continued

Specific objectives	Success criteria
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

APPs, advanced physiotherapy practitioners; FCPs, first contact advanced physiotherapy practitioners.

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 81] Approval was granted on 30 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 81] 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 redesign of the essential full RCT.

Contributors TDN is a clinical advanced practice physiotherapist and PhD candidate at the University of Birmingham (UK). ABR is a reader in musculoskeletal rehabilitation sciences and lead supervisor. JFM 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. TDN wrote the first draft of this article and has worked with all authors to develop subsequent drafts. All authors gave final approval prior to publication. Patients and the general public were involved in the design of this study via PPI evaluation groups.

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Patient consent for publication Not required.

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