**Exploring the impact of Pain Management Programme attendance on CRPS patients’ decision making regarding immunosuppressant treatment to manage their chronic pain condition**

Murray, C.a, Harrison, S.b, Goebel, A.c† & Twiddy, H.d†\*

Author affiliations

1. Assistant Psychologist, BSc Psychology, MSc Psychology. The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK
2. Assistant Psychologist, BSc Psychology. The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK
3. Reader and Honorary Consultant in Pain Medicine, PhD, FRCA FFPMRCA, Pain Research Institute, University of Liverpool, Liverpool L69 3BX and The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK
4. Clinical Psychologist, BSc Psychology, DClinPsy. The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK

† Shared authorship.

\*Corresponding author: Pain Management Programme, The Walton Centre NHS Foundation Trust, Liverpool, L9 7LJ, UK. E-mail: Hannah.twiddy@thewaltoncentre.nhs.uk

**Abstract**

**Objectives:** Complex regional pain syndrome (CRPS) is a rare chronic pain condition for which no curative treatment exist. Patients in tertiary centres are often required to make decisions about treatment options. This study was conducted to explore how prior attendance of a pain management program might alter patients’ decision making processes,

**Method:** This qualitative study uses focus groups to gather patient views on an immunosuppressant drug treatment (mycophenolate) for the management of CRPS. Participants were allocated to one of three focus groups based on their treatment journey; Group 1 (N=3) were involved in a recent mycophenolate drug trial; Group 2 (N=5) were neither involved in the trial nor attended a Pain Management Programme (PMP); Group 3 (N=6) were not involved in the trial but had attended a Pain Management Programme. Outcomes were considered within the framework of Leventhal’s Common Sense Model (CSM) in relation to the decision making process.

**Results:** Thematic analysis identified differing themes for each group. Group 1: [1] Medication as a positive form of treatment, [2] The trial/drug, [3] Pacing. Group 2: [1] Medication as form of treatment, [2] Other forms of support/treatment, [3] Side effects of mycophenolate. Group 3: [1] Varied view of medication, [2] Consideration of other forms of support, [3] Side effects.

**Conclusions:** Attendance on a PMP might provide patients with skills to better manage uncertainty when faced with various treatment options. Leventhal’s model goes some way to explaining this. The specific importance of, and benefit from understanding pacing when commencing an effective drug treatment for chronic pain became apparent.

**Key words**

CRPS, mycophenolate, Focus groups, chronic pain, treatment decision making, pain management.

1. **Background and aims**

Complex regional pain syndrome (CRPS) is a chronic pain condition described as “a often-debilitating, painful condition in a limb, associated with sensory, motor, autonomic, skin and bone abnormalities” [1 ] which is experienced following, although not exclusively, an injury or trauma. Classically, the condition has been underdiagnosed, with healthcare professionals having to use clinically derived diagnostic criteria. [2] Recent revisions of the diagnostic criteria support better recognition of the condition and its symptomology. [3]

The treatment of CRPS can prove complex [4,5]; research indicates that appropriate treatment involves a number of distinct, parallel approaches. [6-8]

The UK Royal College of Physicians set out clinical guidelines [1] for the treatment of CRPS. These ‘four pillars of treatment’, are 1) physical and vocational rehabilitation, 2) pain relief (medication and procedures), 3) psychological interventions, and 4) patient information and education to support self-management.

Provision of information, and education can support patients in making treatment choices. Making such choices is part of the process of shared decision making between clinician and patient, which has been shown to be particularly important in the context of chronic illness. [9]

There are many internal and external factors that influence an individual’s decision making regarding treatment. It is important for us to consider these factors when exploring the impact that having a chronic pain condition can have on this decision process. To understand these factors, Leventhal’s Common Sense Model (CSM) [10] proposes a parallel-response framework embedded in an individual’s socio-cultural context. The model suggests that receiving the diagnosis of a chronic illness can lead to a perceived threat to health and/or wellbeing (e.g. fear or distress). Patients develop strategies for managing these perceived threats, and they continuously (re)appraise these strategies based on their effectiveness. Decision making processes are integral to these strategies (See Fig.1). Cheung et al. [11] found that patients’ decision-making processes were influenced by; 1) beliefs about their condition; 2) self-imposed treatment boundaries following prior treatment experiences; 3) external influences and health care professional input confirming the influence of both internal and external factors on treatment decision making.

Nicklas et al. [12] have specifically applied this model to chronic pain, positing that patients who believe they have greater personal control over perceived pain-related threats to health and emotional wellbeing are more reluctant to completely rely on analgesics. This suggests that perceived control over the personal impact of chronic pain can influence decision making regarding medication as a form of treatment.

Further qualitative studies have explored decision making and medication. Generally, a majority of patients express reservations [13] and aversions [14] to medication, despite still considering drugs as a preferred treatment method; hence these results indicate ambivalent perceptions of medication treatments. A proposed solution to this ambivalence is to align treatment with a person’s personal values [11], which would involve a better clinician understanding of the patient’s perceptions, past experiences and pre-existing beliefs.

Very recent discoveries have suggested that autoimmune processes contribute to causing CRPS and some other chronic pain conditions, and that these conditions may therefore be treatable with medications that modulate the immune system (15-17]. Immune-modulating drugs can cause specific serious side effects such as sepsis, severe infections, cancer, or meningitis, that differ from those effects typically elicited by analgesic drugs such as opioids or anti-epileptics. We were interested to gain an understanding about the factors involved in CRPS patients’ decision making in this context. More specifically, we wished to understand how patients would weight advantages and disadvantages of immune drug treatment on the background that their own condition, CRPS, while very painful is non-destructive, i.e. unlike in other conditions treated with such drugs, a decision *against* such a treatment will not result in tissue damage.

Mycophenolate is a relatively new, small molecule immune suppressant drug, which in the UK is licensed in Transplant Medicine, and further used across a range of conditions including in Neurology, Dermatology and Rheumatology. It supresses both T-cell and B-cell responses. Since abnormal B-cell activity resulting in the production of autoantibodies is thought to contribute to causing persistent CRPS, mycophenolate is hypothesised to be potentially effective; preliminary evidence for mycophenolate efficacy in persistent CRPS is available from both a case series of five patients treated at a US centre [18], and from our small parallel, open, randomised, proof of concept trial in 12 patients of whom four reported profound pain relief.[19] While effective in several conditions, and generally well tolerated, treatment with mycophenolate may very rarely result in the development of severe adverse reactions including skin cancer or lymphoma, serious infection and sepsis, and potentially the usually-lethal progressive multifocal leukoencephalopathy (PML) - a brain infection, although the latter is not fully confirmed. Unlike some more established immune suppressant drugs, mycophenolate can also cause serious damage to the unborn child and therefore strict precautions must be put in place ensuring that the drug is not given during pregnancy. We took advantage of an opportunity to recruit patients following their involvement in our trial involving mycophenolate (MYPS Trial).

**Aims of the study**

The current study attempts to gather patients’ perceptions of:

1) The advantages/disadvantages of treatment of their condition with mycophenolate’.

2) Observations during the trial appeared to suggest that some patients were perhaps rather indiscriminate in their judgement of any potential drug side effects; we therefore also sought to explore how the experience of an interdisciplinary, biopsychosocial approach to their treatment might affect patients’ decision making about treatment with mycophenolate.

1. **Method**
	1. Sampling

All participants required a diagnosis of CRPS in accordance with Budapest clinical criteria [6]; they had a disease duration of >18 months, and rated their average pain as >5 on a 11-point scale of intensity (0=’no pain’, 10=’pain as bad as you can imagine’). Participants were recruited and allocated to focus groups according to their prior treatment experience; involvement in the MYPS Trial (Group 1); neither involvement with MYPS Trial nor attended a PMP (Group 2); no involvement in MYPS trial and attended a PMP (Group 3).

Group 1 were identified from their involvement with the MYPS Trial and having received active drug and were invited to take part in the focus group.

Groups 2 and 3 were recruited from a Registry holding participants’ information who had attended an initial assessment for a 16 Day (120h) multidisciplinary Pain Management Programme in Liverpool, UK. Consent was given at the point of initial assessment for the PMP to be contacted in relation to future research projects. Recruitment posters and leaflets were also displayed at the Walton Centre pain management program.

* 1. Procedure

Participants were contacted by phone to determine their interest in the study and were recruited per phone after a consideration period of 2 weeks. Groups 2 and 3 were provided an additional information sheet[[1]](#footnote-1) giving details of mycophenolate to consider as they were unfamiliar with the drug. All participants were asked to provide informed consent once they had considered all the information provided to them regarding their involvement in the study.

* 1. Design

Focus groups can be viewed as a ‘group discussion’ in which the facilitator is the mediator. The function of the mediator is to present the pertinent question and allow for the group to discuss/produce their own narrative. Puchta & Potter [20] assert that the interaction between participants is where the information is gathered, with the moderator taking a relational role. The interactions from all three focus groups were audio recorded and transcribed.

Each group was facilitated by the same Clinical Psychologist and Assistant Psychologist for continuity. Participants allocated to Group 1 had recent involvement in the randomised proof of concept trial [1] involving the drug (mycophenolate) (N=3); Group 2 had not been involved in the trial or attended a PMP (N=5); and Group 3 consisted of individuals who had not been involved in the trial but had completed a PMP at a minimum of 6 months prior to the study (N=6).

Patients were invited to discuss their view on the costs to them, and benefits of this type of immunosuppressant treatment.

* 1. Analysis

Table. Phases of thematic analysis. [21]

|  |  |
| --- | --- |
| Phase | Description of the process |
| 1 | Familiarising yourself with your data | Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas |
| 2 | Generating initial codes | Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code |
| 3 | Searching for themes | Collating codes into potential themes, gathering all data relevant to each potential theme |
| 4 | Reviewing themes | Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic ‘map’ of the analysis |
| 5 | Defining and naming themes | Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.  |
| 6 | Producing the report | The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.  |

A theoretical approach to thematic analysis, as outlined by Braun and Clarke [21], was adopted to analyse the data transcribed. This allowed for “a detailed analysis of some aspects of the data” [21 p.84], and acknowledged that researchers and data did not exist in a vacuum of pre-existing understanding or bias. The data was analysed by a researcher not involved in the focus groups to give a fresh perspective on the data set. The independent researcher (IR) analysed the data for themes following the steps outlined by Braun and Clarke. The IR completed steps 1-4 (Table), to the point of creating thematic maps, and then involved the full research team for steps 4- 6 to ensure that this accurately reflected the focus groups and rationale for the project.

* 1. Ethics

Ethical approval was granted by the NRES Wales Ethics Committee 4 -17/WA/0206.

1. **Results**
	1. *Group1 - involved in the randomised proof of concept trial and took medication (N=3)*

The three participating patients in this group had each documented beneficial effects from mycophenolate treatment during the trial; 2/3 patients had been classed as ‘responders’ - they had not recorded any severe side effects; the third patient had had to stop taking mycophenolate before trial completion due to an exacerbation of her pre-existing inflammatory skin-condition.

The group were positive about medication in general as a form of treatment for CRPS. This theme was consistent throughout the group’s discussions (Fig. 2.1). There was little deviation from medication, or consideration for other forms of treatment/support. The focus group’s narrative on medication was that it was *less intrusive* than other forms of treatment. They also described having more ‘control’ *over* medication, compared to other forms of therapy, particularly spinal cord stimulator treatment[[2]](#footnote-2), which is more difficult to reverse.

“*If the tablet does not agree with you, you can stop it. Straight away. You know, you give it up*.”

“*Something like that* [Spinal Cord Stimulator] *being inserted into your body, it is something major. Reading all the side effects, you could have said, you know, no that sounds dangerous*.”

“*Yes. I can stop that whenever I want to do it*.”

Medications, and particularly mycophenolate were seen as providing control over pain:

 *“Yes. If you have had the pain that long, you need to try and take control over it.”*

*“When you are off medication you shut yourself away.”*

*“on the higher dose, it was, you know, it was back to me. Kind of thing, Like, you know, I was before I had this…”*

In addition, the participants suggested that mycophenolate had a positive impact on their wellbeing. There appeared to be a sense that this drug had helped them to return to a former sense of self. The comparison with other forms of treatment appeared to suggest that mycophenolate was a preference. The advantage seemed to be based on a perceived sense of control; both in its purpose for managing pain; and the consequent control it provided over their wellbeing. Participants felt that the drug had helped improve confidence in their ability to do more i.e. work, and helped improve their mood.

*“I actually would be able to do an extra day in work on the medication because it was under control. You know, I would be able to do more.”*

*“you get some pain still, but you know. I don’t know, it is like you are back to being you again. Not having to put up with chronic pain every single day.”*

*“I could go out and do things what I had not done for years. You know, it was just a better way.”*

*“I feel 90% better in myself”*

*“You are just happy again, you know….. It is just hard.”*

Subthemes of medication providing increased control, improved wellbeing, and ability to do more meaningful activity seemed to be consistent throughout Focus Group 1’s discussions.

The group also discussed specific side effects of mycophenolate and whether they were present or caused concern. There did not appear to be many concerns expressed regarding side effects experienced whilst trialling mycophenolate. There were suggestions that ‘stopping medication abruptly’ had led to some concerns.

“*Yes, you just stopped, and that was another side effect for me. I am thinking, well is he going to stop it? The pain comes back like you have just hit the wall*.”

“*Is there headaches from the medication? (Facilitator)*

*After you finish (Participant)*

*After you finish? So in the withdrawal (Facilitator)*

*And when you first start them as well. (Participant)*

*Well mine was just the headaches were…when you first went on it*”

“I think the benefits of it [medication] are worth the side effects.”

“*I did not get told nothing. They just said, like that is it now basically. You had to fill in them diaries to say how you felt.”*

Although not a substantial subtheme, there was discussion around headaches on commencing and ceasing the trial that participants appeared to attribute to the abrupt end of taking the drug. Suggestions of weaning off the medication were made to counteract this effect. Despite this, the group still remained positive about this medication.

*“I did not think nothing of it. I have tried everything else.”*

*“They have all got risks. Like, anything like controlled drugs, and you can get addicted. You know, there are all things. Isn’t there?”*

*“I just worried over my body. Will I be ill again all the time? All the bugs. Yes, I did have quite a few colds and chest infections, but to be out of pain, I would rather have that.”*

*“You would just be taken off it. As they say, it was only a trial to see how you got on with it. If it comes on the market, then maybe they can have it for life or something like that.”*

From discussions it appeared that participants were willing to take the risk regarding experienced or potential side effects for the benefit of pain relief.

Participants noted one challenge with the pain relief they experienced whilst trialling mycophenolate, which related to pacing their physical activity.

*“You used to pay for it more the next day.”*

*“I used to think I could do everything with it. All day I was fine…then the next day you paid for it”*

*“You do feel pain as such, but not as deep as what you did.”*

This discussion suggested that participants found that they were doing more whilst they were relieved of pain, however, they would subsequently experience more intense pain the following day. They suggested the drug masked physical limitations in the context of pain causing them to engage in higher levels of over activity.

* 1. *Group 2- neither involved in the randomised proof of concept trial nor attended PMP (N=5)*

Group 2’s responses also reflected a positive view of medication in general, particularly relating to an improvement in their day-to-day functioning and relationships with family.

*“Yes, to be able to go to the toilet without screaming in pain because…”*

*“It’s your children. My children had to do a lot for me when I started being ill and everything. Adding problems. You know, they have got their own lives now, University and everything.”*

*“Like, being less of a burden*.*”*

*“I go to college 1 day per week, and when I get the CRPS, everyone. It is now got to the point now where the I hate going.”*

This theme had similarities to Group 1, in that a suggestion of an improvement in quality of life was an advantage of taking medication in general. When specifically discussing mycophenolate it appeared that, after being provided information (supplementary appendix), they would still try the drug.

*“My painkillers at the moment are still working, but if there is nothing left for people to try, then this sounds like a good option.”*

*“I think the benefits of it [medication] are worth the side effects.”*

*“With myself, it is like, I would personally. I mean I would try anything that may help me long-term…”*

*“To be honest with you, a lot of the side effects is what we get with other things but that we have to deal with on a day-to-day basis.”*

For some patients, these positive reflections appeared despite recognising mycophenolate-associated specific side effects. However, some direct concerns were raised by other participants who observed the need for further information before considering to use mycophenolate.

*“Because you have to list the disadvantages, all the negative. And it is like, well straightaway that is damaging because you are thinking….. It mentions death”*

*“…because I think she has got experience with it and told me those side effects, you know, that a lot of people are aware of this, that and the other, it is all about people who know what has happened to other people, or even talking to….. Now funnily enough, my mum takes this drug”*

*“About long-term use. What evidence is there for long-term use?”*

The type of information, both positive and negative appeared to be important along with the source of the information. Some participants required more information from people who had received the treatment and from a trusted source e.g. family member, friend etc. Others suggested requiring evidence provided by medication trials.

Group 2 also explored further support/treatments that might be available, alongside medication. Mental health support, although not specific, was discussed as potential additions to treatment.

*“They finally diagnosed it, but they did not give me any kind of mental help, and I think that is the first thing that should be there, is that, you know, therapy…”*

*“It is all right if you talk to someone, but then you come away and then it is like that from friends, family, whatever. You go around in circles.”*

The group also felt a helpline specifically for CRPS would be helpful.

*“…somebody just to talk to at the end of the phone or whether it is someone who can say… When you are in that situation, because other people’s acceptance as well as your own acceptance, or to be on the other end of an email – you can say, I am having a real down point.”*

*“I think I would say 24/7 for people, if they have got concerns or worries, this is happening. You feel like a hypochondriac.”*

This extended to the helpline being facilitated by individuals with lived-experience of CRPS as it was suggested that healthcare professionals can often lack in expertise/experience of the condition, leading to frustration with services.

*“Actually someone there who has actually got it. Yes. Somebody who has actually got it, so they know your ups and downs. They know you are limited in doing things. You may have a bad day, and they are there to talk to.”*

*“Someone who actually understands CRPS….The anxiety and depression and not just the pain. If someone understands what we are going through, a help line.”*

*“The doctors don’t know what it is like…. they can say that they do because they are a doctor, but until you have it, you have no idea. I did not know pain like this could exist.”*

* 1. *Group 3 - attended PMP not involved in the randomised proof of concept trial*  (N=6)

Group 3’s discussions regarding medication as a form of treatment appeared varied, in that they stated some benefits of medication in terms of improvement to functioning and employment (Fig. 2.3). However, this was based on individual circumstances and what worked for that person.

*“I want to go back to work, so I would love a drug that would allow me to do that. I need to retrain for something different to get back to work because I would not be able to go to the job that I done.”*

*“It is just you have got to look at your own lifestyle”*

 *“I am still trying to keep a normal life with my family, taking my son out and stuff, but you know, some of the side effects there, if I am feeling dizzy and sick, I cannot drive my son to his sports.”*

*“Now, I have got to be honest, I did not think about the side effects of the drugs. I did not think about my family. I was just more I needed to keep my role.”*

The negative impact of the side effects of medication in general appeared to relate to the impact this could have on their relationship with their families. It suggests that this group weighed up the potential costs and benefits of medication and whether this was right for them at that time.

A further theme was identified of side effects in relation to mycophenolate. The group suggest that they would require more information before taking the medication due to the potential effects.

*“but then I thought – Well, not everybody gets those side effects. Just because it is listed there, it does not mean that these are going to happen to you, so….. People who are taking it, has it took their pain away?”*

 *“So for me, I would need to know what the likelihood was of those side effects did most people get?”*

*“For me, it would be what was the feedback from the other focus groups.”*

*“I think as well with the small cohorts that you have a trade-off – is it that bad that you would be prepared to try…The cohort has got to be massive”*

Further to this, the group suggested that trusted feedback would be valued more. Participants expressed that they would value the feedback from people who had trialled mycophenolate. They also indicated that information from larger cohorts in research would also be valued in relation to pain reduction and side effects.

*“So I would have to think, you know, well I may be at more risk to get cancer anyway, so you would have to look at what health concerns are already in your family.”*

*“I think it is because the side effects sound so brutal, don’t they? That is the difference.”*

*“So if your body is already going through it with previous medications, I do not think it is advised to…. Well obviously you cannot do it because your doctor won’t allow you because of it.”*

Overall, decision making appeared to be considered from various angles, based on personal circumstance and the information provided, with the suggestion of requiring more information before a decision could be made.

The group also considered other supports available to, aside from medication. One of these considerations was psychological support. This was in addition to the medication and considered as part of pain management as whole.

*“You go to the Pain Management and that for me, Pain Management, is all the psychology side of it, and I think that is a great medicine. I think that is a better medicine than the drugs that we are taking, taking an edge off it. For me personally.”*

*“I think you know another thing we should be offered support is, having like a Psychologist to go to or a counsellor. Because it is a cycle, and in the end everything just wells up and then you are just on rock bottom then and you have to pick yourself back up again.”*

*“I think that everything that was offered to me I took, and I think the only time after that, now being faced with this, I think – No. Because as you say, we know it [pain] is not going…”*

*“…you just go for anything that you can go for to ease that pain. And that was, I needed something, whereas but then again, being on the Pain Management Programme, it makes you realise that there is not a cure and you have just got to deal with it and accept what is happening and still keep that little hope that something does come in.”*

Further to psychology as a specific consideration, the attendance on the Pain Management Programme had altered participants’ perceptions of pain management as a whole. The specific benefits of psychology and perceptions of pain management appeared to be broadly considered in this group. There were also suggestions regarding acceptance of pain and not focusing on medication as a “cure”.

This group appeared to be more balanced in their decision making when considering other forms of treatment. In particular discussions focused on SCS as an alternative treatment for medication.

*“If that can help me rather than go to drastic measures. I would probably…. If there is only a 20% chance of it working anyway, spinal cord stimulator, I would rather try that.”*

*“You see 2 years ago or whenever, I would have done that [SCS]*. *because I was up for it, to do it…. Now looking at it, I am actually glad that I probably did not, but I was wanting to do it.”*

 *“So if I could have that rather than medications. Because medication has wrecked my body.”*

Discussions focused on considerations of treatments in a more balanced way, with the weighing up of the costs and benefits of treatments. This was a distinctive characteristic of this group compared to Groups 1 and 2 in terms of identified themes. Group 3’s discussions appeared also broader in their decision making regarding treatments for pain management.

1. **Discussion**

We aimed to explore chronic pain patient’s considerations about immune modulation treatment with mycophenolate. We conducted three focus groups, which were distinguished from each other by the past treatment experiences of their respective participants. We found that main themes varied between these three groups, and that patients who had previously completed a multidisciplinary pain management program appeared to have a wider and more balanced approach toward decision making about mycophenolate treatment (Figures 2.1-2.3).

Leventhal’s theory could go some way to explaining these outcomes. This theory embeds individual’s decision making about treatment in an individual’s socio-cultural context and suggests that receiving different forms of information about chronic conditions can lead to perceived threats to wellbeing. The responses from the focus-group that had previously attended a pain management program (PMP) suggested that they had developed a larger number of internal evaluation strategies when encountering uncertainty around treatment. This is evidenced through their consideration both of the positive and negative impacts of medication, their consideration of additional forms of treatment, and their reflection on not only their own experiences but also on those of their families.

These results suggest that PMP treatment may influence the way in which patients make decisions about future treatments; this is consistent with previous evidence about an interdisciplinary/ biopsychosocial approach to the treatment of chronic pain [22], and CRPS. [8] Studies that have focused specifically on patients’ sustained *reduction* in medication intake following PMP attendance have found mixed results. [23,24] McCormick et al. [8] found a short term medication reduction post-PMP suggesting a possible PMP effect on decision making around medication treatment in patients with CRPS. One possible mechanism involved in such post-PMP medication reduction could be attainment of ‘Psychological Flexibility[[3]](#footnote-3)’ (PF). Guildford et al. [24] found that an increase in PF mediates reduction in analgesics post-PMP in their cohort. To our knowledge, no previous studies have explored the potential impact of PMP attendance on decisions about *new drug treatment post-PMP*; the present study provides a first, qualitative representation of this from the perspective of the patient – participants who attended a PMP appeared to have both a more in depth and a more balanced view of such new treatment compared to other groups. The study could also suggest that people who haven’t attended a PMP may be more likely to take more risk in their mode of treatment due to desperation managing their pain. More research is clearly required.

We also found that patients previously involved in the randomised proof of concept trial for mycophenolate (Group 1) described experiencing increased activity-engagement whilst on the medication. In turn, the increase in activity appeared to have a positive impact on their wellbeing and quality of life (e.g. mood and confidence). However, there were concerns regarding the effect the medication had on pain thresholds, with the potential overdoing of activity and subsequent experience of pain the following day. This suggests that the reduction in pain intensity the drug provided may have led some trial participants to engage in activities they may have usually paced differently. This finding could have implications for the future conduct of drug trials much like the randomised proof of concept trial group 1 were involved with highlighting that integration of education about additional pacing strategies into such trials may be useful.

1. **Limitations**

A limitation to the present study were the small sample sizes for Groups 1 and 2 (N=3, 5); optimal number of participants in focus group are often considered around 6-12 individuals. [26] Therefore, the findings may not yield the diversity of information required to make generalisations to the population they represent. However, the study provides evidence to suggest that the subject of treatment experience and treatment decision making may benefit from further research. Further to this, exploring the benefit of attending a PMP and the role of psychological flexibility in enhancing the formal decision making process should also be considered.

1. **Implications for clinical practice**

Whilst not all patients may require PMP intervention, the current research study posits that PMP participation may provide tools allowing patients to manage uncertainty when considering their healthcare treatment options and potential research study participation. Further research is required to understand which patients will benefit most from PMP care in this context, and whether certain PMP elements should also be integrated into programmes that prepare patients with chronic pain for their potential participation in clinical trials.

1. **Conclusion**

This qualitative study explores how differing treatment journeys might influence patients’ decision making about future treatment options. Those participants who attended a PMP appeared to think more broadly about the advantages and disadvantages of complex pharmacological choices. Leventhal’s parallel-framework model may go some way to explaining how the information received on a PMP can influence decision making regarding treatment. Independently, the current study suggests that integration of pacing-training should be considered to improve patient experiences in clinical trials assessing potentially very effective medications.

1. **Author’s Statements**

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**Informed consent:** Informed consent has been obtained from all individuals included in this study.

**Ethical approval:** The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors’ institutional review board or equivalent committee.

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1. See Appendix 1 [↑](#footnote-ref-1)
2. A Spinal Cord Stimulator (SCS) is a type of implantable neuromodulation device that is used for the treatment of certain pain conditions. [↑](#footnote-ref-2)
3. “Psychological flexibility spans a wide range of human abilities to: recognize and adapt to various situational demands; shift mindsets or behavioral repertoires when these strategies compromise personal or social functioning; maintain balance among important life domains; and be aware, open, and committed to behaviors that are congruent with deeply held values.” [25, p.1] [↑](#footnote-ref-3)