Abstract

Background: Chronic pain is predominantly managed in primary care, although often ineffectively. There is growing evidence to support the potential role of nurses and pharmacists in the effective management of chronic pain.

Objective: To evaluate the effectiveness of a pain clinic jointly managed by a nurse and pharmacist.

Design: A mixed-methods design consisting of qualitative interviews embedded within a quasi-experimental study.

Settings: A community-based nurse-pharmacist led pain clinic in the north of England.

Participants: Adult chronic pain (non-malignant) patients referred to the pain clinic.

Methods: Pain intensity was the primary outcome. Questionnaires (The Brief Pain Inventory (BPI), the Hospital Anxiety and Depression scale (HADS), the SF-36 and the Chronic Pain Grade (CPG) questionnaire) were administered at the baseline, on discharge and at 3-months post discharge (BPI and HADS only). Patient satisfaction was explored using face-to-face, semi-structured qualitative interviews.

Results: Seventy nine patients with a mean age of 46.5 years (SD ±14.4) took part in the quasi-experimental study. Thirty-six and nine patients completed the discharge and 3-month follow-up questionnaires respectively. Compared to baseline, statistically significant reductions were noted for two of the outcome measures: pain intensity (P=0.02), and interference of pain with physical functioning (P=0.02) on discharge from

the service. Nineteen patients participated in qualitative interviews. The patients were, in general, satisfied with the quality of service. Four contributing factors to patient satisfaction were identified: ample consultation time; in-depth specialised knowledge; listening and understanding to patients' needs; and a holistic approach.

Conclusion: Nurse and pharmacist managed community-based pain clinics can effectively deliver quality pain management services as they offer an interdisciplinary holistic approach to pain management. Such services have the potential not only to reduce the burden on secondary care but also decrease long waiting times for referral to secondary care. Further research is required to support the development of evidence based referral guidelines to such services.

Keywords: Chronic Pain; Primary care; Pharmacists; Nurse; Mixed-methods

Introduction:

Chronic (non-malignant) pain affects millions of adults globally, disrupting their personal, social and professional lives, and contributing significantly to the overall burden on healthcare systems and society. Chronic pain patients utilize significantly more healthcare resources than patients with other long term conditions [1, 2]. In the US, the overall annual cost associated with chronic pain has been estimated to range from $560 to $635 billion (£ 341 billion to £387 billion), more than the annual costs of heart disease ($309 billion; £188 billion), cancer ($243 billion; £148 billion), and diabetes ($188 billion; 114 £billion) [3].

In most instances, chronic pain patients are managed within primary care. However, issues like under treatment of chronic pain [4], abuse of opioid analgesics [5], lack of monitoring of repeat prescriptions leading to deteriorating patients' quality of life [6], and increasing burden on secondary care have been well documented in the literature, necessitating development of specialised community-based pain management services. There is growing evidence to support the role of nurses and pharmacists in chronic pain management [7, 8, 9]. Pharmacist-led interventions have been shown to reduce pain intensity, improve physical functioning and reduce adverse events among chronic pain patients [7]. Similarly, nurse-led interventions have been shown to reduce the chronic use of non-steroidal anti-inflammatory drugs (NSAIDs) [8], and improve physical functioning [9] and self-management skills.

Keeping in view the potential usefulness of nurses and pharmacists in chronic pain management and the limited capacity of general practitioners (GPs) in managing chronic pain, the Leeds Community Healthcare NHS Trust, part of the UK National Health Service, initiated a nurse-pharmacist managed pain clinic for patients with chronic pain in the community setting. The working of the clinic has been described in detail elsewhere [10]. Briefly, the role of the pharmacist, who spent one day per week at the pain clinic, was to conduct medication review with the aim of ensuring safe and effective use of analgesics. The nursing intervention focused on educating patients about pain, clarifying any misconceptions, and encouraging patients to develop self-management skills. A retrospective study reported a significant reduction in pain intensity (P < 0.001) [11]. However, the small sample size and the use of pain scores alone as an outcome measure, limit the usefulness of the findings. The present study

was designed to further build on the existing research evidence on the effectiveness of the pain clinic using a mixed-methods approach.

Methods

Among various mixed-methods designs available, an embedded design consisting of a quasi-experimental (quantitative) study and a descriptive qualitative study was chosen [12]. In embedded design there is one principal method (qualitative or quantitative) and it is given priority depending on the purpose of the research and the other method provides supportive data [12]. The embedded design is particularly useful when a single dataset is not sufficient and different questions requiring different methodologies need to be answered within a single study [12]. The rationale for choosing an embedded design has been discussed in detail elsewhere [13]. The study was conducted at a pain clinic, situated in the north of England. The ethics approval was obtained from the local NHS ethics committee (Ref no. 11/YH/0415)

All patients referred to the pain clinic were assessed for eligibility to participate in this study by the first author (MAH) and/or clinical nurse specialist (KM). Patients meeting the following inclusion criteria were invited to participate: age >18 years, history of pain for >3 months and adequate ability to read and understand English. Pregnant women and patients with malignant pain, psychiatric disorders or requiring acute medical/surgical intervention for their pain relief were excluded. The required sample size was calculated to be 79, with 80% power, a 95% confidence interval, a minimum clinically important difference of 1.1 points (on 0-10 Numerical Rating Scale for pain intensity) and anticipating a 15% dropout rate [14]. The minimum clinically important

difference was considered for sample size calculation so that the study was powered sufficiently to at least detect minimum clinically important differences.

Outcome measures

Outcome measures included: pain intensity (primary), physical functioning, emotional functioning, quality of life and chronic pain grade. Pain intensity and physical functioning were assessed using the Brief Pain Inventory (BPI) – a valid and reliable tool which assesses pain intensity (average, least, worst, pain right now) and pain interference with 7 daily life activities, including general activity, walking, work, mood, enjoyment of life, relations with others and sleep [15]. The 14-item Hospital Anxiety and Depression Scale consisting of 2 subscales: Anxiety (HADS-A) and Depression (HADS-D) was used to assess emotional functioning [16]. The mean cut-off score for HADS-A and HADS-D was 8, to indicate anxiety and depression, respectively [16]. The SF-36, a generic valid and reliable questionnaire, was used to assess quality of life [17]. Pain severity was assessed using the chronic pain grade (CPG) questionnaire, a 7-item questionnaire that classifies chronic pain patients into one of the four 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 [18].

Demographic and clinical data were collected using a standardized, pilot-tested, and structured questionnaire by reviewing case notes and patient interviews (by MAH). The patients completed four self-administered questionnaires (mentioned above) 1) on their first visit to the clinic, 2) on discharge (last visit) from the clinic and 3) 3 months

after discharge. The 3-month follow-up questionnaires (only the Brief Pain Inventory and the Hospital Anxiety and Depression Scale) were mailed to the respondents in a prepaid self-addressed return envelope, limited to the first 30 discharged patients only.

Qualitative phase

For the descriptive qualitative study, semi-structured, face-to-face interviews were conducted using an interview guide. The patients were interviewed within 2 weeks of their discharge by MAH either at patients' homes or at the pain clinic, depending on their preference. A combination of two purposive sampling techniques, convenience sampling and maximum variation sampling [19], were used to recruit patients. Initially for the first five interviews, convenience sampling was used and patients meeting the inclusion/exclusion criteria and consenting for an interview were recruited. In order to ensure representation of different types of patients referred to the clinic, the remaining 14 interviewees were recruited using maximum variation sampling. Patients of different ages, sexes and pain scores (baseline and discharge) were interviewed to ensure diversity. "Data saturation"— whereby no new themes emerged from the data guided sample size [19]. Interviews were audio-recorded using an electronic audio recorder. The interview topic guide was designed to cover the following areas: expectations from the service; efficacy of the service (did it help? how?); interaction with nurse and pharmacist (time given for consultation, engaging patient in discussion and designing of therapeutic plan, listening to and understanding the problem); understanding of chronic pain and self-management; and overall satisfaction with the service (experience

compared to other services in past, aspects of the service which need improvement etc.).

Data analysis

The quantitative data were analysed using Statistical Package for Social Sciences (SPSS) for Windows version 20. For scoring SF-36, a scoring software provided by the Quality Metric Incorporated (QM), Lincoln RI, USA was used. Since data were paired, either the paired t-test or the Wilcoxon Signed-Rank test was used as appropriate. To improve clinical interpretation of the results, based on the recommendations of the IMMPACT group on benchmarks for interpreting clinically important change [20], the number of patients demonstrating a minimum clinically important difference was also highlighted.

Thematic analysis was used to analyze the qualitative data [19]. Each interview was transcribed verbatim by a professional transcriber and each transcript was checked against the original recording by the first author (MAH) for accuracy. Following this, each transcript was coded manually line by line by the first author (MAH). The initial coding framework was checked by another two authors (MB, SJC) for accuracy and completeness by reviewing two coded interview transcripts. Once all the interviews were coded, a list of all the codes was generated after removing duplicates and different codes were sorted into potential themes. The relevant data extracts were collated within these potential themes. As the new themes emerged, old ones were reviewed and sometimes renamed in the light of the emergence of new themes. The process continued until the no new themes were generated.

To ensure the credibility and transferability of qualitative findings, peer review/debriefing and providing rich thick description were used [21]. Peer review/debriefing was carried out by two senior qualitative researchers (SJC and MB). A detailed description of the study settings, participants, sampling technique, and data analysis method has been provided to ensure transparency of the findings.

Results:

Quantitative Phase

Sociodemographics

In total, 79 patients were enrolled in the quantitative phase with a mean age of 46.5 years SD ± 14.5 (range 22-86). Approximately, two thirds (67.1%) of the patients were female and more than half of the patients (57.0%) were married or living with partner. Slightly more than a quarter of the patients (25.3%) were unemployed due to pain (Table 1). Low back (68.4%) followed by lower limb (58.2%) were the most commonly reported pain sites. The majority of patients 56 (70.9%) reported to have never been referred to a pain clinic/ pain consultant in the past.

The follow-up (discharge) data were available for 36 patients only as the data collection had to be stopped because the service was unexpectedly decommissioned by the local Primary Care Trust. For the 3-month follow-up, of the 30 patients invited, only nine completed and returned the questionnaires. Therefore, keeping in view poor response rate and subsequent small number of participants, the 3-month follow-up data were not

analyzed statistically as it would have been misleading. The implications of early cessation of data collection have been discussed in the limitations section.

Outcome measures

Pain intensity was the primary outcome. Pain intensity scores were available for 79 and 35 patients at baseline and discharge respectively. Upon discharge, there was a statistically significant reduction for worst pain (P = 0.02) and average pain (P = 0.02). However, for least pain and pain right now the reduction in pain intensity score was not statistically significant (P = 0.12) and P=0.06 respectively (Table 3). Thirteen (37.1%) patients achieved a minimum clinically important difference (10-20% decrease in pain intensity [20]) while two (5.7%) each achieved a moderately important (≥ 30% decrease [20]) and substantially important differences (≥50% decrease [20]) as per the recommendations of IMMPACT group on interpreting clinically important changes.

The overall interference of pain with physical activity scores were available for 79 and 36 patients respectively. There was a significant reduction (P = 0.02) in overall interference of pain with physical functioning upon discharge compared to the baseline score. Fourteen (40%) patients achieved a minimum clinically important difference, at least one point improvement on a 0 to 10 NRS, as per the recommendations of IMMPACT group on benchmarks for interpreting clinically important changes for physical functioning [20].

For quality of life (SF-36), there were no statistically significant differences in the physical component summary (PCS) scores (P=0.15) or the mental component

summary (MCS) scores (P=0.08). For individual domain scores, compared to the baseline score, statistically significant improvements were found in physical role (RP) (P= 0.01), bodily pain (BP) (P=0.01) and social functioning (SF) (P=0.03) at discharge.

For anxiety and depression, both HADS-A and HADS-D were divided into four ranges: normal (0-7); mild (8-10); moderate (11-15); and severe (16-21). Almost two-thirds of the patients (67.1%) had HADS-A scores more than 7, i.e. were likely to have an anxiety disorder (Table 3). Compared to the baseline, there was no statistically significant reduction in the median HADS-A (P= 0.21) or HADS-D scores (P = 0.22). However, for 13 (38.2%) and seven (20.6%) patients there was a reduction in the severity of anxiety and depression respectively by at least one category (e.g. moderate to mild or severe to moderate etc.).

For the CPG, the median pain intensity score was 76.66 (total score 100) (IQR 66.67; 83.33) and the median for disability score was 70 (60.00; 90.00) at baseline. Compared to the baseline, there was a statistically significant reduction in pain intensity (Median 73.33; IQR 55.00; 83.33) at discharge (P = 0.02). However, no statistically significant improvement in disability score was found (P = 0.89) at the discharge (Median 73.33; IQR 51.66; 91.67). In terms of change in chronic pain grade, 7 (20.6%) patients reported improvement by at least one grade. However, the majority of the patients, 21 (61.7%) did not report any improvement (Table 3).

Nature of intervention

Data on the nature of the intervention were available for 35 patients (Table 4). The mean number of visits made by each patient to the pain clinic was 3.05 (S.D=0.97)

(Range 2 to 6). Fourteen (40%) of the patients were discharged after 3 visits (Table 4). In total, 101 medicine-related recommendations were made to the GP with a mean of 2.9 (range 1 to 6) recommendations per patient. For most of the patients [22 (62.8%)] 3 to 5 medicine-related recommendations were made to their GPs. Adding a new drug (n = 30) followed by titrating the dose (n = 29) were the most commonly made pharmacological recommendations. In addition, 34 non-pharmacological recommendations were made in total with a mean of 1.3 (range 1 to 3) per patient. Among non-pharmacological recommendations, pacing of activities (n = 18) was the most common.

Qualitative Phase

In total, 19 participants recruited from the quantitative study sample, including eight men and eleven women were interviewed. The age of the participants ranged from 27 to 74 years. Ten interviews were conducted at patients' homes, eight at the pain clinic and one at the patient's office (during their lunch break). Interviews lasted between 25 and 45 minutes. The sociodemographic characteristics of the participants are given in Table 5.

Satisfaction with the service

In general, the majority of the patients were satisfied with the quality of care that they received at the pain clinic. Four factors were identified during the data analysis which contributed towards positive patient experience with the service: ample consultation time, listening and understanding individual patients' needs, in-depth specialised knowledge, and a holistic approach.

"I think it's a good little service that they've got going on there; I really, really do." [Pt. 12, 39 years old female]

a. Ample consultation time

The patients felt that they were given full freedom and time to express their views. In contrast to the ten minute consultation slot with the GP, the patients had one hour for the initial consultation and 30 to 45 minutes for the follow-up appointments which allowed them to discuss their problems more openly and freely.

"You're very conscious of the amount of time you have with your GP and it was knowing that I was going to see somebody who actually is a pain specialist, you just feel more confident and that because you feel they will take time with you and listen to you and understand…" [Pt. 16, 54 years old female]

"When you come here you don't feel that pressure, so you can be a bit more open and a bit more frank and you can be a bit more descriptive." [Pt. 8, 40 years old female]

b. In-depth specialised knowledge

The in-depth specialised knowledge of both the nurse and pharmacist in terms of chronic pain management was quickly recognized by the patients.

"I think there's also that knowledge base here. They're obviously treating or speaking with people that have got similar symptoms and therefore know what

kind of route to take when it comes to pain management and so on." [Pt. 8, 40 years old female]

"[The clinical nurse specialist] explained what's going off, how it affects me, and then [Pharmacist] we've been sat down and we've been balancing all my medications out, how much there is to take and how much… and what to take and what not to take, you know. So it's been a real…to me it has, it's been a really good thing to have been coming up here to the pain clinic." [Pt. 13, 54 years old male]

The pharmacist focused on optimising the use of analgesics and other medicines involved in pain management. The patients were informed about the side effects and negative impact of over/under dosing.

"I felt she was very professional and she knew what she was doing, which is comforting. I've seen the pharmacist on Tuesday and the way she sort of looked at my medication and she knows what everything's doing, she knows what it should be doing, and she probably knows what I can do without, hence the tramadol [was taken off]." [Pt. 10, 54 years old female]

c. Listening and understanding individual patients needs

The patients found that both the nurse and the pharmacist expressed their interest in listening to patients' views, in contrast to the GPs who the patients perceived as not being interested in obtaining a full medical and medication history. Based on thorough

face-to-face interviews, the nurse and pharmacist developed a therapeutic plan in consultation with the patients.

"She [the clinical nurse specialist] was very good at listening. She was, very good. It was lovely having somebody to talk to who understood what pain does to people and you could talk to her, she were a person that you could talk to, some you can't [slight pause] can you, you know? Some people, they just give off that aura, they don't really care, you know. But she were very good, she was yes." [Pt. 14, 64 years old female]

"I think it's because there's a sympathetic ear and people will listen. And there seems as if this understanding and they're offering advice that we'll take on board, whereas we've not really had that… we've not felt that comfortable with the GP because she openly admitted that she didn't really know anything about fibromyalgia and therefore she didn't really know how to treat it." [Pt. 8, 40 years old female]

d. Holistic approach

The clinic offered a more holistic approach towards pain management compared to the GP. Both pharmacological and non-pharmacological therapeutic options were explored for each patient and individualized therapeutic plans were developed.

"Well really I suppose here they go through absolutely everything you know so it's a lot more in-depth and looking at the whole picture rather than simply trying to give you medication for a problem like the GP does and then

refer you to physio etc. It's……..[Pauses]. Here it's a much more holistic approach really and they try and cover absolutely everything for you and see what other services they may be able to refer you to or ask your GP to refer you to. So I think really it's a complete programme so it's good in that way." [Pt.11, 44 years old female]

After assessing individual patient's needs, the patients were also referred to other services such as the expert patient groups, musculoskeletal services, and psychological services if required. The patients also found these referrals beneficial, contributing to an overall satisfaction with the service.

"They have taken steps to help the emotional side, which that's, you know, sort of getting out and meeting people. And [the CNS] picked up on that very quickly, very, very quickly."[Pt. 10, 54 years old female]

"They [pain clinic] referred me to a physiotherapist who specialised in chronic pain. And so through seeing that physiotherapist I've learnt different ways of managing the pain which I found to be more effective than the medication I was on." [Pt. 18, 27 years old female]

Issues with the pain clinic

The patients also highlighted some negative issues with this service. They were not pleased by the fact that the pain clinic did not prescribe medicines to them and they had to go to their GPs to get the medicines. Patients felt that this caused unnecessary delay and had expected to get their medicines at the pain clinic.

"When I found that I was going to have to go back to him for the prescription I was a bit in shock really. I'm thinking what? He's referred me to you for you to... saying that you'll be able to look at these things and I've come here hopefully to get these things and then you're saying I've got to wait another two weeks while you send a letter to my doctor and then he'll just write a prescription....[Pt. 19, 47 years old male]

Some of the patients also felt that they were not appropriate for this service and should not have been referred here. They considered that they had pain for quite a long time and knew about the various self-management strategies discussed at the pain clinic including being active, exercise and pacing activities.

"I think it [the service] was more aimed at getting people re-motivated past their pain, so we did talk a little bit about painkillers and modified those a bit, but the main part of pain clinic to me seemed to be about getting people to get up and go and take additional steps that maybe they weren't already doing, which really wasn't kind of suitable for me I don't think. I don't ever sit down; I don't have time, so I think maybe I wasn't really their target audience." [Pt. 1, 36 years old female]

Discussion:

Over the past few years, there has been growing interest in the use of mixed-methods approaches in health services evaluation, as they allow the use of multiple methods to comprehensively answer different research questions [9, 21-24]. This study used a

mixed-methods approach which generated both effectiveness and satisfaction data within a single study, thus providing a holistic evaluation of the service.

The majority of the patients were women and predominantly middle aged (36-50 years). Chronic pain is more prevalent among women and they have been reported to use more healthcare resources than men, which may explain the higher number of female patients in the sample. More than a half (56.5%) of the patients had had chronic pain for more than 3 years and, more importantly, for 70% of the patients this was their first visit to a specialised pain service/clinic. The interplay of a number of factors including patients' medical help seeking behavior, GPs' lack of willingness to refer patients to a specialised pain service and, lack of awareness among the GPs and patients about the existence of such clinics may partly explain the delay in referral [25]. Importantly, during the qualitative interviews quite a few patients highlighted that they had had to repeatedly ask their GPs for referral before they were eventually referred.

Almost two thirds of the patients in our study had anxiety and depression. Anxiety and depression are common comorbidities and are associated with poorer prognosis among chronic pain patients [26]. Patients in the qualitative interviews highlighted the significant impact of chronic pain on their mental and physical functioning and described a two way relationship between pain and depression. The National Health Survey in the UK reported that participants in chronic pain grade IV (high disability-severely limiting) were more likely to be anxious and depressed than the participants with grade I (low disability-low intensity) and II (low disability-high intensity) [27]. In the present study, more than 60% of the patients fell under Grade IV (high disability-severely limiting),

explaining a high incidence of anxiety and depression among patients referred to the clinic.

The recommendations made by the IMMPACT group guided the selection of outcome measures [20]. These were statistically significant changes in the "worst pain", "average pain" and pain interference with physical functioning. It has been suggested that the population distribution of pain scores do not usually have a normal distribution and are 'U-shaped'; therefore, merely reporting changes in the means/medians for continuous data (e.g. pain intensity) can be misleading as patients tend to have either very good or very poor pain relief [28]. To avoid this limitation and to improve clinical interpretation of the results, percentages of patients responding to treatment have been reported as well for two of the outcome measures: pain intensity and physical functioning, as IMMPACT group recommendations were available for these two outcomes measures only [20]. No statistically significant reductions were noted for anxiety (P=0.21), depression (P=0.22), the physical component summary (PCS) score or the mental component summary (MCS) score. The lack of intervention effect in terms of anxiety, depression, and quality of life might be attributed to the small sample size. It is also possible that the intervention was not effective or the outcome measures were not sensitive enough to detect a difference. These issues require further exploration.

Patient satisfaction was explored using face-to-face qualitative interviews. Patients were generally satisfied with the quality of care provided by the nurse and the pharmacist at the pain clinic. Ample consultation time, in-depth specialized knowledge, listening and understanding individual patient's needs, and a holistic approach were identified as

factors contributing to patients' satisfaction. Non-pharmacological alternatives were suggested in instances where the patient had: adherence problems; issues related to the side effects/tolerance; or non-pharmacological interventions were considered helpful. The holistic approach was evident from the nature of recommendations made at the clinic. For 35 patients, 101 medicine-related (mean 2.9; range 1 to 6) and 42 non-pharmacological recommendations (mean 1.3; range 1 to 3) were made to the GPs and patients, suggesting that both pharmacological and non-pharmacological needs were assessed and addressed.

Limitations

The major limitation of the present study was the inability to meet the desired sample size. Discharge data were available for 36 patients only as the service was unexpectedly decommissioned by the local primary care trust (PCT). Subsequently, the services of the clinical nurse specialist were absorbed into a musculoskeletal service at the same community health center and the services of the pharmacist were discontinued. Since there were structural changes in the provision of service, collecting further follow-up data would not have been appropriate. The inability to gain the required sample size (i.e. the study was underpowered) could lead to Type II error, explaining a lack of intervention effect on the quality of life, anxiety and depression outcomes in the present study. On the other hand, the significant intervention effect on pain intensity and physical functioning, might be due to Type I error, a false positive. Therefore, the results should be interpreted with care. However, during the qualitative interviews patients highlighted the positive impact of the pain clinic on their pain

intensity, physical functioning and quality of life. Integrating qualitative and quantitative data helped to overcome the sample size limitation by providing patients' perspectives to complement the numerical data. It was deemed inappropriate to employ statistical methods to impute missing data, fearing data artificiality, as it accounted for more than 50% of the data. Another associated limitation was poor response to 3-month follow-up questionnaires despite the fact that personalised letters were sent to patients to improve the response rate. Consequently the 3-month follow up data were not statistically analysed.

Conclusion

Interdisciplinary community based pain clinics jointly run by nurses and pharmacists have the potential to improve chronic pain management in the community. In addition to reducing pain intensity and improving physical functioning, such community-based clinics can not only improve access to specialised pain service but also reduce burden on the secondary care. The cost-effectiveness of such services should be evaluated as it would aid service commissioners in the design and implementation of such services in future. The ample consultation time with patients allowed the nurse and the pharmacist to obtain a full medication and medical history and develop an individualised management plan addressing both the pharmacological and non-pharmacological needs of the patients. In terms of the patients' perspective, they felt that they were treated with respect and empathy and were generally satisfied with the quality of service. There is a need to develop evidence-based referral guidelines for such community based clinics to ensure that only the patients who are likely to benefit from such services are referred there. GPs should be encouraged to refer patients to such

services early during the course of the treatment as GPs' lack of specialised knowledge

and short consultation time are barriers to effective pain management.

References:

1. Blyth FM, March LM, Brnabic AJM et al. Chronic pain and frequent use of health care. Pain 2004;111:51-58

2. Breivik H, Collett B, Ventafridda V et al. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. *Eur J Pain* 2006;10: 287-333.

3. Gaskin DJ, Richard P. The economic costs of pain in the United States. J Pain 2012; 13:715-724.

4. Hanlon JT, Fillenbaum GG, Studenski SA, et al. Factors associated with suboptimal analgesic use in community-dwelling elderly. *Ann Pharmacother* 1996;30:739-44.

5. Couto JE, Romney MC, Leider HL, et al. High rates of inappropriate drug use in the chronic pain population. *Popul Health Manag 2009;*12**:**185-190

6. The Accounts Commission for Scotland. *Supporting prescribing in general practice.* Edinburgh, UK: Accounts Commission; 1999. Available: www.audit-scotland.gov.uk/ docs/health/1999/nr_9909_prescribing_general_practice .pdf (accessed Apr. 22, 2013).

7. Hadi MA, Alldred DP, Briggs M et al. Effectiveness of pharmacist-led medication review in chronic pain management: systematic review and meta-analysis. Clin J Pain 2014; 30: 1006–1014

8. Jones AC, Coulson L, Muir K et al. A nurse-delivered advice intervention can reduce chronic non-steroidal anti-inflammatory drug use in general practice: A randomized controlled trial. Rheumatology 2002;41: 14-21

9. Ryan S, Hassell AB, Lewis M et al. Impact of a rheumatology expert nurse on the wellbeing of patients attending a drug monitoring clinic. J Adv Nurs 2006; 53:277-286.

10. Hadi MA, Alldred DP, Closs SJ, et al. A combined nurse-pharmacist managed pain clinic: joint venture of public and private sectors. Int J Clin Pharm 2012;34:1-3.

11. Briggs M, Closs SJ, Marczewski K, et al. A feasibility study of a combined nurse/pharmacist-led chronic pain clinic in primary care. Qual Prim Care 2008;16:91-4

12. Creswell WJ, Plano-Clark VL. Designing and Conduction Mixed Methods Research, 2nd edn. Thousand Oaks, CA: Sage Publications, 2011

13. Hadi MA, Alldred DP, Closs SJ et al. A mixed-methods evaluation of a nurse-pharmacist-managed pain clinic: Design, rationale and limitations. Can Pharm J 2013; 146: 197-201

14. Eng J. Sample size estimation: how many individuals should be studied? Radiology 2003;227:309-13.

15. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 1994;23: 129-38.

16. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 1983;67:361-70.

17. Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): conceptual framework and item selection. Med Care 1992;30:473-83.

18. Von Korff M, Ormel J, Keefe FJ, et al. Grading the severity of chronic pain. Pain 1992;50:133-49.

19. Green J, Thorogood N. Qualitative Methods for Health Research, 2009, London, Sage.

20. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. J Pain 2008; 9: 105-121

21. Strauss A. Qualitative analysis for social scientists, 1987, New York, Cambridge University Press.

22. O'cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. J Health Serv Res Policy 2008; 13: 92-98.

23. Hadi MA, Alldred DP, Briggs M, et al. Mixed methods research in pharmacy practice: Basics and beyond (Part 1). Int J Pharm Pract 2013;21:341-345

24. Hadi MA, Alldred DP, Briggs M, et al. Mixed-methods research in Pharmacy Practice: Recommendations for quality reporting (Part 2). Int J Pharm Pract 2014; 22:96-100

25. Glachen M. Chronic pain: Treatment barriers and strategies for clinical practice. J Am Board Fam Pract 2001;14:211-218.

26. Boersma K, Linton S. Expectancy, fear and pain in the prediction of chronic pain and disability: a prospective analysis. Eur J Pain 2006;10:551-7

27. Bridges S. Health Survey for England - 2011: Chapter 9, Chronic pain. Available at: https://catalogue.ic.nhs.uk/publications/public-health/surveys/heal-surv-eng-2011/HSE2011-Ch9-Chronic-Pain.pdf [Accessed 6 November 2014].

28. Mcquay H, Carroll D, Moore A. Variation in the placebo effect in randomised controlled trials of analgesics: all is as blind as it seems. Pain 1996;64:331-335.

Table 1. Sociodemographic characteristics of the patients

Characteristic	N (%)
Age	
(*Mean: 46.49 ; SD:14.5) Range (22-86)*	
18-35	18 (22.8)
36-50	37 (46.8)
51-65	17 (21.5)
>65	7 (8.9)
Gender	
Male	26 (32.9)
Female	53 (67.1)
Marital Status	
Single	24 (30.4)
Married/living with partner	45 (57.0)
Divorced/separated	6 (7.6)
Widowed	3 (3.8)
Undisclosed	1 (1.3)
Employment status	
Public	3 (3.8)
Private	19 (24.1)
Self-employed	3 (3.8)
Retired	14 (17.7)
Unemployed (pain)	20 (25.3)
Unemployed (other reason)	14 (17.7)
Student	2 (2.5)
Undisclosed	4 (5.1)
Ethnicity	
White	67 (84.8)
White others	3 (3.8)
Asian/Asian British	6 (7.6)
Arab	2 (2.5)
Undisclosed	1 (1.3)

Education level

Undisclosed	10 (12.7)
GCSE/O-Level	29 (36.7)
A-level/NVQ	19 (24.1)
Diploma	5 (6.3)
Degree	10 (12.7)

Pain Sites*

Head, Face and Neck	39 (49.4)
Upper shoulder	28 (35.4)
Thoracic region	7 (8.8)
Abdominal region	5 (6.3)
Low back	54 (68.3)
Lower Limb	46 (58.2)
Pelvic region	7 (8.8)
Anal, perineal	2 (2.7)

Pain Duration (Years)

< 1 year	13 (16.5)
1 to 3	21(26.6)
3-5	19 (24.1)
5-10	17 (21.5)
>10	9 (11.4)

Number of comorbidities

None	34 (43.0)
1	19 (24.1)
2	15 (19.0)
3	10 (12.7)
4	1(1.3)

Past visit of pain clinic/consultant

No	56 (70.9)
Yes	23 (29.1)

* Patients were allowed to choose more than one pain site.

Table 2. Comparison of pain intensity, pain interference with physical functioning scores at baseline and discharge.

	N	N*	Median (IQR)	Z	**P-value
BPI Pain intensity					
Worst Pain					
Baseline	79	35	8.0 (7.0;9.0)	- 2.4	**0.02**
Discharge	35		7.5 (5.0; 8.0)		
Least Pain					
Baseline	79	35	5.0 (3.0; 7.0)	-1.5	0.12
Discharge	35		4.0 (2.0; 6.0)		
Average pain					
Baseline	79	35	7.0 (5.0; 8.0)	-.2.3	**0.02**
Discharge	35		6.0 (4.0;7.0)		
BPI Pain interference					
Baseline	79	35	7.1 (5.7;8.2)	-2.3	**0.02**
Discharge	36		6.1 (4.0; 8.7)		
QoL (SF-36)			**Mean (SD)**	**T**	
PCS					
Baseline	74	33	28.8 (11.0)	1.4	0.15
Discharge	35		30.8 (12.9)		
MCS					
Baseline	74	33	36.3 (15.1)	1.8	0.08
Discharge	35		41.2 (14.6)		

N*= Number of patients for whom both baseline and discharge scores were calculated. **
Calculated using Wilcoxon-Sign Rank or Paired-T test as appropriate; BPI= Brief Pain Inventory
PCS = Physical Component Summary score; MCS = Mental Component Summary score

Table 3: Comparison of Anxiety, Depression and Chronic pain Grade at baseline and discharge.

	Baseline N (%) N = 76	Discharge N (%) N = 34	Change in category	N (%) N = 34	*P-value
HADS-A					
Normal	25 (32.9)	14 (41.2)	≤ -1	13 (38.2)	
Mild	14 (18.4)	10 (29.4)	0	13 (38.2)	
Moderate	24 (31.6)	7 (20.6)	≥ 1	8 (23.5)	
Severe	13 (17.1)	3 (8.8)			
Overall score (*Median (IQR)*)	10 (7.0; 14.0)	8.5 (5.7; 12.2)			0.21
HADS-D					
Normal	30 (39.5)	16 (47.1)	≤ -1	7 (20.6)	
Mild	11(14.4)	5 (14.7)	0	21 (61.8)	
Moderate	27 (35.5)	10 (29.4)	≥ 1	6 (17.6)	
Severe	8 (10.5)	3 (8.8)			
Overall score (*Median (IQR)*)	10.0 (5.0; 13.0)	8.0 (3.7; 12.2)			0.22
CPG Grade					
I	2 (2.6)	4 (11.8)	≤ - 1	7 (20.6)	
II	13 (17.1)	2 (5.9)	0	21 (61.7)	
III	11 (14.5)	7 (20.6)	≥ 1	6 (17.6)	
IV	50 (65.8)	21 (61.8)			

* Calculated using Wilcoxon-Sign Rank test. HADS-A = Hospital Anxiety and Depression Scale – Anxiety; HADS-D = Hospital Anxiety and Depression Scale –Depression; CPG = Chronic Pain Grade

Table 4. Nature of recommendations made at the pain clinic

Item	N (%)
Number of visits	
2	11 (31.4)
3	14 (40.0)
4	8 (22.9)
5	1 (2.9)
6	1 (2.9)
Recommendation made to the GP	
Yes	34 (97.1)
No	1 (2.9)
Nature of pharmacological recommendation	
Dose titration	29 (28.7)
Stopping a drug	19 (18.8)
Adding a new drug	30 (29.7)
Substituting a drug	23 (22.8)
Nature of non-pharmacological interventions	
Exercise	7 (20)
Life style modification	9 (25.4)
Pacing activity	18 (51.4)
Referrals	
Physiotherapy	3 (8.5)
Spinal injection	6 (17.1)
Psychological therapy	3 (8.5)
Support group	6 (17.1)

Table 5. Demographics of patients participated in qualitative interviews

ID	Age in Years	Gender	Employment status	Marital status	Chronic pain duration in Years	Pain intensity (baseline)
Pt.1	36	Female	Full-time	Married	5-10	5
Pt. 2	49	Male	Full-time	Married	5-10	5
Pt. 3	63	Male	Retired	Married	5-10	5
Pt. 4	30	Male	Full-time	Married	5-10	6
Pt. 5	74	Female	Retired	Undisclosed	< 1	0
Pt. 6	58	Female	Unemployed	Divorced	> 10	7
Pt. 7	39	Male	Unemployed	Single	1- 3	7
Pt. 8	40	Female	Part-time	Married	< 1	7
Pt. 9	51	Male	Part-time	Married	3-5	10
Pt. 10	54	Female	Undisclosed	Divorced	3-5	7
Pt. 11	44	Female	Part-time	Single	1-3	5
Pt. 12	39	Female	Full-time	Married	> 1	8
Pt. 13	54	Male	Unemployed	Widowed	5-10	10
Pt. 14	64	Female	Retired	Married	> 10	5
Pt. 15	55	Male	Full time	Married	3-5	9
Pt. 16	54	Female	Part time	Married	1-3	6
Pt. 17	48	Female	Unemployed	Married	>10	4
Pt. 18	27	Female	Unemployed	Married	1-3	5
Pt. 19	47	Male	Full time	Single	>10	7