A mixed-methods evaluation of a nurse-pharmacist–managed pain clinic: Design, rationale and limitations

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Introduction

Chronic pain affects 1 in 5 adults globally.¹ A multidisciplinary approach is often required to effectively manage chronic pain. The limited capacity of general practitioners (GPs) and restricted access to pain clinics hinder effective management.^{2,3} Suboptimal prescribing of analgesics⁴ and inadequate monitoring of medicines⁵ are also well documented in this context. The recent English Pain Summit advocated that chronic pain should become a “high street disease, recognized and visible to all, with equitable access to treatment, care and education.”⁶ The increasing number of nurse and pharmacist prescribers presents an opportunity for professionals other than GPs to take on key aspects of pain management. Evidence to support the role of pharmacists and nurses in pain management is growing.^{7–10} However, the optimum configuration of such services ensuring maximum clinical and cost-effectiveness is not known. Rigorous evaluations of novel pain management approaches are essential for future health service provision.

A community-based nurse-pharmacist–managed pain clinic was developed in Leeds, United Kingdom, in 2005 with the aim of effectively managing chronic pain within primary care and to reduce disease burden in secondary care. The working of the clinic has been explained in detail elsewhere.¹¹ Briefly, when referred by a GP, patients are directed to the nurse-pharmacist–managed pain clinic or

secondary care based on clinic guidelines. The nurse obtains a history of chronic pain, educates patients about pain, clarifies misconceptions and encourages self-management. The pharmacist obtains the medical and medication history and undertakes medication reviews with the aim of reducing adverse effects and drug interactions, as well as improving analgesia and adherence. Finally, the nurse and the pharmacist discuss and agree upon the treatment plan with the patient and the GP is informed about the suggested plan. Each consultation lasts for 60 minutes, and patients are usually discharged after 3 to 6 sessions.

A feasibility study found a significant reduction in pain scores at discharge from the clinic ($p < 0.001$) together with reduced referrals to secondary care.¹² Use of pain scores alone as an outcome measure, small sample size ($n = 37$) and lack of long-term follow-up data limits the findings of the study and warrants well-designed research to further strengthen the evidence.

Aim and objectives

The aim of the present study is to evaluate the impact of a nurse-pharmacist–managed pain clinic on patient-reported outcomes.

The objectives are to

1. Study the referral pattern of patients attending the pain clinic.
2. Assess the impact of the clinic on pain intensity, physical functioning, emotional functioning and quality of life.

3. Explore patients' views, experiences and satisfaction with the service.

Methods

In this mixed-methods study, an embedded design is employed.¹³ Embedded design consists of one principal method (qualitative or quantitative), depending on the research question, with the other method providing a secondary or supportive role.¹³ It is useful when a single data set is not sufficient and different questions requiring different methodologies need to be answered within a single study. The study has been granted research ethical and governance approval by the relevant authorities.

Quantitative phase

We are conducting a quasi-experimental study using a single-group pretest-posttest study design. Quasi-experimental studies are useful if randomized controlled trials (RCTs) are not possible for logistic or ethical reasons.¹⁴ The unavailability of suitable "controls" was a major problem in designing the RCT. Waiting list controls are inappropriate as a waiting time of 6 months or more has been associated with deterioration of health-related quality of life and an increase in depression scores.¹⁵ Recruiting patients receiving "usual care" through GPs is not practical, as there is currently no mechanism to identify chronic pain patients receiving care from GPs. Furthermore, as per the new guidance of the Medical Research Council, the design and implementation of RCTs for complex interventions require a series of steps.¹⁶ More information about the population and how the intervention affects the target population is required before designing an RCT. This proposed research will answer these questions, thus informing the design of a future RCT.

All patients referred to the pain clinic are assessed for eligibility by the research pharmacist (MAH) or clinical nurse specialist (KM). The patients complete the self-administered questionnaires (explained below) 1) on their first visit to the clinic, 2) on discharge from the clinic and 3) after 3 months of discharge. Follow-up questionnaires will be mailed to the respondents in a prepaid self-addressed return envelope (Figure 1). The 3-month follow-up will be limited to the first 30 patients only. With 80% power, a 95% confidence interval and anticipating a minimum difference of 1.1 points

(on the Numerical Rating Scale), the sample size was calculated to be 68.¹⁷ Anticipating a 15% dropout rate, we are aiming to recruit 79 patients meeting the following inclusion criteria: age >18 years, history of pain for >3 months and adequate ability to read and understand English. Pregnant women and patients with malignant pain, organic brain disease or psychiatric disorders or requiring acute medical/surgical intervention for their pain relief are excluded.

Outcome measures

Outcome measures include pain intensity (primary), physical functioning, emotional functioning, quality of life and chronic pain severity (Table 1).¹⁸⁻²¹ Demographic and clinical data are collected using a standardized structured questionnaire.

Qualitative phase

A descriptive qualitative study²² using semi-structured, face-to-face interviews will be conducted to explore patients' views about their expectations and satisfaction with the service. Qualitative research is best suited when issues surrounding health services are studied from patients' and professionals' perspectives.²³ Patients will be recruited using purposive sampling and interviewed within 2 weeks of their discharge. To ensure a diversity of views, patients of different ages, sexes and pain scores (baseline and discharge) will be interviewed. The interviews will be conducted either at patients' homes or at the clinic, depending on their preference. The sample size for qualitative research is guided by "data saturation"—whereby no new themes emerge from the data.²⁴ It is anticipated that 15 to 25 interviews will be required to achieve data saturation. Interviews will be audio-recorded, transcribed verbatim and analyzed using thematic analysis.²⁵

Discussion

Mixed-methods design: Rationale and design strengths

Rigorously conducted and transparently reported mixed-methods designs offer a number of advantages over mono-method research designs, especially in practice disciplines.^{13,26} It allows researchers to combine strengths of qualitative and quantitative methods to comprehensively answer the research question.

FIGURE 1 The research process

The mixed-methods design in this study has been used primarily to answer different research questions requiring different methods within a single study. The quantitative component will address the effectiveness component and the qualitative component will explore issues around patient experience and satisfaction, helping to understand and explain why and how the intervention works and how the service can be improved. The use of mixed methods will allow the generation of multiple data sets and perspectives, thus providing a more broad understanding than using either a qualitative or quantitative approach alone.

Design limitations

There are 2 main limitations in this study. First, RCTs provide the best evidence for evaluating effectiveness. The reasons for not doing a RCT have been discussed in the Methods section. Maturation¹⁴ (naturally occurring changes over time) and history¹⁴ (events occurring alongside with the intervention causing the observed

effect) pose threats to the internal validity of quasi-experimental designs. Furthermore, uncontrolled quasi-experimental designs tend to overestimate the effect size.¹⁴ Careful consideration will be given to these issues during data interpretation and limitations will be highlighted. Furthermore, qualitative interviews will empower the participants to reflect on their experiences of the service, its suitability and its helpfulness in managing chronic pain. Second, questionnaires are being used to assess pain, physical functioning, depression and quality of life. Questionnaires are inherently subject to recall and response biases. However, questionnaires have well-demonstrated validity and reliability.

Practice and policy implications

The National Health Service (NHS) in the United Kingdom is undergoing substantial reforms to empower patients and clinicians to ensure quality delivery of services.²⁷ There is a desire to shift care from hospitals

TABLE 1 Outcome measures and scales

Outcome measures	Scale	Scale characteristics
Pain intensity (primary outcome)	Numerical Rating Scale (NRS)	The NRS measures pain intensity on an 11-point scale (0-10) ranging from 0 = no pain to 10 = worst imaginable pain.
Physical functioning	Brief Pain Inventory (BPI)	The BPI measures pain interference with 7 daily life activities, including general activity, walking, work, mood, enjoyment of life, relations with others and sleep. ¹⁸ Each item is scored on an 11-point (0-10) scale ranging from 0 = does not interfere to 10 = completely interferes.
Quality of life	SF-36	The Medical Outcomes Study–Short Form version 2 (SF-36v2) consists of 8 subscales: Physical Functioning, Physical Role, Bodily Pain, General Health, Vitality, Social Functioning (SF), Emotional Role and Mental Health. ²¹ Scores for each variable are added and then transformed into a Likert scale ranging from 0 = worst to 100 = best.
Emotional functioning	Hospital Anxiety and Depression Scale (HADS)	The HADS consists of 2 subscales: Anxiety (HADS-A) and Depression (HADS-D). ²⁰ Each subscale consists of 7 items, and each item has 4 numerical response options from 0 to 3, with a minimum score of 0 and a maximum of 21 for each subscale. The mean cut-off score for HADS-A and HADS-D is 8, to indicate anxiety and depression, respectively.
Pain severity	Chronic Pain Grade (CPG) Questionnaire	The CPG is a 7-item questionnaire that classifies chronic pain patients into 1 of the 4 hierarchical categories according to pain severity: grade I, low disability–low intensity; grade II, low disability–high intensity; grade III, high disability–moderately limiting; and grade IV, high disability–severely limiting. ¹⁹

to community and therefore, new services have been developed in community settings. For NHS commissioners, quality research evidence from both the “effectiveness” and “patient’s perspective” is critical so that care provided within community settings is meeting patients’ needs and is not a barrier

to accessing secondary care. The proposed study will develop evidence for this innovative nurse-pharmacist–managed pain clinic.

Progress to date

Patient recruitment began in January 2012, and to date, 79 patients have been recruited. ■

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