PROTOCOL
Improving Patient Choice in Treating Low Back Pain (IMPACT - LBP)

NIHR RfPB Ref – PB-PG-0808-17039

Contents

Background

Low back pain (LBP) is a common disabling and expensive disorder. In 1998 treating this cost the NHS £1632M.[1] NICE guidelines for the early management of chronic non-specific LBP recommend that clinicians consider offering patients with chronic LBP a course of one of a range of different therapies (acupuncture, exercise, manual therapy), depending on the patient's preference.[2] These therapies yield modest beneficial effects at a modest cost. The clinical effects and the cost-effectiveness of these different treatments are of a similar magnitude, so there is no clear basis for preferring any one of these treatments for use in the NHS.[2] However, it is likely that some patients will obtain more benefit from one type of treatment rather than another. An understanding of the factors which inform patient choice and decision-making will help patients make the best decision for them. This will help maximise the uptake and effectiveness of these treatments.

Informed patient choice improves health and patient centred outcomes and is central to 'Creating a Patient Led NHS' and the NHS Constitution.[3-5] A patient-centred approach using shared decision-making (SDM), involves the patient and healthcare professional discussing treatment options and agreeing a management plan.[6,7] This approach is widely advocated but its use in practice is challenging.[8] SDM involves adopting a patient-centred approach; taking patient expectations, preferences, concerns and ideas into account. In contrast, informed decision-making presents patients with relevant information and options without the healthcare professional expressing a preference. This 'informed model' gives patients autonomy but fails to take into account the shared interaction.[9] We prefer to call this patient-practitioner interaction 'informed shared decision making' (ISDM). The quality of patient-practitioner interactions may be crucially important in improving back pain outcomes.[10]

Coaching to support patients making decisions is effective in aiding patients' knowledge, information recall, and participation in decision making.[5] Decision aids are 'interventions designed to help people make specific and deliberate choices among options by providing information about the options and outcomes relevant to a person's health status'.[5] These provide information to facilitate patients' involvement in the decision making process. Patient expectations and preferences also play a role in decision-making and may affect outcomes. Patients with a higher expectation of recovery have reported higher functional improvement.[11] Within randomised controlled trials (RCTs) those randomised to their preferred treatment gain more benefit.[12] One RCT of LBP treatment found that those who expected better outcomes with treatment gained more

benefit than those who did not, another one failed to show that expectations affected outcome.[13,14] Patient preferences may also affect treatment adherence.[15]

Patients want a patient-centred approach to decision-making incorporating communication, partnership and health promotion.[16] Problems arise because guidelines make assumptions about peoples' preferences. Clinicians do not always involve patients in decision-making; possibly because they feel ill trained to do so.[17] Despite this, GPs have positive views about SDM and can gain the skills required to implement SDM in practice.[18,19] An RCT of this approach did not find significant differences in patient-based outcomes.[20] There are very few studies of physiotherapists' beliefs about the treatment of back pain.[21]

Building on previous work, we want to test the hypothesis that an ISDM model, used at first contact with physiotherapy services, can improve outcomes for patients with LBP. This proposal focuses on exploring the process of decision making, developing a manualised decision support package (DSP), training physiotherapy staff in its use, and testing its effect on patient satisfaction.

A cluster randomised control trial testing the hypothesis that improved ISDM improves clinical outcomes and the cost-effective use of healthcare resources is beyond what is practical with the RfPB funding and unlikely to be funded without good quality feasibility data. If we can show improved satisfaction with treatment in this pilot it will form the basis for a future application for a definitive RCT with clinical and cost-effectiveness as its outcomes.

Research Objectives
The overall aim of this project is to develop and test a Decision Support Package (DSP) to help patients seeking care for back pain to make better, more informed choices, about their treatment. In this pilot study we will:

> 1:- Developing an understanding of the factors which inform choice and decision-making.
> 2:- Using this information we will develop a manual, and training package, to help health professionals with the informed shared decision-making process.
> 3:- We will test this intervention in a pilot RCT to measure the effects on patient satisfaction.

Primary outcome measure:
We will use satisfaction with treatment at three months using a five-point Likert Scale (very satisfied to very dissatisfied) as our primary outcome.

At baseline and three months we will collect:
Pain duration
Work & benefit status
Treatment preferences
LBP-related disability
LBP & disability over the preceding month
Health-related quality of life
Health utility
Anxiety and depression
Self-efficacy for people with chronic pain

Fear avoidance beliefs

Methods

This proposal starts from the NICE chronic Low Back Pain (LBP) guidelines which advise offering a course of manual therapy, exercise therapy, or acupuncture.[2] They advise that choice of course of therapy should be informed by patient preferences. We anticipate that, following implementation of the NICE guidelines, these therapies should be routinely available. In practical terms, the point of decision-making is likely to be at first assessment within a physiotherapy department. Our focus is on decision making in this consultation.

Recruitment

We will identify participants from those seeking treatment from the physiotherapy service at Coventry PCT. We will include patients referred by other primary and secondary care professionals and self-referrals.

Table 1: Inclusion/exclusion criteria

Inclusion criteria	Exclusion criteria
People seeking treatment for non specific LBP	Severe psychiatric disorder
Ages ≥18	Severe personality disorders
fluent spoken and written English	A terminal or critical illness
	Possible serious spinal pathology (e.g. tumour, sepsis or fracture)

We will develop, and test, a complex intervention within the MRC framework for complex interventions.[22] The final intervention will be a decision support package for patients with LBP.

1) UNDERSTANDING WHAT IS NEEDED

A) Information and evidence for decision making

NICE have reviewed the evidence for the treatment decisions. The information about the treatments and evidence in our DSP will be based on this guidance, the BeST data and any subsequent high quality RCTs.

B) Literature review

We have not found any published DSPs for LBP. However, decision aids have been developed for other conditions.[5,23-25] We will systematically seek studies of decision aids for treatments, for benign disorders, with multiple moderately effective treatment options. We will extract data about the components of these interventions and the mechanisms by which they are thought to act. For example, for a decision aid about natural health products at menopause, it was found women were influenced by other people's opinion and cost.[26] We will also systematically identify qualitative studies of people with chronic back pain that include accounts of why they chose different therapies.

C) Secondary analysis of interview data

We have interview data from people living with back pain undertaken to investigate change over time when living with back pain. We will re-analyse these data to identify influences on treatment decisions.

D) Patients' perspective

Informed by A-C we will develop an initial screening questionnaire to explore current patient preferences and to identify people interested in participating in our focus groups. We will approach around 100 people seeking care from the physiotherapy department for LBP. Interested respondents will provide a sampling frame for our focus groups. Our purposive sampling with be informed by age, duration and severity of LBP, previous treatments, and satisfaction with current treatment.

We will run two focus groups to develop a broad understanding of the factors that inform choice and decision making among patients with back pain in which we will explore:
- how patients make decisions and choices about treatments for their back pain
- what information patients would like to help them make more informed choices
- what patients think of the existing material on offer to them.

E) Physiotherapists' and experts' perspective

To develop a broad understanding of therapists', and experts', views and experiences of informed shared decision making for LBP treatments, we will:

a) recruit physiotherapists who regularly provide first contact care for low back pain from a neighbouring PCT to a nominal group a formal consensus method using statistical aggregation.[27]

b) undertake a Delphi study with 'experts' in the experience of LBP such as patient group leaders, expert patients, advocacy group activists, and 'experts' in decision support & decision aids.

Analysis of qualitative data

Qualitative data will be analysed by the researcher in collaboration with other members of the research team using the FRAMEWORK method to identify key concepts and themes.[28]

2) DESIGNING AND DEVELOPING THE INTERVENTION

Using the data from part one, we will design a DSP to help patients make better informed choices. This work will be carried out in collaboration with physiotherapists, patients, and experts in the field of decision support and decision aids. At this time it is difficult to predict the exact nature of the DSP – this will depend on the findings from part one. However, we anticipate that there will be: an information package that summarises the nature of each intervention; a rationale for the interventions and what is known about their effectiveness and cost-effectiveness. This will be suitable for use by both patients and therapists. We anticipate a training programme for physiotherapist to improve their knowledge of the treatment options and their skills in ISDM. The DSP will be designed to be easily implementable into routine NHS care.

Visual images maybe useful in the DSP therefore we will ask a select number of patients receiving the different treatments supported in our DSP to have their photograph taken during the treatment

session. We will provide patients with a patient information leaflet explaining the use of the photographs and ask them to sign a consent form if they wish to take part.

3) OPTIMISING THE DSP

We will randomly allocate half of the physiotherapists to deliver the intervention. In the early phase we will ask physiotherapists to test the intervention in an uncontrolled manner allowing us to test practicality and feasibility in the clinical environment. We will assess this by direct observation of the consultation process and focus groups with patients and physiotherapists. This will allow us to optimise the intervention before starting the pilot RCT.

4) PILOT RCT

Coventry PCT physiotherapy service sees 300 new LBP referrals a month, with many patients seen within four weeks of initial referral. The service uses a paper free referral system making it the patients' responsibility to call the 'Back Pain Hotline' and book an appointment following advice from their GP. A rapid assessment of potential participants is needed to ensure service quality is not affected.

a) At the first point of contact with the physiotherapy service, the hotline staff will make the patient an appointment. The physiotherapy department will send each participant an invitation letter, patient information sheet, consent form, reply slip and pre paid envelope by first class post. In the invitation letter participants will be advised to complete and return the reply slip if they do not wish to participate. Potential participants will be advised the research team will contact them, to discuss the study and answer any questions, if no response is received within seven days from when the invitation pack was sent to them asking them if they want to participate and to ask them to return the baseline questionnaire. We believe this is ample time for the potential participants to read the information provided to them before completing and posting their baseline questionnaire and signed consent forms. The approaches will be made from the physiotherapy clinic to ensure that no patient specific data leaves the PCT. We have used a similar approach successfully, and without complaints from those approached, in a population survey where a poor response rate was anticipated.[29]

Participants who meet the inclusion criteria and send back a completed baseline questionnaire and consent form will be included in the trial.

b) Upon receipt of the completed consent form and baseline questionnaire, an eligibility form will be completed for every potential participant. The participants' details for those who meet the inclusion criteria will be communicated to the research team member based at the physiotherapy department. Participant allocation to the study arms will be via cluster randomisation by therapist. Those who have an appointment with a physiotherapist randomised to the intervention arm will receive the Decision Support Package two weeks before their initial appointment.

c) Participants will attend a one to one assessment by a physiotherapist, either usual care or DSP enhanced. They will be informed of the treatments on offer. The patient will have the opportunity to discuss and choose their treatment.

d) After the consultation the patient will be sent a brief questionnaire addressing their satisfaction with the decision-making process. They will return this by post to the study team.

e) The participants will then complete their course of treatments in the usual manner. We anticipate that all of these treatments will be complete within three months. We will send follow-up questionnaires, including questions on satisfaction with treatment, and standard back pain outcome measures by post, three months after randomisation.

f) Recruited participants follow-up

We will send postal reminders after two and four weeks, and if necessary, we collect a minimum data set by phone from non-responders. As the recruitment team will have the participants contact details, a letter will be sent two weeks from their follow-up due date, asking them to return the follow-up questionnaire, if not received a week after it has been posted to them. We will collect core outcome measures via telephone if participant is not able to return the form back to the Clinical Trials Unit. This will help reduce loss to follow-up by utilising an established and effective system that utilises reminders by letter/or telephone contact.

Allocation concealment and protection from bias
Physiotherapy randomisation: We will randomise half the physiotherapists to be intervention therapists and half to be control therapists. Physiotherapists' randomisation was carried out by statisticians not otherwise connected to the study. We will seek to minimise the risk of contamination by asking the intervention therapists not to share the material with the control therapists. Any contamination will reduce any apparent treatment effect.

Participant treatment allocation: Patients will then be cluster randomised by physiotherapists. The patients will be allocated to the study arm their consulting physiotherapist has been randomised to. Once the consent form and baseline questionnaire is received, an eligibility form will be completed to ensure which patients meet the inclusion criteria for the study, and those who do, their trial numbers will be communicated to the Principal Investigator at the physiotherapy department. When completing the eligibility form, the study team based at Warwick Clinical Trials Unit will not know which physiotherapist the eligible patient will be seeing therefore not know the patients' allocation arm. The hotline staff members, responsible for making initial assessment appointment for the patients and sending the invitation packs to the potential participants, will be blind to which arm the physiotherapists has been randomised to. Patient allocation to physiotherapist will be random too. To ensure of this, at random time points of the recruitment period, the hotline staff members will be asked by the study team if they were aware which physiotherapist is in which arm.

The study team except for the statistician will remain blind to treatment allocation until after the statistical analyses are complete.

Outcome measures
Our package of outcome measures is based on those we have used successfully in two previous large scale community based trials of LBP treatments and are in line with international recommendations. [30,31]

Baseline data
- Demographic data - age, gender and ethnicity
- Pain site, symptoms, frequency and duration [32]
- Work & benefit status
- Treatment preferences

Primary outcome measure:
We will use satisfaction with treatment at three months using a five-point Likert Scale (very satisfied to very dissatisfied) as our primary outcome. We have used this question in previous back pain trials. It is an amended version of the standardised and recommended single-item question.[33]

A study of this size is unlikely to show a change in clinical outcomes. Satisfaction with treatment is a useful outcome measure that is likely to be more sensitive to change than clinical outcomes. If, in this pilot, we can generate some evidence that we can improve satisfaction we will have a justification for proceeding to a trial to improve clinical outcomes.

Secondary outcome measures:
- Roland Morris Disability Questionnaire (RMDQ) [34] - The leading measure of LBP-related disability in primary care trials.
- Modified Von Korff [35] - A measure of LBP & disability over the preceding month.
- SF-12 - A generic measure of health-related quality of life. [36]
- EuroQol [37] - A generic measure of health utility that is designed for use in RCTs.
- Hospital Anxiety and Depression Scale (HADS) [38] - An established and validated self rating instrument for anxiety and depression.
- Pain Self-Efficacy Questionnaire (PSEQ) [39] - An established measure self-efficacy for people with chronic pain.
- Fear Avoidance Beliefs Questionnaire (FABQ) [40] - The physical sub-scale of FABQ measures attitude to movement in back pain.
- Compliance - we will measure compliance from the physiotherapy department's attendance records.

Immediate follow-up
The immediate follow-up assessment will focus on satisfaction with the decision making process. We will use the 'Satisfaction with Decision Scale'.[41] This is a tool used to measure satisfaction with the health care decision. The scale has been adapted and applied to other conditions. [42]

Three-month follow-up

For this pilot RCT we will do a single follow-up after three months; when treatment will be complete and maximum benefit from treatment is expected. In addition to measuring satisfaction and repeating baseline measures we will collect data on health service use and health transition.[43] We have collected this data in two previous trials. [30,31]

Once the participant's three months follow-up has been received by the IMPACT-LBP research team, a sub-sample of approximately 40 participants, selected on the basis of outcomes and demographic profile will be invited to consider referral to an additional interview study – the EPIC study which is investigating experiences of the treatment, perceived outcomes and the relevance of measures used in IMPACT-LBP.

Exploring Perceptions of Important Change (EPIC) study protocol

The IMPACT research team will develop a profile of participants who return three month follow up questionnaires. The profile will include basic demographics and concordance status – that is a reflection of the match between participant's scores on the Roland Morris questionnaire and the Health Transition Question. Participants will be described as concordant where both measures indicate deterioration or improvement, discordant 1, where the Roland Morris indicates improvement and the response to the Health Transition Question indicates deterioration and discordant 2 where the Roland Morris indicates deterioration and the Health Transition Score indicates improvement. The profile will be used to allocate participants to the EPIC study sampling frame and determine eligibility for the study. IMPACT participants whose profile makes them eligible for EPIC will be sent a follow-up pack including the EPIC study participant information leaflet, and an invitation letter requesting the participant to consider taking part in an interview. Permission to share contact details and outcome measure scores with the EPIC team will also be sought. No further action will be taken where permission is withheld. Where permission is given contact details and outcome measure scores will be provided to the EPIC researcher based at Queen Mary, University of London. The EPIC researcher will contact the potential participant, provide more information as necessary and as appropriate arrange a convenient time to meet. Formal informed consent to interview participation will be obtained prior to data collection. During the interview, which will last around one hour, the participant will be asked about changes in their back pain, what changes were most important to them, to what extent the outcome measures captured information about these aspects, and where they felt the outcome measures could be improved. A full protocol for this study and the related documents has been submitted to South East Coast- Brighton and Sussex Research Ethics Committee for ethical consideration; REC reference number 11/LO/1190.

Sample size

In BeST the difference in satisfaction with treatment at three months was 23.6% compared to 54.3% for control and treatment arm, respectively.[30] Assuming satisfaction is 50% in the control group (similar to the treatment arm in BeST) then to show a similar additional improvement to 75% with 80% power at 5% significance level needs data on 58 participants in each group.

However, we need to adjust for clustering design effect due to the change in study design. By adjusting for cluster randomisation and taking into consideration the number of clusters (number of physiotherapist recruited into the study=11), the cluster size (number of patients per

physiotherapist) at 3 months follow-up where the primary outcome measure of satisfaction with decision-making process is collected would need to be 21-22 patients per physiotherapist. [45] Taking into account the 20% loss to follow-up by 3months follow-up time point, the cluster size at baseline needs to be 26-28 patients per physiotherapist therefore a minimum of 286-308 participants. We would like to recruit a minimum of 300 participants.

With the current number of new referral a month at the Coventry and Warwickshire Hospital Physiotherapy department, the recruitment period is anticipated to be a minimum period of three months, assuming 30% of the new referral each month express interest in taking part in the study.
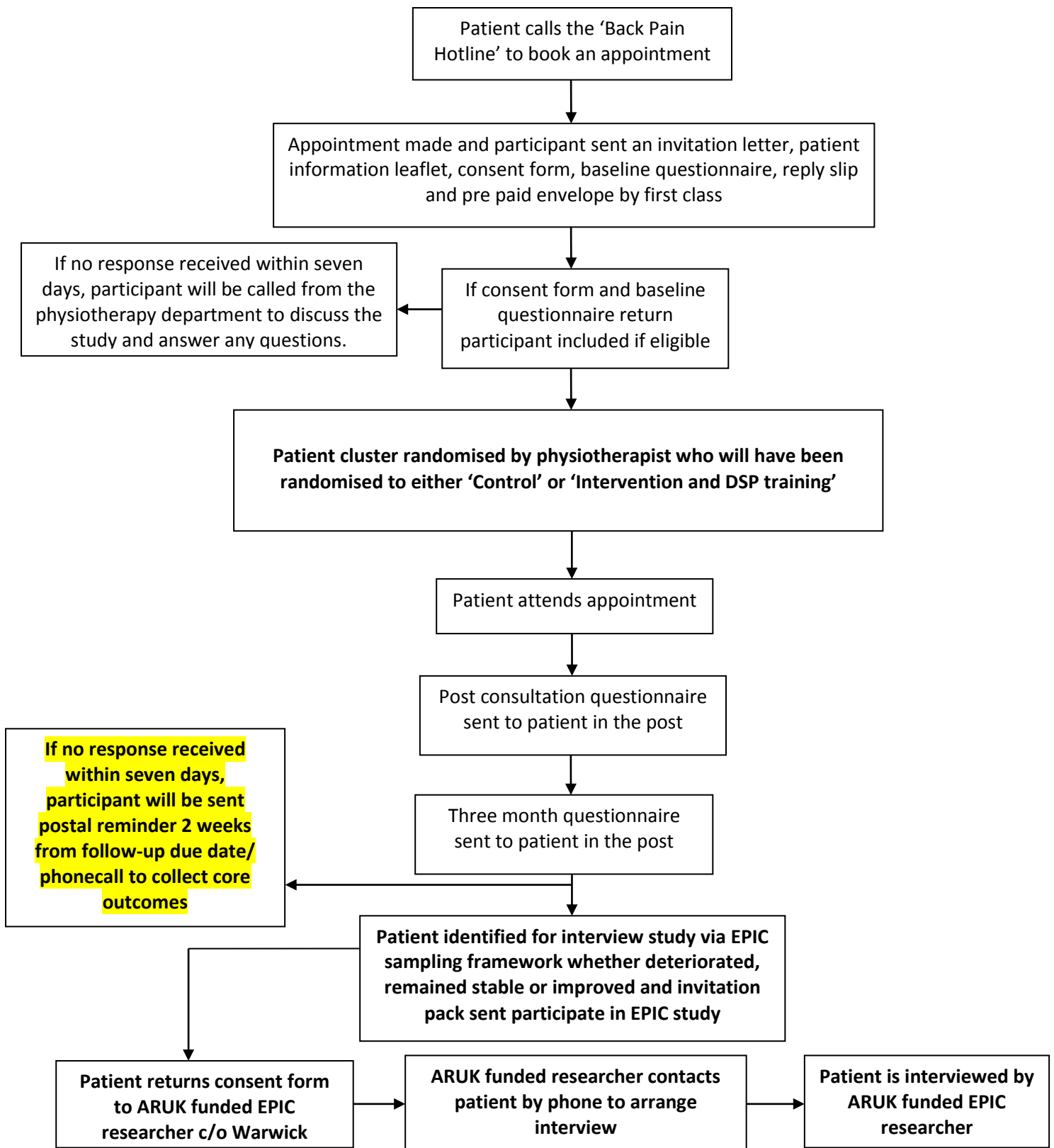
Statistical analysis

Descriptive summary statistics for demographic and baseline data will be provided. The dichotomised responses on the five point Likert scale to the treatment satisfaction question will be analysed by means of a generalised linear mixed model with logit link, fixed effects for intervention and baseline pain severity, and random physiotherapist effects. The estimated intervention effect (odds ratio) will be reported with 95% confidence interval and p-value testing the null hypothesis of no intervention effect. Continuous outcomes will be reported as difference in change from baseline with its 95% confidence interval.

Health economics

We will estimate the mean cost of the intervention and other back pain-related NHS services and participants' out of pocket expenses over the three-month study period. We will collect information on the cost of training for the physiotherapists in the DSP group: including the cost of the tutors' time to prepare and deliver the training, the cost of participants' time, travel costs and materials. Therapy cost will be collected from PCT records. The three month follow-up questionnaire will include questions about use of medication (prescribed and over-the-counter), GP attendances, inpatient stays, outpatient consultations, and visits to other therapists (NHS and private). Healthcare cost will be estimated using unit costs from the NHS tariff and standard references texts.[44]

The difference in mean costs and the difference in mean QALYs will be estimated with 95% confidence intervals, allowing for the effects of treatment, baseline pain severity, and treating physiotherapist. These estimates will help us to assess the potential benefits of conducting a definitive trial and economic evaluation. For example, if the DSP is associated with greater healthcare costs and no apparent improvement in health outcomes over this initial three-month period, it is unlikely that further research would be worthwhile, particularly if there is also no clear evidence of a strong patient preference for use of the DSP. However, if cost savings and/or health improvements are observed, it is possible that DSP may be a cost-effective intervention and further research would be warranted.

Study Flow Chart - RCT

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                    ┌─────────────────────────────┐
                    │  Patient calls the 'Back Pain│
                    │  Hotline' to book an         │
                    │  appointment                 │
                    └──────────────┬──────────────┘
                                   ↓
        ┌──────────────────────────────────────────────────┐
        │ Appointment made and participant sent an          │
        │ invitation letter, patient information leaflet,    │
        │ consent form, baseline questionnaire, reply slip   │
        │ and pre paid envelope by first class               │
        └──────────────────────────┬───────────────────────┘
                                    ↓
┌─────────────────────────┐   ┌──────────────────────────┐
│ If no response received  │←──│ If consent form and      │
│ within seven days,       │   │ baseline questionnaire   │
│ participant will be      │   │ return participant       │
│ called from the          │   │ included if eligible     │
│ physiotherapy department │   └────────────┬─────────────┘
│ to discuss the study and │                ↓
│ answer any questions.    │
└─────────────────────────┘
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Patient cluster randomised by physiotherapist who will have been randomised to either 'Control' or 'Intervention and DSP training'

Patient attends appointment

Post consultation questionnaire sent to patient in the post

Three month questionnaire sent to patient in the post

If no response received within seven days, participant will be sent postal reminder 2 weeks from follow-up due date/ phonecall to collect core outcomes

Patient identified for interview study via EPIC sampling framework whether deteriorated, remained stable or improved and invitation pack sent participate in EPIC study

Patient returns consent form to ARUK funded EPIC researcher c/o Warwick

ARUK funded researcher contacts patient by phone to arrange interview

Patient is interviewed by ARUK funded EPIC researcher

References

1. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84(1):95-103.
2. Savigny P, Kuntze S, Watson P, Underwood M, Ritchie G , Cotterell M, Hill D, Browne N, Buchanan E, Coffey P, Dixon P, Drummond C, Flanagan M, Greenough,C, Griffiths M, Halliday-Bell J, Hettinga D, Vogel S, Walsh D. Low Back Pain: early management of persistent non-specific low back pain. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners. 2009.
   http://www.nice.org.uk/nicemedia/pdf/CG88fullguideline.pdf
3. Department of Health (2005) Creating a Patient Led NHS: Delivering the NHS Improvement Plan. Department of Health.
4. The NHS Constitution, NHS London, 2009.
5. O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Rovner D, Holmes-Rovner M, Tait V, Tetroe J, Fiset V, Barry M, Jones J. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews 2003, Issue 1. Art. No.: CD001431. DOI: 10.1002/14651858.CD001431.
6. Stewart M. Patient-centred Medicine: transforming the clinical method. 2003, Oxford, Radcliffe Medical Press.
7. Thistlethwaite J. Shared decision making and decision aids - a literature review. Aust Fam Physician 2006;35(7):537-40.
8. Edwards A, Elwyn G, Wood F, Atwell C, Prior L, Houston H. Shared decision making and risk communication in practice: a qualitative study of GPs' experiences. British Journal of General Practice. 2005 Jan;55(510):6-13.
9. Tomlinson T. The physician's influence on patient's choices. Theorr Med 1968;7:105-21.
10. Foster NE, Pincus T, Underwood MR, Vogel S, Breen AC, Harding G. Treatment and the process of care in musculoskeletal conditions; a multidisciplinary perspective and integration. Orthop Clin North Am 2003;34:239-244.
11. Myers SS, Phillips RS, Davis RB, Cherkin DC, Legedza A, Kaptchuk TJ, Hrbek A, Buring JE, Post D, Connelly MT, Eisenberg DM. Patient expectations as predictors of outcome in patients with acute low back pain. Journal of General Intern Medicine. 2008 Feb;23(2):148-53.
12. Preference Collaborative Review Group. Patients' preferences within randomised trials: systematic review and patient level meta-analysis. BMJ 2008;31;337:a1864.
13. Kalauokalani D, Cherkin DC, Sherman KJ, Koepsell TD, Deyo RA. Lessons from a trial of acupuncture and massage for low back pain: patient expectations and treatment effects. Spine. 2001 Jul 1;26(13):1418-24.
14. Underwood MR, Morton V, Farrin A; UK BEAM Trial Team. Do baseline characteristics predict response to treatment for low back pain? Secondary analysis of the UK BEAM dataset. Rheumatology, 2007 Aug;46(8):1297-302.
15. Underwood M, Ashby D, Carnes D, Castelnuovo E, Cross P, Harding G, Hennessy E, Letley L, Martin J, Mt-Isa S, Parsons S, Spencer A, Vickers M, Whyte K. (2008) 'Topical or oral ibuprofen for chronic knee pain in older people. The TOIB study.', Health Technology Assessment, (1366-5278).
16. Little P, Everitt H, Williamson I, Warner G, Moore M, Gould C, Ferrier K, Payne S. Preferences of patients for patient centred approach to consultation in primary care: observational study. BMJ. 2001 Feb 24;322(7284):468-72.
17. Blendon RJ, Schoen C, DesRoches C, Osborn R, Zapert K. Common concerns amid diverse systems: health care experiences in five countries. Health Aff (Millwood) 2003;22(3):106-21.
18. Thistlethwaite J, Heal C, Tie RN, Evans R. Shared decision making between registrars and patients--web based decision aids. Aust Fam Physician 2007;36(8):670-2.

19. Elwyn G, Edwards A, Hood K, Robling M, Atwell C, Russell I, Wensing M, Grol R; Study Steering Group. Achieving involvement: process outcomes from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. Family Practice. 2004 Aug;21(4):337-46.

20. Edwards A, Elwyn G, Hood K, Atwell C, Robling M, Houston H, Kinnersley P, Russell I; Study Steering Group. Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. Family Practice. 2004 Aug;21(4):347-54.

21. Parsons S, Harding G, Breen A, Foster N, Pincus T, Vogel S, Underwood M (2007) 'The Influence of Patients' and Primary Care Practitioners' Beliefs and Expectations About Chronic Musculoskeletal Pain on the Process of Care: A Systematic Review of Qualitative Studies', Clinical Journal of Pain, 23 91 – 98.

22. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, Guthrie B, Lester H, Wilson P, Kinmonth AL. Designing and evaluating complex interventions to improve health care. BMJ 2007,3;334(7591):455-9.

23. Légaré F , O'Connor A, Graham I, Saucier D, Côté L, Cauchon M, Paré L. Supporting patients facing difficult health care decisions. Use of the Ottawa Decision Support Framework. Can Fam Physician. 2006; 52: 476-477.

24. Légaré F , O'Connor AM, Graham I, Wells GA, Jacobsen MJ, Elmslie T, Drake ER. The effect of decision aids on the agreement between women's and physician's decisional conflict about hormone replacement therapy. Patient Educ Counseling 2003, 50(2): 211-21.

25. Williams L, Jones W, Elwyn G, Edwards A. Interactive patient decision aids for women facing genetic testing for familial breast cancer: a systematic web and literature review. J Eval Clin Pract. 2008 Feb;14(1):70-4.

26. Légaré F, Stacey D, Dodin S, O'Connor A, Richer M, Griffiths F, LeBlanc A, Rousseau JLC, Tapp S. 2007. Women's decision-making about the use of natural health products at menopause: a needs assessment and patient decision aid. Journal of Alternative and Complementary Medicine. 13(7): 741-750.

27. Jones, J., Hunter D. Using the Delphi and nominal group technique in health services research. In: Qualitative Research in Health Care, 2nd edn. (ed. Pope, C & Mays, N). British Medical Journal, London, pp40-49.

28. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In Bryman A, Burgess RG, eds. Analysing Qualitative Data, pp 173-94. London: Routledge, 1994.

29. Choudhury Y, Hussein I, Bremner S, Eldridge S, Underwoood M. Methodological challenges and approaches to improving response rates in population surveys in areas of extreme deprivation: comparison of two pilot studies and a nested randomised controlled trial of personal correspondence. Submitted BMC HSR.

30. Lamb SE, Lall R, Hansen Z, Castelnuovo E, Withers EJ, Nichols V, Griffiths F, Potter R,Szczepura A, Underwood M. on behalf of the BeST trial group. A multi-centred randomised controlled trial of a primary-care based cognitive behavioural program for low back pain. The Back Skills Training Trial – "BeST" HTA 2009 (3780-7450).

31. UK BEAM Trial TEAM (Underwood M). 'UK Back pain Exercise And Manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care.' BMJ 2004, 229:1377-1381.

32. Dionne CE, Dunn KM, Croft PR, Nachemson AL, Buchbinder R, Walker BF, Wyatt M, Cassidy JD, Rossignol M, Leboeuf-Yde C, Hartvigsen J, Leino-Arjas P, Latza U, Reis S, Gil Del Real MT, Kovacs FM, Oberg B, Cedraschi C, Bouter LM, Koes BW, Picavet HS, van Tulder MW, Burton K, Foster NE, Macfarlane GJ, Thomas E, Underwood M, Waddell G, Shekelle P, Volinn E, Von

Korff M. A consensus approach toward the standardization of back pain definitions for use in prevalence studies. Spine (Phila Pa 1976). 2008 Jan 1;33(1):95-103.

33. Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G. Outcome measures for back pain research: A proposal for standardised use. Spine 1998, 23(18) 2003-13.

34. Roland M and Morris R: A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. Spine 1983, 8:141-144.

35. Von Korff M, Ormel J, Keefe FJ and Dworkin SF: Grading the severity of chronic pain. Pain 1992, 50:133-149.

36. Garratt AM, Ruta DA, Abdalla MI, Buckingham JK and Russell IT: The SF36 health survey questionnaire: an outcome measure suitable for routine use within the NHS? BMJ 1993, 306:1440-1444.

37. The EuroQol Group. EuroQol – a new facility for the measurement of health-related quality of life. Health Policy 1990, 16:199-208.

38. Zigmond AS, Snaith, RP. The Hospital Anxiety and Depression Scale. Acta Psychiatrica Scandinavica 1983, 67, 361-370.

39. Nicholas MK. Self-efficacy and chronic pain. In Paper presented at the annual conference of the British Psychological Society, St. Andrews, Scotland; 1989.

40. Waddell G, Newton M, Henderson I, Somerville D and Main CJ: A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993, 52:157-168.

41. Holmes-Rovner M, Kroll J, Schmitt N, Rovner D, Lynn Breer M, Marilyn L. Rothert ML, Padonu G, Talarczyk G. Patient Satisfaction with Health Care Decisions: The Satisfaction with Decision Scale. Med Decis Making 1996, 16:58.

42. Wills CE, Holmes-Rovner M. Preliminary validation of the Satisfaction With Decision scale with depressed primary care patients. Health Expect 2003;6(2):149-59.

43. Beurskens AJ, de Vet HC, Koke AJ. Responsiveness of functional status in low back pain: a comparison of different instruments. Pain 1996;65(1):71-6.

44. Curtis L, Netten A. Unit Costs of Health and Social Care 2006 Personal Social Services Research Unit, University of Kent, Canterbury, 2006.

45. Eldridge, Sandra M, Ashby, Deborah and Kerry, Sally.Sample size for cluster randomized trials: effect of coefficient of variation of cluster size and analysis method. International Journal of Epidemiology 2006, 35 (5):1292-1300.