'The Doctor doesn't need to see you now': reduction in general practice appointments following group pain management

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Abstract

Background: Patients living with chronic, non-malignant, musculoskeletal pain are frequent visitors to general practice (GP) services, placing a large burden on resources. Pain management programmes (PMPs) are recommended for chronic pain patients and aim to teach self-management techniques. While there is evidence for their clinical effectiveness, few studies have explored whether there is a reduction in primary care healthcare use after attending a PMP.

Aim: This study sought to address this by gathering data on pain-related primary care appointments before and after attending a PMP.

Design and setting: Medical records of 50 patients attending a group outpatient PMP were obtained to determine whether the number of pain-related GP appointments differed 1 year after attending the programme compared with the year beforehand. Robust data were obtained from GP appointment systems and a retrospective observational design was utilised.

Results: The results indicated a 43.9% decrease in the number of GP appointments in the year following a PMP, a change that was statistically significant.

Conclusion: The findings of the study show that there are fewer pain-related appointments in primary care in the year following a group outpatient PMP compared with the preceding year. It is possible that the self-management techniques taught on the programme lead to a reduction in patient's need to consult their GP as frequently about their pain. However, limitations in the current research mean that the reduction in appointments cannot be definitively attributed to PMP attendance and suggestions for future research are discussed.

Keywords

Chronic pain, pain management, cost of illness, general practice, multidisciplinary

Introduction

Chronic, non-malignant, musculoskeletal pain is a widespread health issue that affects an estimated 7.8 million people in the United Kingdom and accounts for 4.6 million general practice (GP) consultations a year.¹ It is often associated with complex changes in the way nerves function due to increased sensitisation and these changes cannot always be addressed by medical interventions.^{2,3} Consequently, patients may spend

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years seeing both primary care and secondary care physicians seeking a cure that does not exist. This can increase their distress and places a large burden on National Health Service (NHS) resources.⁴

Multidisciplinary pain management programmes (PMPs) are recommended for dealing with the distress and disability caused by chronic pain.⁵ These offer a psychoeducational group approach which helps patients develop self-management strategies to deal with the problems associated with persistent pain (e.g. depression, anxiety, decreased physical activity, disturbed sleep). Past research has demonstrated that PMPs are effective in improving patients' mood, increasing physical activity, decreasing the use of prescribed medication and encouraging return to work.⁶⁻¹¹

In the current economic climate, it is also important to demonstrate the cost-effectiveness of treatment approaches. In 2002, it was estimated that around £69 million was spent on the management of chronic pain patients in primary care in the United Kingdom.¹² Health inflation and the rising number of patients with chronic pain mean that this will inevitably have increased. Research has shown that PMPs may reduce the reliance patients with chronic pain have on healthcare professionals, thereby reducing the cost of their healthcare. A review by Pike et al.¹³ found that cognitive behavioural therapy (CBT) approaches for chronic pain reduced healthcare utilisation. Clare et al.¹⁴ examined the effect that a CBT-based PMP had on pain-related secondary care healthcare use (e.g. consultations with specialists specifically for their chronic pain). They found that in the 12-month period after the PMP, there was a 90.5% reduction in the number of pain-related appointments compared with 12 months before the PMP. Clare et al.'s¹⁴ study made use of robust data collection methods from hospital records, whereas previous research had relied on self-report questionnaires¹⁵ which are subject to reporting bias.

While there has been increased interest in the effect PMPs can have on secondary care appointments, return to work and medication costs¹⁶ remarkably little research has looked at the impact of such programmes upon primary care appointments. It is important that the impact on primary care is also explored as the management of chronic pain accounts for around 4.6 million appointments per year in primary care, which equates to 793 whole time general practitioner posts.¹² An extensive literature research revealed only a few studies that specifically explored the impact of PMPs upon primary care healthcare use. Van Hooft et al.¹⁷ found that patients reported a decrease in primary care consultations 2 years after completing a PMP when compared with healthcare use prior to the PMP. These findings were supported by Van Eijk-Hustings et al.'s¹⁸

study, who found a reduction in GP appointments after a PMP for patients with fibromyalgia. However, a study by McCracken et al.,¹⁹ which also made use of self-report techniques, found that a PMP had no significant effect upon primary care healthcare utilisation. Although some of these results are encouraging, the data were collected via self-report questionnaires requiring patients to recall their primary care appointments. The reliability of such data is questionable as self-report is open to human error regarding memory as well as reporting bias.

A German study²⁰ examined the impact of an inpatient PMP upon primary care healthcare use by collecting data directly from medical records. The researchers found a 53.5% reduction in primary care appointments 12 months post-PMP. While the study did make use of a reliable data collection method, all primary care appointments were included in the analysis rather than focusing on appointments specifically relating to patients' chronic pain. Patients with multiple comorbidities may have attended for reasons other than their pain which limits the conclusions that can be drawn about the effects of the PMP.

Sleptsova et al.²¹ conducted a study where the effect of PMP on healthcare utilisation among Turkish immigrants living in Switzerland was measured. Rather than relying on self-report measures, information from insurance companies was collected. The results indicated no significant effect upon healthcare utilisation. While Sleptsova et al.²¹ made use of a more reliable data collection method, it is not clear whether their study examined primary care utilisation, secondary care utilisation or a combination of both. Nor it is evident whether their data focused on pain-related or general healthcare use.

This study sought to address some of the aforementioned issues and build upon previous research. The aim was to examine the pattern of pain-related appointments in primary care for a cohort of patients attending a PMP using robust data collection methods. Whereas Thieme et al.²⁰ examined the impact of an inpatient PMP upon primary care healthcare use, this study explored the impact of an outpatient PMP. Specifically, this study sought to gather data on the frequency that patients with chronic, non-malignant musculoskeletal pain visited their GP for issues regarding their pain condition in the year prior to their participation in a multidisciplinary PMP, as well as the year after the programme. The cost of these appointments was then calculated using up-to-date information from the Department of Health. It was hypothesised that after completing a PMP patients would visit their GP less often for issues concerning their pain condition, resulting in decreased costs of pain-related primary healthcare use.

Method

Participants

Ethical approval for the study was granted by the audit department of Lewisham & Greenwich NHS Trust, London, England. The cohort of participants in this study comprised 78 patients who had completed a group outpatient PMP. All patients included in this study were consecutive participants of the PMP. Prior to starting the PMP, patients provided written consent for the collection of data on their healthcare utilisation. In addition, patients were also asked to provide written consent for the service to collect psychometric data. No patients refused to have their healthcare utilisation or data collected.

All of the GPs for these patients who completed the PMP were contacted and asked to provide data regarding pain-related primary care appointments for the 1 year before the patient attended the PMP as well as the year after the programme finished. Details on the guidance given to GPs on the data collection are given in the section on data collection and statistical analyses. Data were successfully obtained for 50 patients with no information provided by the GPs for the remaining 28 patients. A heuristic approach to response rates suggests a 60% rule.²² The response from the GPs in this study provided 65% of the data requested.

Patient demographics can be found in Table 1. The majority of patients taking part in the study were female. Although a recent systematic review of research on chronic pain in the United Kingdom demonstrated that there was a consistently higher prevalence of chronic pain in female participants than in male participants,²³ the patient group in this study contained a much higher percentage of women than men. The mean age of the sample was 44.8 years old, in line with the Chief Medical Officers²¹ special report on chronic pain which highlighted that patients are most likely to present with chronic pain between the ages of 40 and 50. The patients in this study had experienced pain from 1 to 50 years, with a mean duration of 11.26 years. Further information about the patients included in the study can be found in the 'Results' section.

Design and intervention

The study utilised a single-group retrospective observational design. Patients were referred to the PMP service either by their GP, consultant in pain management, rheumatologist, orthopaedic surgeon, or by a musculoskeletal physiotherapy specialist. The service required patients to actively opt in following referral and also offered alternatives to the group PMP as outlined in Figure 1.

Table 1. Patient demographics.

Gender (%)		Age in years (SD)	Duration of pain in years (SD)
Male	Female		
4 (8%)	46 (92%)	44.8 (9.1)	11.3 (10.6)

SD: standard deviation.

Once referred, patients were invited to an introductory meeting where the purpose of the PMP was explained and they had the opportunity to ask questions about the programme. It was made clear at this point that the programme did not aim to reduce the level of pain experienced but instead focused on reducing the distress and disability caused by chronic pain. Those who were interested in the group PMP were asked to opt in by contacting the team and they were then offered an individual multidisciplinary assessment to evaluate whether the programme would be suitable for them. The assessment lasted approximately 3 hours, where the patient was seen separately by a consultant clinical psychologist, clinical physiotherapy specialist and a clinical nurse specialist. The assessment with the consultant clinical psychologist explored issues regarding mood, health beliefs, family environment and social factors. The clinical physiotherapy specialist took a medical history, conducted a thorough physical examination as well as reviewed hospital records and relevant radiographs to exclude red flags. The clinical nurse specialist also took a medical and drug history, as well as explored alcohol and illicit substance use.

Inclusion criteria for participation were that the patient had to have non-malignant musculoskeletal pain which had lasted for more than 6 months and was interfering with activities of daily living and associated with psychological distress. Pain interference and psychological distress were assessed in the multidisciplinary assessments, as well as through psychometric measures discussed in the 'Clinical Effectiveness' section. Exclusion criteria included actively seeking new investigations or treatments (excluding ongoing medication), diagnosis of malignant, inflammatory or neurological disease, current drug/alcohol addiction or current major psychiatric illness such as psychosis. However, patients with severe anxiety or depression were not excluded from entry to the programme. Patients who required an interpreter were seen individually and their data were not included in the current analysis. In addition, patients undergoing litigation were only offered a place on the programme after this was complete.

Following assessment, those patients who were offered a place were enrolled on to the next available

Figure 1. PMP care pathway.

PMP. Patients were asked to complete a written consent form outlining their willingness to take part in the PMP and have data regarding their healthcare use collected, alongside psychometric measures of distress and assessment of levels of physical activity. Each programme consisted of 3-hour group sessions which were held weekly for 10 consecutive weeks, giving a total of 30 hours PMP content. PMPs were run in groups of approximately 10 patients. The PMP was a psychoeducational group based on cognitive-behavioural principles and the content included the following: information on acute/chronic pain, medication use, safe movements, pacing, activity goals, problem-solving, dealing with difficult thoughts and feelings, relaxation, communication, distraction, sleep and stress management. Two follow-up appointments were offered at 6 weeks and 6 months after the 10-week programme. A combination of the requirement to actively opt-in to all aspects of the service as well as alternative options being provided alongside the group PMP meant that from a total of 225 potential referrals just over a third (34.6%) were offered and also completed a group outpatient programme. This is a similar proportion to that reported by other pain management groups serving comparable inner city populations with complex health and social needs (personal communication).

All PMP groups were facilitated by the same staff members (consultant clinical psychologist, clinical physiotherapy specialist and clinical nurse specialist) using the same structure and format each time.

Data collection and statistical analyses

Primary care healthcare use. Data regarding the number of pain-related appointments in primary care for each of the 50 patients were collected for 12 months prior to the PMP and 12 months after the final session of the 10-week programme. Requests for data were initially made by fax to each GP. This was followed by a telephone request if required. Although different GP practices make use of different medical records systems, all software allows GPs to summarise a consultation onto a patient's notes, including a clinical code linking the consultation to a diagnosis. This allows easy identification of the reason patients have visited the practice for each appointment. Data were collected on appointments attended, telephone consultation or booked appointments that were not attended (but which still cost the practice time and money).

In general, medical records were forwarded to the research team who extracted the data on the pain-related appointments. This was done by reading the appointment summary and clinical code for each appointment to determine whether it related to the patient's chronic pain condition. However, a few GP practices submitted data directly to the research team. In such instances where practices submitted data directly, instructions were given to GPs to only include appointments that related to a patient's chronic pain condition. Further advice was provided by telephone where GPs had any questions about the process.

Table 2. Clinical outcome measures before the start of the PMP and at the end of the PMP.

Measure	Mean (SD)		N	t test	p value	Effect size Cohen's <i>d</i>
	Pre-PMP	Post-PMP				
BDI	28.3 (9.4)	21.2 (11.2)	44	4.264	<0.001	0.76
PSEQ	24.0 (12.7)	26.6 (11.7)	45	-1.050	0.150	-0.20
TSK	43.2 (9.0)	35.9 (9.1)	45	6.119	<0.001	0.81
PCS	33.4 (10.5)	24.4 (12.6)	45	6.621	<0.001	0.86
BPI-P	6.5 (1.9)	6.1 (2.0)	45	1.439	0.079	0.19
BPI-I	7.6 (1.8)	6.4 (2.2)	45	4.265	<0.001	0.652
Sit to stand	8.4 (4.7)	11.3 (5.6)	35	4.112	<0.001	0.62

BDI: Beck Depression Inventory; PSEQ: Pain Self-Efficacy Questionnaire; TSK: Tampa Scale for Kinesiophobia; PCS: Pain Catastrophising Scale; BPI-P: Brief Pain Inventory-Pain; BPI-I: Brief Pain Inventory-Interference.

In order for an appointment to be counted as relating to the patient's chronic pain condition, there needed to be an obvious link in the medical record for that appointment. For example, a patient attending an appointment for a pain medication review or low mood due to their pain would have that appointment counted in the data. Appointments with a relevant clinical code (e.g. fibromyalgia, chronic back pain, chronic pain) would also be included. Appointments that related to acute pain (e.g. a new injury from a fall) were not included in the analysis.

Appointments were initially reviewed by an assistant psychologist. Where the reason for an appointment was unclear or went beyond the knowledge of an assistant psychologist, advice was sought from a physiotherapy clinical specialist and clinical nurse specialist.

Clinical effectiveness. Clinical outcomes regarding changes in distress were measured using psychometric questionnaires. These included the Beck Depression Inventory-II (BDI-II²⁴), Pain Self-Efficacy Questionnaire (PSEQ²⁵), Tampa Scale for Kinesiophobia (TSK²⁶) and Pain Catastrophising Scale (PCS²⁷). Pain disability and interference were assessed using the Brief Pain Inventory (BPI²⁸). The BPI measures pain interference by assessing impact of pain upon general activity, mood, walking ability, normal work, relationship with other people, sleep and enjoyment of life. A physical assessment measuring the number of sit-to-stands each patient could do in 1 minute was also conducted.

Statistical analyses. IBM SPSS Statistics 20 was used for statistical analyses. As data regarding healthcare use failed to meet assumptions of normality, a Wilcoxon signed rank test was used to analyse the non-parametric data. Data regarding clinical outcomes did meet assumptions of normality and were therefore analysed

using a series of *t* tests with an adjusted alpha level to control for multiple comparisons.²⁹

Results

Prior to starting the PMP, 53% of patients were classed as severely depressed, 27% as moderately depressed, 13% as mildly depressed and 7% as not depressed. These classifications were based on the BDI-II.²⁴ Table 2 provides information regarding the clinical outcomes of the PMP. Only clinical outcome data for the 50 patients whose GPs provided healthcare utilisation data are included in Table 2. Of those 50 patients, not all completed psychometric or sit-to-stand measures. The primary reason for this was some patients found the measures too time-consuming and did not wish to complete them.

Of the GPs contacted, 64% provided the data requested. Comparing information on patient's age, duration of pain and clinical outcomes for those patients for whom the GPs had supplied appointment data with those patients whose data had not been supplied showed no significant differences (see Table 3).

The median number of appointments 12 months prior to the start of the PMP was 5.5 (standard deviation (SD) 5.98; range=0–35), with a total of 319 appointments. After 12 months the end of the PMP, the median number of appointments was 3 (SD 3.59; range=0–20), with a total of 179 appointments. This represented a significant reduction in the number of pain-related healthcare appointments after the PMP ($Z = -3.712, p < .001$).

The average cost of an 11.7-minute GP appointment is estimated to be £45 using published data on healthcare costs.³⁰ Applying this figure to this study's data, the cost of pain-related primary care appointments for the patients 12 months pre-PMP was £14,335, compared to £8055 12 months post-PMP.

Table 3. Comparison of patients whose healthcare utilisation data was collected compared with those whose were not.

Measure	Mean (SD)		N		<i>t</i> test	<i>p</i> value	Effect size Cohen's <i>d</i>
	Data obtained	Data not obtained	Data obtained	Data not obtained			
Age	44.8 (9.1)	47.7 (9.9)	50	28	-1.312	>0.05	-0.30
Duration of pain	11.3 (10.6)	12.4 (9.4)	50	28	-4.86	>0.05	-0.11
BDI	28.2 (9.2)	29.3 (13.9)	50	28	-0.385	>0.05	-0.09
PSEQ	23.4 (13.1)	24.2 (13.7)	50	27	-0.246	>0.05	-0.06
TSK	43.5 (8.7)	43.4 (8.4)	50	27	0.045	>0.05	0.01
PCS	33.1 (11.1)	34.1 (12.5)	50	27	-0.360	>0.05	-0.08
BPI-P	6.5 (1.8)	6.6 (1.7)	50	28	-0.363	>0.05	-0.06
BPI-I	7.6 (1.7)	7.1 (1.9)	50	28	1.173	>0.05	0.28

BDI: Beck Depression Inventory; PSEQ: Pain Self-Efficacy Questionnaire; TSK: Tampa Scale for Kinesiophobia; PCS: Pain Catastrophising Scale; BPI-P: Brief Pain Inventory-Pain; BPI-I: Brief Pain Inventory-Interference.

Discussion

Summary

This study aimed to examine the pattern of primary care pain-related healthcare use for a cohort of patients attending an outpatient group PMP. Importantly, a robust data collection method was used which utilised the computerised appointment records kept by GP surgeries, rather than relying on patients' recollections about how many appointments they had attended, which are open to response and memory biases. The results demonstrated that the number of pain-related GP consultations was significantly reduced in the 1 year after the programme when compared with 1 year beforehand and calculated the cost-savings associated with this reduction. Although the lack of a control group means that this change cannot be definitively attributed to the self-management techniques taught on the programme, it is unlikely that this decrease in consultations represents a natural decline over time as there was a wide range in the number of years the patients on the programme had experienced pain, with an average duration of more than 11 years.

In addition, this study supported previous research demonstrating clinical effectiveness of PMPs, with significantly lower levels of distress and disability following the programme when compared with pre-programme data.

Limitations and strengths

This study was limited by the lack of a control group which means that the improvements in distress and decreased healthcare use cannot be definitively attributed to attendance at the PMP. Future research would benefit from using a matched control design in order to determine whether the impact on primary care attendances was due to participation in the PMP or the

placebo effect. Alternatively, a waitlist control or repeated measurement at two time points before attending the PMP may give some insight into whether the change in primary care attendance was part of a natural decline over time.

The study was further limited by the necessary reliance on staff in the GP practices to collect information on healthcare use. This meant that there were missing data for the patients whose GPs did not reply to the request for information. In addition, there is potential for error in extracting the data about pain-related appointments. In order to try and address this, possible medical summaries were forwarded to the researchers so that appointments could be calculated as accurately as possible. There were some rare occasions where GP staff calculated the number of appointments themselves, and it is possible that any errors in calculation may not have been picked up by the research team. However, for the vast majority of patients, medical records were reviewed by the researchers and provided more objective information on appointments than data gathered by self-report.

It should also be noted that the current research was conducted with a select group of patients. First, the patients were self-selected in terms of who opted in for the initial group meeting and also the individual assessment. Following this, the team only offered a proportion of these patients a place on the programme and the current research was only conducted on those who had complete pre-post programme data. This represented 34.6% of the total number of patients referred to the service. Data suggest that, in general, patients included in this study are representatives of chronic pain patients seen in pain clinics based on gender and age.^{1,31} However, there was a higher percentage of female participants than has been found in a recent meta-analysis of the prevalence of chronic pain in the United Kingdom.²³ This could reflect a bias in the

number of women who are referred to a self-management programme compared with men or a greater willingness on the part of female patients to opt in to a PMP. This would be an interesting area for further research. The patients included in this study were representative of chronic pain patients seen in pain clinics based on the severity of their depression. About 53% of patients met criteria for severe depression at the start of study, and in comparison, approximately 50% of patients seen in a pain clinic have depression.^{32,33}

This study measured one aspect of chronic pain economic burden, and it could be argued that factors such as cost of secondary care attendance and medication use should have also been measured. However, research regarding the impact PMPs have upon secondary care healthcare utilisation and medication use already exists,^{11,14} whereas previously there has been limited research exploring the pattern of primary care attendance following a PMP using robust methods of data collection.

Finally, only 64% of the GPs contacted actually provided the data requested, which added an additional level of selection. However, comparing information on patient's age, duration of pain and clinical outcomes for those patients for whom the GPs had supplied appointment data with those patients whose data had not been supplied showed no significant differences.

Despite these limitations, this study has a number of strengths. The use of robust data collection regarding healthcare utilisation, instead of relying on self-report data, allowed accurate examination of pain-related appointments. Such an approach eliminates any bias that patients might have in recalling the number of appointments they have made over a period of 2 years. In addition, this study was able to identify healthcare use specifically related to patients' chronic pain condition. This allowed the researchers to control for the effects of patients with multiple comorbidities who may have visited their GP for issues unrelated to their chronic pain.

All patients took part in a PMP programme facilitated by the same consultant clinical psychologist, physiotherapy clinical specialist and clinical nurse specialist. In addition, the format and structure of the PMP were the same for all patients. This helped eliminate any differences between PMP groups that might have occurred if different staff members had facilitated different PMP groups. However, it does raise the question of how much of the improvement in clinical outcomes was due to the presenters and how much to the content of the programme. This could be assessed with a comparison group covering the same content but with different presenters. However, this was beyond the capacity of this study.

Comparison with existing literature

This study adds to the growing body of research that has demonstrated the benefits for patients from attending a multi-professional PMP in terms of reduced distress and disability. It also suggests that there may be a wider benefit for the healthcare economy as the study found that pain-related appointments in primary care for a cohort of patients attending a PMP reduced in the year following the programme. The findings of this study support the results of a previous study by Clare et al.,¹⁴ who found a 90.5% reduction in secondary care healthcare use for patients who attended a PMP. While the 43.9% reduction in number of pain-related primary care appointments in this study is encouraging, it is clearly not as large a decrease as that is seen in secondary care. A possible explanation for this is that following a PMP, patients will still need to visit their GP for regular reviews of medication, whereas patients no longer require secondary care appointments as their self-management skills have improved following the PMP, which reduces the need for interventions such as injections or surgical procedures.

In line with previous research on the clinical effectiveness of PMPs, this study found that there were significant improvements in levels of depression, fear of movement, catastrophising thoughts and physical function, although the change in self-efficacy was not statistically significant. Importantly, these results were obtained despite the fact that 53% of patients starting the programme met the criteria for severe depression. The explicit aim of the PMP was to reduce the distress and disability associated with chronic pain, rather than directly changing the pain itself; therefore, it was not surprising that there was little change in patients' reports of pain. This would imply that the decrease in GP consultations was not due to a remission in pain. However, the significant reduction in the amount in which pain interfered with patients' lives suggests that they may have started to develop strategies to self-manage their condition and thereby limit the impact it had on daily activities.

There is surprisingly little research on the cost implications of reduced healthcare use following attendance of a PMP, particularly in primary care. This study used published tariffs to calculate the cost-savings of a reduction in GP consultations. Unfortunately, it was not possible to factor in the cost of running the PMP as unlike some PMPs which are funded by individual tariffs for each clinical contact; this service was funded on a block contract and incorporated clinical activities other than the group programme (such as individual work with patients who require an

interpreter) and so a cost per patient attending the group programme could not be extracted.

Implications for research/practice

Health services are struggling to cope with demand and there has been an increasing emphasis on the importance of self-management for chronic health problems. This study suggests a possible link between patients attending a PMP and reduced reliance on primary care for pain management. Further work is now required in order to determine whether this change can be attributed directly to participation on the PMP through comparison with a control group, such as a group of patients who meet for the same amount of time as those on the programme to talk about their pain, but without the provision of specific information on coping strategies and self-management. In order to verify that the change in primary care attendance was not due to natural decline over time, a further study would need to be conducted using a waitlist control or repeated measurement at two time points before attending the PMP.

It is intended that a follow-up study will be carried out on this study's cohort to examine whether the reduction in healthcare use continues in the long term. In addition, a possible area for future research could be to explore the views of GPs after their patients have attended a PMP.

There is already evidence to suggest PMPs significantly reduce pain-related secondary care healthcare use.¹⁴ If further research can build upon this study and definitively establish a link between PMPs and decreased pain-related primary care healthcare use, there would be a strong argument to increase the availability of PMPs to patients. Currently, PMPs are not available for all patients who have chronic pain, despite being proven to be a clinically effective approach. It has never been more important for services to consider the cost-effectiveness of the approaches they offer. This study along with previous research raises the exciting possibility of PMPs being an attractive option for commissioners due to the reduction in the strain on limited resources and reduced healthcare costs.

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Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Ethical approval

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Informed consent

Written informed consent was obtained from all subjects before the study.

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