

Guidance controversy may impact individuals with chronic pain

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Abstract

Chronic pain affects around 20% of UK adults, impacting individuals significantly, leading to disability, depression and adverse social consequences, with many unable to work.

This article looks at the recently published NICE guidelines, including the Chronic Primary and Secondary Pain (CPP and CSP) categorisation, and the evidence based used in their development. The guidelines are a step in the right direction, with the potential to raise awareness of the condition, encourage consistency in treatment and shared decision-making and ultimately improve the quality of life of people who have often previously felt neglected by the healthcare system. However, their publication has not been without controversy. This includes the clear shift away from initiating painkillers, particularly opioids, with anti-depressants being the only pharmacological treatment recommended, along with non-pharmacological treatments such as acupuncture. Another concern is that the distinction between CPP and CSP has not been widely implemented into clinical practice which may limit the effectiveness of the guidelines. Creating such guidelines that attempt to generalise across a vast variety of conditions that can be highly individual was always going to be a challenge. However, drawing upon a broader evidence base to mitigate the current lack of large-scale clinical trials could have addressed some of the controversies.

Abbreviations

CBT – cognitive behavioural therapy

FOPM – Faculty of pain medicine

GPs – General Practitioners

NICE – National institute for health care excellence

TENS – Transcutaneous electrical nerve stimulation

Key terms

Pain – unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.¹

Chronic pain (CP) – pain characterised by significant emotional distress or functional disability² that persists or reoccurs for more than three months.³

Chronic Primary Pain (CPP) – chronic pain with no underlying condition that adequately accounts for the pain or impact.³

Chronic Secondary Pain (CSP) – caused by an underlying condition such as osteoarthritis, rheumatoid arthritis and endometriosis.³

The National Institute for Health and Care Excellence (NICE) released the first guidelines for the management of chronic primary pain on 7 April 2021.

This article describes CPP from a medical perspective in the context of the recently published NICE guidelines. It draws upon freely accessible studies referenced in the guidance along with systematic reviews highlighted by commentators in their response to the guideline's release.

Around 20% of UK adults suffer from CP,^{1,4} which is likely to increase with an ageing population.⁵ The new guidelines categorise CP into CSP and CPP3 both impacting individuals significantly, leading to disability,² depression,^{4,6} adverse social consequences⁶ and sleep disturbances⁴ with many unable to work.^{1,6} Creating clinical guidelines can improve not only the quality of life but the consistency of care for people who often feel neglected by the healthcare system,⁷ with individuals referring to their CP as an invisible illness.⁶

The guideline's key aim³ was to focus on person-centred collaborative care and shared decision making for those aged 16 and above. This includes understanding the contributing patient-related factors of the pain as well other aspects that may influence it, including substance misuse, housing and employment. A consequence of the guidelines was a shift away from the routine use of opioids,¹ non-steroid anti-inflammatory (NSAIDs), anti-epileptic drugs and a shift towards anti-depressants.³ The guidelines recommended other non-pharmacological approaches such as exercise, CBT and acupuncture but did not encourage other methods such as TENS machines.³

Shared-decision making has become a widely used practice in which patients and clinicians share information and opinions to reach

a treatment decision. Although this has been linked to improved outcomes and better adherence, it may be particularly challenging in chronic pain. The new guidelines may introduce challenges, for example around the use of opioids. The wide use of opioids in the past is now discouraged and this could create disagreements between patient and clinician.⁸

The reception to the guidelines was mixed. The majority of responses were supportive of person-centred care,⁹ but the Faculty of Pain Medicine (FoPM) and Cochrane are concerned about some of the bigger changes to current care such as the pharmacological management changes.^{7,9} Fewer than 15% of surveyed FoPM members have used the diagnosis of CPP in clinical practice, with over 80% disagreeing with the guidance on managing CPP from the released guidelines.⁶ In general, there is little consensus amongst the healthcare community on diagnosing and managing CP, which may be in large part due to the challenges in its study and the potential stigma.¹⁰

Why is studying CP so difficult and what are the key concerns with the new guidelines?

Pain is subjective and, therefore, a challenge to capture personal and contrasting experiences of pain.⁷ Due to this, how data involving pain are analysed can substantially influence the outcome.⁹ Focusing on CPP, which encompasses a broad range of conditions, creates a challenge in defining recommendations that would be appropriate and workable for all patients.⁷

A fundamental concern with the guidelines was that the evidence used was based on small sample sizes. Research has shown that trial with sample sizes of less than 50 participants return 48% larger effect estimates for treatments than for those with over 1000.¹¹ Furthermore, seemingly valuable Cochrane systematic reviews looking at interventions (pharmacological and non-pharmacological) were excluded from the evidence used to underpin the guidance.⁹ Also, conditions (e.g. lower back pain and sciatica) already covered by their own guidelines were excluded. Further, these guidelines were for those aged 16 and above; however, 16–17-year-olds would be included in paediatric-focused studies and therefore not part of the evidence used to inform this guidance. This can lead to a void in evidence for this age group due to not being represented in the studies used.⁷ Such factors could suggest a relatively narrow evidence scope and risk a selection bias.⁷

Pharmacological management

Table 1 summarises the recommendations for pharmacological interventions for CPP in the NICE guidelines.

Table 1. Pharmacological recommendations for CPP in the NICE guidelines³

Recommended	Not recommended
Antidepressants: amitriptyline, citalopram, duloxetine, fluoxetine, paroxetine or sertraline	Antiepileptic drugs: including gabapentinoids
	Antipsychotic
	Benzodiazepines
	Corticosteroid trigger point injections
	Ketamine
	Non-steroidal anti-inflammatory drugs
	Local anaesthetics (topical or intravenous), unless as part of a clinical trial for complex regional pain syndrome
	Local anaesthetic/corticosteroid combination trigger point injections
	Opioids
	Paracetamol

A key concern was that GPs (General Practitioners) could stop useful prescriptions (e.g. painkillers).⁹ However, the guidelines emphasise shared-decision making; if existing medication is causing little harm, they can continue on a safe dose.³ A meta-analysis on CP has highlighted the difficulties in establishing the efficacy of painkillers. The results were found to not be normally distributed, often with a bimodal distribution with very good or very little pain relief. Another key issue is the high placebo response rates. In both crossover and parallel trials, there were modest response rates with active treatments over the placebo.¹²

A commonly used drug to treat CP is opioids. However, the safety and efficacy of opioids remain controversial, with the risk of serious adverse reactions of addiction, overdose, death,¹ sleep problems and depression.¹³ Additionally, other side effects include constipation, dizziness and nausea.¹³

Despite the lack of strong evidence for its effectiveness and safety concerns, opioid dosage has been increasing in recent years.¹ A 50mg increase in morphine almost doubles the risk of developing an addiction.¹⁴ Widespread media reporting highlights that this is a global issue, with many countries facing issues from adverse risks associated with opioid use. In Canada, the worker’s compensation board found in 1998 the average dose was less than 500mg of morphine or equivalent rising dramatically to over 6000mg in 2010.¹⁵ Although the trend over time is less clear in the UK, the prescription rate of codeine has increased five-fold between 2006 and 2017.¹⁶

High-dose¹ opioids (more than 200mg) have previously been used for the treatment of CP prior to these guidelines being published. However, an overview of Cochrane reviews found no studies covering high-dose use for CP, showing the critical lack of evidence in this area. Normally, it would be recommended to conduct more research into the efficacy of high-dose opioids. However, this should be done with caution due to the high risk of serious adverse reactions. The author states, “no evidence base argument can be made on the use of high-dose opioids in clinical practice.”

Another Cochrane review¹³ looked at adverse events associated with medium- and long-term opioid use. This review found that due to the high adverse risks associated with opioid use, the clinically relevant benefit must be demonstrated before long-term use could be considered with additional concerns when moving from medium to long-term use. Although the quality of the reviews was strong, there was limited reporting of adverse events, which would need to be improved for future trials.

Over recent years there has been a consensus emerging that although long-term opioid use may work in individual cases, it should not be the general rule.^{1,13} Delays in accessing timely care from the right professional leads to the declining potential for rehabilitation and ultimately can result in people relying on addictive substances.⁶ Such factors support the intentions of the published guidance to reduce the reliance on opioids. However, given that this has been known for many years, it raises questions as to why it took so long for the guidelines to be released and how many more people could have benefitted in the interim.

The only pharmacological intervention recommended by NICE was six different anti-depressants for those over 18. It highlighted the benefit of anti-depressants, even without a depression diagnosis, in improving quality of life, sleep and psychological distress.³ However, a Cochrane meta-analysis looking at anti-depressants in the management of CP found no previous systematic reviews or meta-analyses comparing the difference in efficacy of different anti-depressants.¹⁷ At this point in time there is no clear guidance to inform the choice of which anti-depressant to optimise patient outcomes.

Non-pharmacological

Table 2 summarises the recommendations for non-pharmacological interventions for CPP in the NICE guidelines.

Table 2. Non-pharmacological recommendations for CPP in the NICE guidelines³

Recommended	Not recommended
Exercise and physical exercise programmes	Electrical physical modalities: TENS, ultrasound, interferential therapy
Psychological therapy: ACT and CBT	
Acupuncture	Psychological therapy: Biofeedback

One controversy was the recommended use of acupuncture.³ One randomised controlled trial in the guidelines compared acupuncture to sham acupuncture for 100 individuals with fibromyalgia. However, the study found acupuncture did not perform any better than sham acupuncture. One limitation was no group went through the usual care pathway.¹⁸ Another was that the required duration and frequency could not be achieved of an acupuncture session through the allowed 5 hours, as an average session is between 20 minutes and one hour.¹⁹ It is striking that in contrast to these guidelines, the NICE guidance on lower back pain and osteoarthritis classify acupuncture as “do not offer” due to the lack of evidence on its efficacy.⁷ The focus on acupuncture may suggest that the majority of CPP is musculoskeletal and could encourage an overly sedentary lifestyle when exercise and physical activity have been shown to offer benefits.⁹

On exercise, the guidelines recommended supervised programmes and staying physically active long-term for general health benefits. The evidence, from a total of 91 studies and 3 Cochrane reviews, was dominated by two conditions: fibromyalgia (58 studies and all 3 Cochrane reviews) and chronic neck pain (31 studies).²⁰

One study, with a small sample size (54), looked at aquatic training on symptom improvement for women with fibromyalgia. Although they gained improved fitness, no clinical association could be made to improving symptoms.²¹ A key limitation is that not everyone can access such facilities. Another trial looked at the impact of Zumba and aerobic exercise on working memory and motor function.¹⁹ This trial included 60 individuals with fibromyalgia randomly allocated to either of these or the standard care control group. Although significant improvement in both were seen, as well as the controls remaining virtually unchanged, these were not followed up to monitor long-term outcomes. A key positive is that exercise is likely to carry minimal risk of serious adverse reactions,²² as seen in a Cochrane meta-analysis on fibromyalgia⁴ and another study on chronic neck pain.²³

Tens, ‘pain relief involving the use of mild electrical current’²⁴ was not recommended due to a lack of evidence supporting its efficacy.³ A Cochrane review did not conclude whether they were effective due to the small sample sizes and poor data quality. There was minimal risk of adverse reactions. There is a clear need for more reliable studies considering the devices are simple to use, portable and relatively inexpensive with the possibility to scale up.²⁵

Conclusion

Effective management of CP can significantly improve quality of life and reduce the strain on the NHS. While the publication of these guidelines has been controversial, with several concerns raised by key medical bodies, they are a step in the right direction. The emphasis on shared decision making begins to address the issue of many patients feeling unheard by their practitioner. The publication has also raised awareness of the key challenges in managing CP.

A key controversy is the shift away from initiating painkillers, particularly opioids, for individuals with CPP, which have historically

been a common approach up until now. Although this distinction between CPP and CSP have been adopted by the NICE guidelines it has not been widely implemented into clinical practice. This raises concerns that many individuals with CPP will continue to rely on opioids.

Considering a wider evidence base to inform the guidance could address some of the controversies including the emphasis on acupuncture. Furthermore, there needs to be more large-scale trials for chronic primary pain given the limited research on the CPP and CSP classification within the new guidelines.

The guidelines are only one element of effective management for CP and therefore there needs to be more co-operation between pain specialists who are working on the front line with individuals with CP and those who commission care, which would ultimately lead to better outcomes for the patients.

What works for CP seems to be very much down to an individual, therefore, making guidelines that try and generalise treatments for such a vast variety of conditions is inevitably going to be a challenge. Would a trial-and-error approach between doctor and patient, with greater flexibility than the guidelines currently allow, lead to better outcomes?

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