Lauren J Scott, Joanna M Kesten, Kevin Bache, Matthew Hickman, Rona Campbell, Anthony E Pickering, Sabi Redwood and Kyla Thomas

Evaluation of a primary care-based opioid and pain review service:

a mixed-methods evaluation in two GP practices in England

Abstract

Background
Opioid prescribing to treat chronic non-cancer pain has rapidly increased, despite a lack of evidence for long-term safety and effectiveness. A pain review service was developed to work with patients taking opioids long-term to explore opioid use, encourage non-drug-based alternatives, and, where appropriate, support dose reduction.

Aim
To evaluate the service and its potential impact on opioid use, health and wellbeing outcomes, and quality of life (QoL).

Design and setting
Mixed-methods evaluation of a one-to-one service based in two GP practices in South Gloucestershire, England, which took place from September 2016 to December 2017.

Method
Quantitative data were collected on baseline demographics; data on opioid use, misuse, and dose, health, wellbeing, QoL, and pain and interference with life measures were collected at baseline and follow-up. Twenty-five semi-structured interviews (n = 18 service users, n = 7 service providers) explored experiences of the service including perceived impacts and benefits.

Results
Of 59 patients who were invited, 34 (57.6%) enrolled in the service. The median prescribed opioid dose reduced from 90 mg (average daily morphine equivalent; interquartile range [IQR] 60 to 240) at baseline to 72 mg (IQR 30 to 160) at follow-up (P<0.001); three service users stopped using opioids altogether. On average, service users showed improvement on most health, wellbeing, and QoL outcomes. Perceived benefits were related to wellbeing, for example, improved confidence and self-esteem, use of pain management strategies, changes in medication use, and reductions in dose.

Conclusion
The service was well received, and health and wellbeing outcomes suggest a potential benefit. Following further service development, a randomised controlled trial to test this type of care pathway is warranted.

Keywords
chronic non-cancer pain; health promotion; opioids; pain; primary health care.

INTRODUCTION

Chronic non-cancer pain (CNCP), defined as a painful condition lasting ≥3 months and not associated with a cancer diagnosis, is believed to affect 35% to 51% of adults in the UK.[1] Opioid prescribing to treat CNCP has rapidly increased in the last 20 years,[2–8] despite a lack of evidence for the long-term safety and effectiveness of these drugs.[9–12]

Long-term opioid use is associated with significant healthcare, workplace, and criminal justice costs,[13–15] and serious adverse events including opioid dependence and opioid-related deaths.[16–19]

Further, the risk of harm increases at high doses, and further benefit is unlikely above an average daily morphine equivalent dose of 120 mg.[20] However, people with prescription opioid dependency may not access traditional substance misuse clinics because they do not perceive themselves to be dependent.[21]

Public Health England recommends that commissioners seek to provide separate treatment and support for patients dependent on prescription opioids.[22] However, evidence for the effectiveness of interventions for reduced prescribing or opioid cessation in people with CNCP is scarce.[23]

The South Gloucestershire pain review service was designed to investigate the feasibility of implementing a service in primary care for patients with CNCP treated with long-term opioid painkillers. The novel service aimed to promote appropriate pain management; improve health, wellbeing, and quality of life (QoL); improve patients' understanding of opioid painkiller dependence and related harms; and help patients explore their use of opioids, supporting dose reduction where appropriate.

The aim of this study was to evaluate the pain review service in terms of health and wellbeing outcomes, opioid use, and potential impact, and to help inform future service provision. Details of the service acceptability are presented elsewhere.[24]

LJ Scott, MSc, senior research associate in quantitative applied health research; **JM Kesten**, PhD, senior research associate in social science (qualitative) research, National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West (NIHR CLAHRC West), University Hospitals Bristol NHS Foundation Trust; Population Health Sciences, Bristol Medical School, University of Bristol, Bristol. **K Bache**, BSc, pain review service coordinator, Developing Health and Independence, Addiction Rehabilitation Centre, Bristol. **M Hickman**, MSc, PhD, professor in public health and epidemiology, Population Health Sciences, Bristol Medical School, University of Bristol; NIHR Health Protection Research Unit in Evaluation of Interventions, University of Bristol, Bristol. **R Campbell**, MSc, PhD, FHEA, professor of public health research, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol. **AE Pickering**, PhD, MBChB, FRCA, professor of neuroscience and anaesthesia, Department of Anaesthesia, University Hospitals Bristol NHS Foundation Trust; School of Physiology, Pharmacology and Neuroscience, University of Bristol, Bristol. **S Redwood**, EdM, MA, RGN, RSCN, senior research fellow in ethnography, NIHR CLAHRC West, University Hospitals Bristol NHS Foundation Trust, Bristol; Population Health Sciences, Bristol Medical School, University of Bristol, Bristol. **K Thomas**, MBBS, MSc, MSc Res, PhD, FFPH, consultant senior lecturer in public health medicine, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol; South Gloucestershire Council.

Address for correspondence

Lauren Scott, National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West, University Hospitals Bristol NHS Foundation Trust, 9th Floor Whitefriars, Lewins Mead, Bristol BS1 2NT, UK.

Email: Lauren.Scott@bristol.ac.uk

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How this fits in

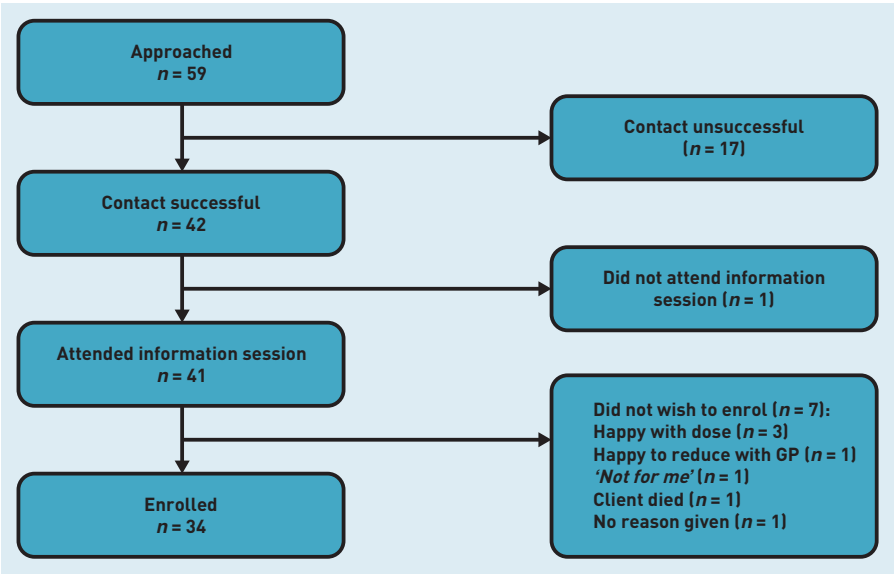
Long-term use (≥3 months) of prescription opioid painkillers in patients with chronic non-cancer pain is associated with opioid dependence, addiction, and opioid-related deaths. National guidance recommends that commissioners provide separate services, preferably in primary care, for patients who have become dependent on prescription opioid painkillers. The South Gloucestershire pain review service is a novel, primary care-based service aimed at helping patients with chronic non-cancer pain using long-term opioid painkillers, to explore their use of opioids, support non-pharmacological pain management strategies, and reduce their opioid dosage where appropriate. The service was well received and showed promising results including potential improvements in wellbeing, quality of life outcomes, and a reduction in opioid dosage.

METHOD

Recruitment to the pain review service

The service was delivered by two project workers across two GP practices in South Gloucestershire. Patients eligible for inclusion had received ≥3 opioid painkiller prescriptions in a 3-month period, had taken opioids for ≥3 months (long-term opioid use), and were not using illicit drugs or receiving end-of-life care. GPs identified patients for the service using the opioid risk assessment tool (ORAT). Where possible, GPs discussed service participation with patients directly, before referring them to the project worker who posted an invitation letter and information sheet. Patients who responded were invited to attend an information session. Those who attended and were interested in continuing in the service were enrolled.

Figure 1. Patient flowchart.



Pain review service

The South Gloucestershire Council Public Health and Wellbeing Division commissioned the service for 2 years from September 2016. Project workers performed a comprehensive and holistic assessment of service users, exploring the medical and psychosocial factors involved in their opioid use. An individually tailored pain management plan was developed including setting daily goals, developing a relaxation plan, introducing gentle exercise, dealing with low mood, and improving sleep. In addition, access to alternative care and support options were available, including physiotherapy and relaxation groups. Type of opioid drug and dose were reviewed, and support with reduction in dose was provided if appropriate. The service was delivered on a one-to-one basis; the number and frequency of sessions were determined by service user needs and within project workers' availability. Further details of the service can be found in the authors' linked article by Kesten *et al*.[24]

Data collection

Quantitative. Anonymised case report forms were created to collect quantitative data. Data on response to invitation, attendance at the information session, and enrolment were recorded for all invited patients. Baseline demographic data, employment, relationship status, disabilities, and previous use of a pain clinic service were recorded for enrolled service users. Baseline opioid drug, overall duration, reason for original prescription, and motivation for use were documented, along with other baseline medications.

Scores for the following were recorded at baseline and follow-up: opioid dose (measured as average daily morphine equivalent);[25] current opioid misuse measure (COMM)[26] (COMM; scored 0–68 with scores ≥9 considered positive for misuse); brief pain inventory (BPI)[27,28] (BPI; severity scored 0–40, interference scored 0–70, and percentage pain relief from medications scored 0–100); Warwick–Edinburgh mental wellbeing scale[29] (scored 0–70 with a change of 3–8 points considered 'meaningful'); and treatment outcomes profile (TOP)[30] (TOP; all scored 0–20) for physical health, psychological health, and QoL.

Numbers and reasons for discharge and drop-out from service; number of

Table 1. Baseline characteristics, medications, and presenting issues[a]

Characteristics	Enrolled service users	
	n/N	%[b]
Female sex	22/34	64.7
Age, years, mean (SD)	51	10
White ethnicity	31/31	100.0
Employment status[c]		
Employed	6/31	19.4
Unemployed	23/31	74.2
Retired	2/31	6.5
Relationship status[c]		
Single	6/31	19.4
Married	19/31	61.3
Separated	3/31	9.7
Divorced	1/31	3.2
Other	2/31	6.5
Disability	20/27	74.1
Previous pain clinic use[c]	22/31	71.0
Baseline medications, excluding opioids		
Benzodiazepines	12/34	35.3
Amitriptyline	12/34	35.3
SSRI antidepressants	8/34	23.5
Gabapentin	7/34	20.6
Other antidepressants	6/34	17.6
Pregabalin	4/34	11.8
SNRI antidepressants	1/34	2.9
Zopiclone	1/34	2.9
Psychological comorbidities[c]		
Sleep issues	17/30	56.7
Depression	13/29[d]	44.8
Anxiety/panic attacks	9/29[e]	31.0
Experience of child abuse	9/30	30.0
Social isolation	7/29	24.1
Experience of domestic abuse	5/29	17.2
Substance misuse	3/29[f]	10.3
Low mood	3/29	10.3
Alcohol misuse	2/29[f]	6.9
Other mental health issues	2/29[f]	6.9
Eating disorder	1/29	3.4
Post-traumatic stress disorder	1/29	3.4
Self-harm	1/29	3.4
Negative self-talk/thoughts	1/29	3.4

[a]All details are self-reported except baseline medications. [b]Unless otherwise stated. [c]Denominators reflect the total number of service users for whom these data were collected. Therefore, denominators of less than 34 indicate missing data. [d]Twelve diagnosed. [e]Six diagnosed. [f]All diagnosed. SNRI = serotonin and norepinephrine reuptake inhibitors. SSRI = selective serotonin reuptake inhibitors.

appointments made, kept, cancelled, and not attended; and duration of follow-up were also recorded.

Data were collected for all patients invited to use the service between September 2016 (service commencement) and December 2017. Data regarding visits and treatments were collected up until February 2018 for enrolled service users. There was no set follow-up time-point for this study; follow- up data were collected from the final visit within the study period where possible, or the closest visit to this if final-visit data were missing. All data were self-reported except opioid and other medication use, which were extracted from the GP electronic record system (EMIS) by the project workers.

Qualitative. Project workers facilitated recruitment of 18 service users for semi-structured interview by asking those willing to take part to complete a 'consent to contact' form. The second author then posted these service users an information sheet explaining the study and inviting them to contact them if they wished to participate. Interviews were also conducted with the service providers: project workers ($n = 2$), the project workers' manager ($n = 1$), and GPs in participating GP practices ($n = 4$); the second author approached these participants directly.

Interviews were conducted face-to-face or by telephone depending on interviewee preference. Written or verbal informed consent was obtained before every interview. Service user interviews explored experiences of the service, and service provider interviews explored the partnership between GPs and project workers. Service acceptability was also discussed in all interviews; results are presented elsewhere.[24]

Sample

Over the proposed 2-year recruitment period, 30–40 service users across two GP practices were expected to be invited to take part. This was a pragmatic sample given the funding, time, and capacity of the project workers. All service users who enrolled between September 2016 and December 2017 were included in the quantitative analysis, and a convenience sample provided qualitative interview data.

Analysis

Quantitative data were summarised using means and standard deviations (SD), medians and interquartile ranges (IQR), or counts and percentages as appropriate. As data were not normally distributed, the Wilcoxon signed-rank test was used to assess changes between baseline and follow-up opioid dose. Due to the small sample size, and consequent limited power, other outcomes were not formally statistically compared. All quantitative data management and analysis was carried out using Stata 15.1.

Qualitative interviews were audiorecorded, transcribed verbatim, anonymised, and analysed thematically.[31]

Table 2. Baseline opioid use[a]

Opioid use	Enrolled service users	
	n/N	%[b]
Reported reason for original opioid prescription[c]		
Back pain	9/32	28.1
Arthritis	5/32	15.6
Spinal or disc degeneration/deformities	5/32	15.6
Fibromyalgia	4/32	12.5
Other	9/32	28.1
Opioid dose, mg, median (IQR)	90	60 to 240
Opioid drug		
Codeine	17/34	50.0
Tramadol	10/34	29.4
Morphine	9/34	26.5
Oxycodone family	7/34	20.6
Fentanyl	5/34	14.7
Buprenorphine	3/34	8.8
Methadone	1/34	2.9
Multiple opioid drugs	16/34	47.1
Duration of use, years[c]		
0–2	2/29	6.9
3–4	3/29	10.3
5–9	9/29	31.0
10–14	6/29	20.7
≥15	9/29	31.0
Motivation for use[c]		
Pain	32/32	100.0
Coping with feelings	4/32	12.5
Addiction/dependence	3/32	9.4
Sleep	1/32	3.1
Withdrawal allowance	1/32	3.1)

[a]All details are self-reported except for opioid drugs. [b]Unless stated otherwise. [c]Denominators reflect the total number of service users for whom these data were collected. Therefore, denominators of less than 34 indicate missing data. IQR = interquartile range.

NVivo 10 (QSR International) was used to aid data management.

Quantitative and qualitative data were analysed independently by two researchers and integrated using the 'following a thread' technique[32] (a method of integration at the analysis stage) through discussion of the key findings and themes in both datasets.

RESULTS

Recruitment, attendance, and retention

Between September 2016 and December 2017, 59 patients were invited to take part in the service. Of these, 42 patients responded to the invitation, 41 attended an information session, and 34 (57.6%) enrolled, (Figure 1). The enrolled service users had a mean age of 51 years (SD 10) and 65% were female (Table 1). Many service users were also taking other medication at baseline: 12/34 (35.3%) were taking benzodiazepines; 12/34 (35.3%) amitriptyline; 8/34 (23.5%) SSRI antidepressants, and 7/34 (20.6%) gabapentin, (Table 1). Back pain was the most common reported reason for original opioid prescription (9/32, 28.1%; Table 2). Eighteen of the service users were interviewed (see Supplementary Table 1 for details of these participant characteristics).

Seven service providers were also interviewed, including two project workers, the project workers' manager, and four GPs in participating GP practices.

Reasons for non-participation were only recorded for the seven patients who attended an information session and chose not to enrol (Figure 1). The most common reason was that they were happy with their opioid dose and did not perceive a problem (3/7; 42.9%). Data from the service user interviews provided possible other reasons for non-response. For example, one participant was hesitant to enrol because of a negative previous experience of pain clinics, and another stated an uncertainty about the potential benefits of the service.

Across all enrolled service users, 535 appointments were made; 390 were kept (72.9%), 101 were cancelled (18.9%), and 44 were not attended (8.2%). During the interviews, service users reported missing appointments because of 'bad pain days' and conflicting appointments.

In patients still using the service when data collection finished ($n = 17$; 50%), the median duration of service use was 7.7 months (IQR 3.2 to 13.3) and the median number of attended appointments was 12 (IQR 6 to 20); in patients who were discharged/lost to follow-up ($n = 17$; 50%), the median duration was 3.8 months (IQR 1.1 to 9.1), and the median number of attended appointments was 6 (IQR 1 to 11).

Reasons for discharge from service: no longer taking opioids (3/17; 17.6%); reduction in opioid dose (4/17; 23.6%); happy as is (2/17; 11.8%); no time (1/17; 5.8%); and fears that reduced pain may lead to reduced disability benefits affected one patient (1/17, 5.8%); and six patients were lost to follow-up, that is, stopped returning calls from the project worker (6/17, 35.3%).

Project worker 1 described the service duration as varying for each service user, with shorter expected duration for service users who were either keen to reduce their use of opioids or achieve a specific goal, or who did not engage with the service within the first couple of sessions.

Awareness and understanding of pain

Several service users described having a greater understanding of pain, the function of opioids, and their effectiveness for chronic pain treatment; this was echoed by the GPs. Service users described

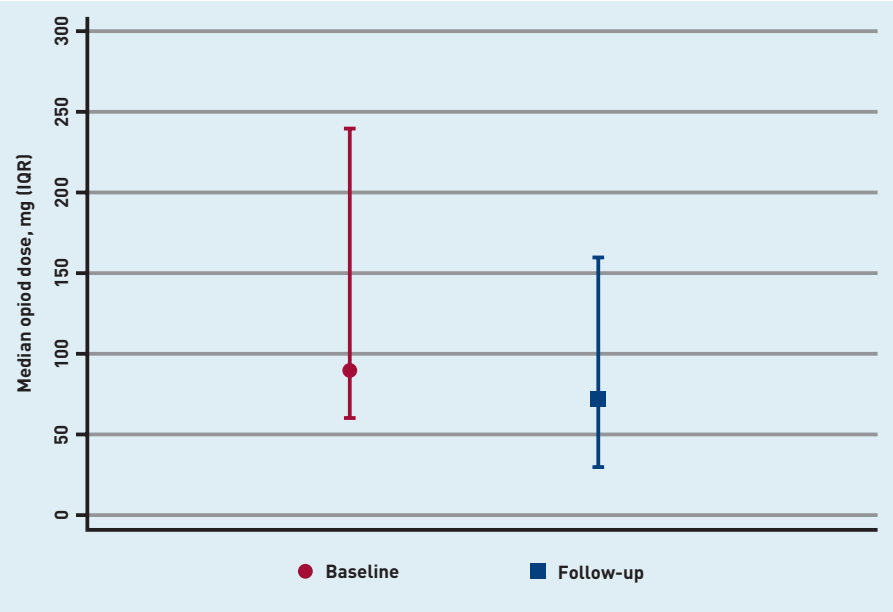


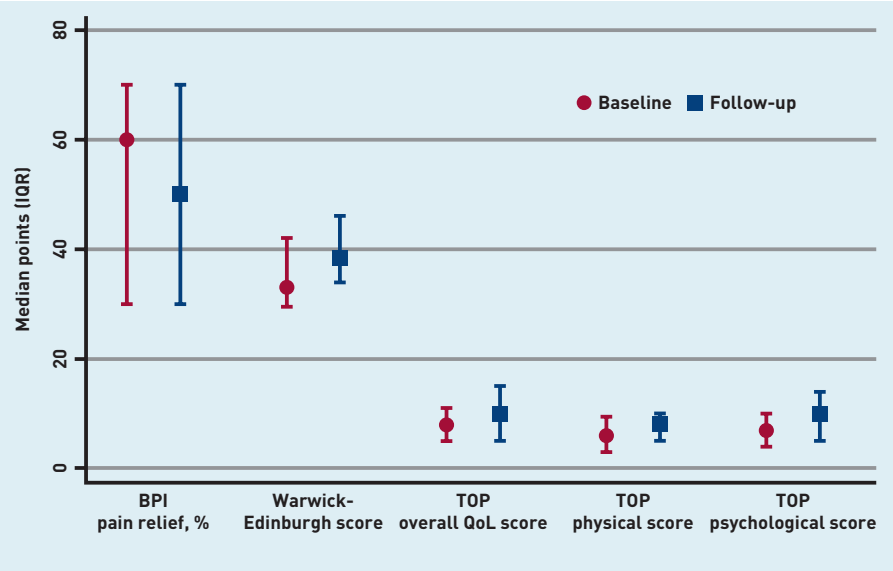
Figure 2. Prescribed opioid dose at baseline and follow-up. P-value for change <0.001. IQR = interquartile range. Opioid dose measured as average daily morphine equivalent.

increased awareness of the relationship between thought processes, emotions, and experiences of pain.

By tracking patterns in pain and opioid use, one project worker and a small number of service users noticed that opioids were not always taken in response to pain levels, as illustrated by the following quote:

'... I assumed I was taking it when I needed for pain but having a couple of [...] *pain charts and things like that I realised I was actually taking it on quite a regular type of — yes and I didn't realise that at all.'* (Participant [P] 8, service user [SU])

Figure 3. Wellbeing and QoL outcomes at baseline and follow-up (higher = better). PI = brief pain inventory. IQR = interquartile range. QoL = quality of life. TOP = treatment outcome profile. Warwick–Edinburgh = Warwick–Edinburgh mental wellbeing scale.



Service users were able to consider approaches to modify their opioid use after becoming aware of how they managed their pain.

Opioid use and pain management

Of the service users, 82.8% (24/29) had been taking prescription opioids for ≥5 years, with 31.0% (9/29) taking opioids for at least 15 years, (Table 2).

The median prescribed opioid dose reduced from 90 mg (IQR 60 to 240) at baseline to 72 mg (IQR 30 to 160) at follow-up (P<0.001; Figure 2); 15 service users reduced their dose (44.1%), (3 [8.8%] reduced to zero), 19 stayed on the same dose (55.9%), and none increased. Of service users prescribed >120 mg per day at baseline, 4/14 (28.6%) had dropped to below 120 mg by follow-up.

Using the COMM scale, 24/28 (85.7%) service users were 'misusing' opioids (scores ≥9) at baseline compared with 15/22 (68.2%) at follow-up.

In support of this, one GP felt that overuse of medication among service users had reduced, as demonstrated by the following:

'So the people requesting their medication, "I've lost my prescription", is always an interesting one. "I'm going on holiday", "My Grandma is ill, I need to go to Devon, can I have my prescription early?" The various excuses that patients use seems to have reduced and withered away.' (P19, GP)

In addition to reduced dose, the interviews highlighted several ways in which service users had modified their opioid use, such as, changing medication type and form, for example, pain patches, using paracetamol before opioids, not using opioids for 'break out' pain, using medication less frequently, and spreading the dose out over the day. The following quote came from a service user who found that the service enabled them to take their opioids less often and slowly reduce the dose:

'In the beginning I was clock watching. I was getting to say quarter to the hour and I was thinking, oh quarter of an hour I can take some more tablets [...] *The* [service gave] *me the confidence to just nudge it a little bit further apart between taking them and then dropping the dose down* [...] *so it was a controlled reduction.'* (P1, SU)

Most service users described changing their pain management approach and how they responded to pain. The following techniques were mentioned during

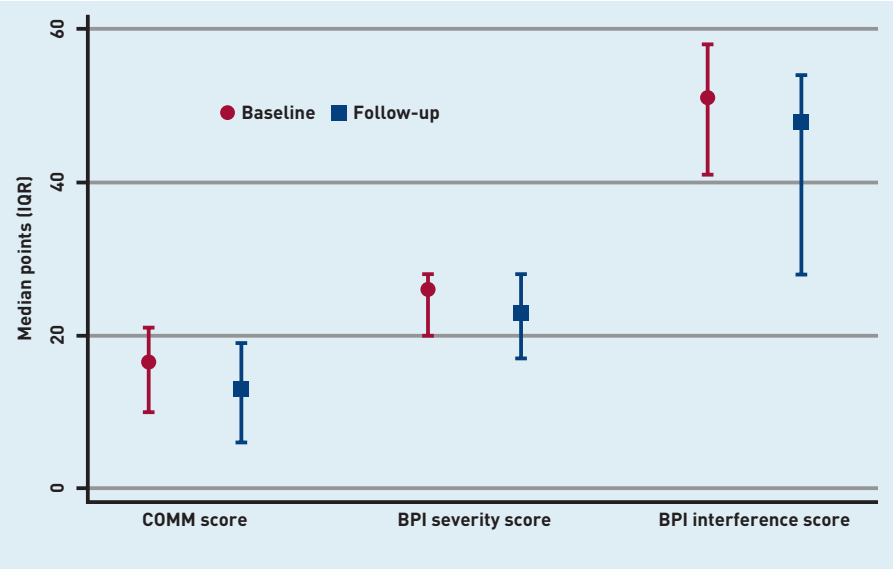


Figure 4. Wellbeing and QoL outcomes at baseline and follow-up (lower = better). COMM = current opioid misuse measure. BPI = brief pain inventory. QoL = quality of life.

service user interviews: using 'pacing' (breaking up tasks into manageable parts), using relaxation exercises to manage pain, persevering with activities when pain was bad, increasing physical activity, for example, by walking or dancing, and trying to improve their diet.

A small number of service users reported increased pain levels and withdrawal side effects, for example, sweating and headaches, as a result of reducing opioids. These experiences corresponded to the quantitative data showing a small reduction in median BPI percentage pain relief from medications between baseline (60, IQR 30 to 70) and follow-up (50, IQR 30 to 70) (Figure 3).

These data all illustrate that by using the service it is possible for service users to develop new pain management techniques, which may enable them to take opioids less often and/or reduce their dose.

Health, wellbeing, and quality of life

Service users had, on average, improved on most health, wellbeing, and QoL outcome scales (Figures 3 and 4). For example, 14/22 (63.6%) improved by ≥3 points and 9/22 (40.9%) improved by ≥8 points on the Warwick–Edinburgh mental wellbeing scale.

Interviews captured several factors that contributed to improving QoL including self-kindness, starting new hobbies, volunteering, cooking more often, and greater involvement in looking after grandchildren. These activities had positive effects on wellbeing, feelings of self-worth, and distraction from pain symptoms. A small number of service users described having a greater support network and one GP described a service user as less sedated and more able to interact socially. Several service users also described sleep improvements. In contrast, no service users reported a reduction in QoL. The following quote illustrates a GP's experience of the change in their patient's awareness:

'The patient I had from this morning has gone from coming in in a wheelchair to walking in herself [...] *Her speech was always quite slurred. She'd fall asleep in consultations. Really quite sedated. Her degree of alertness is completely different today* [...] *I think the knock-on effect then for her is she's going to fall less. She's got more interaction. You know socially she's able to do more.'* (P19, GP)

Several service users described small positive effects on their mental health, including acceptance of long-term pain, a more positive attitude towards managing their pain and in general, and feeling better in themselves. Service users, project workers, and a GP described service users experiencing increased confidence, self-esteem, motivation to manage their pain, capacity to try new things, and ability to communicate their needs more assertively. The following quote illustrates a service user's improved attitude:

'I feel happier. More positive really, trying to do more things, see more people.' (P12, SU)

It was also recognised that these changes take time and several service users noted that their relationship with pain had not changed. These data demonstrate that the service has the potential to improve wellbeing and QoL. However, it is not clear what aspects of the service may have contributed to these improvements.

Healthcare use and delivery

GPs described fewer consultations with *'high demand'* service users. Similarly, a few service users described reductions in GP consultations and one commented that not being admitted to hospital during service participation was a positive outcome. Despite this, the lead GPs did not feel the service saved them time as they were involved in identifying eligible patients and meeting project workers for service user reviews. GPs also described greater consideration of prescribing appropriateness and reflected that they had more confidence when explaining the

effectiveness of opioids for chronic pain management.

DISCUSSION

Summary

On average, most health, wellbeing, and QoL outcomes improved and many service users also reported improved QoL during interviews. In addition, 15/34 (44.1%) of service users had reduced their opioid dose, three of whom had stopped taking opioids completely, and interview data suggested service users had a better understanding of their pain and pain management.

Strengths and limitations

The main strength of this study was the use of mixed methods to evaluate the service and to understand the potential impact of the intervention on the target group.[33,34] Factors to consider for future service development are discussed in the authors' linked article by Kesten *et al*.[24]

There are four main limitations. First, the sample size was small, and quantitative follow-up data were not available for some service users (particularly those who dropped out early). This not only meant that formally assessing health and wellbeing outcomes was not possible, but also highlighted the need for further consideration about follow-up data collection in future studies. In particular, defining a set follow-up time point for evaluation and collecting data from all service users at that time, regardless of drop-out, would be important.

Second, because of the service users' close relationship with the project workers,[24] they may have been reluctant to provide negative outcomes relating to the service during interviews. However, the findings reflect a range of positive and negative experiences suggesting that service users felt free to express negative experiences.

Third, the data around other medication use, psychological comorbidities, and motivations for opioid use were self-reported, and as such some service users may have omitted details they did not wish to share.

Finally, economic data were not collected so the impact of the intervention on GP resources could not be formally assessed as part of this study. These issues would all need to be addressed in a future larger randomised controlled trial (RCT) or study to formally test the effectiveness of the service.

Comparison with existing literature

The UK Faculty of Pain Medicine recommends that a collaborative treatment plan between patient and doctor should be developed to address long-term prescription opioid use.[35,36] They also recommend a flexible approach, either involving a single clinician or a multidisciplinary team with clear communication and documentation, and that the role of peer support should also be considered.[37]

A recent systematic review examined primary care-based models for medication-assisted treatment (MAT) for opioid use disorder (OUD).[38] MAT combines behavioural therapy and counselling with medications such as methadone, buprenorphine, and naltrexone.

The authors found that successful programmes used multidisciplinary models, integrating clinical teams with other support staff. However, only three studies were based in the UK, and the included studies primarily focused on illicit opioids, not prescription opioid painkillers.

In terms of RCTs, a brief, 3-day, group-based pain management support intervention for chronic musculoskeletal pain (COPERS) was not effective in reducing pain-related disability at 12 months, though benefits were observed for depression and social integration;[39] these results are similar to those found in the presented study.

The I-WOTCH trial is currently underway examining the effectiveness of a group multicomponent self-management intervention combined with individual support for people using strong opioids for chronic non-cancer pain;[40,41] results from this study will be important in adding to the evidence regarding an individually tailored approach.

Implications for research and practice

In the absence of non-opioid/non-drug-based interventions, it should come as no surprise that healthcare professionals are prescribing opioids and that patients are self-medicating in an attempt to address complex conditions. There is a need to focus on improving GP prescribing behaviour so that patients are only started on opioids when appropriate.[42] Where the decision is made to prescribe opioids, patients should be monitored and reviewed more regularly so that opioids are stopped when they are no longer providing any benefit and there is early identification of problems such as dependence.[43]

More research is needed to identify effective primary care-based interventions targeting: primary prevention of opioid painkiller dependence in patients with chronic non-cancer pain, that is, better

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pain management, appropriate opioid prescribing, education about opioid-related benefits and harms, use of prescribing systems, medication reviews, and non-drug-based interventions to address the pain; secondary prevention, that is, early recognition and intervention; and tertiary prevention, that is, pharmacological and non-pharmacological measures.

The present findings suggest that it is possible for patients with chronic non-cancer pain on long-term opioids to be managed in a primary care setting. Service users improved their understanding of pain and pain management, and more than 40% of service users also reduced their opioid dosage. Additionally, GPs reported more informed opioid prescribing with greater consideration of the appropriateness of opioid prescribing, as well as increased confidence in explaining the benefits and harms for this patient cohort. Though the results of the study are promising, further development of the service is required,[24] followed by a more robust evaluation of the intervention, ideally an RCT.

Ethical approval

This study was approved by the Proportionate Review Sub-committee of the West Midlands — Coventry and Warwickshire Research Ethics Committee (reference number: 17/WM/0264) and the Health Research Authority.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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