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An observational study of outcomes associated with virtual pain management programmes based on Acceptance and Commitment Therapy implemented during the COVID-19 pandemic

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Abstract

Objective: In response to COVID-19, *virtual*, group-based interdisciplinary pain management programmes (PMPs) were rapidly implemented. This included implementing different intensities and formats of virtual PMPs to address a range of patient needs and complexity. This observational study investigated outcomes associated with virtual high and low intensity and pre-neuromodulation PMPs based on Acceptance and Commitment Therapy (ACT) as part of routine care during the pandemic. **Methods:** Depending on patients' needs, participants completed a virtual high- or low-intensity PMP, or a virtual PMP in preparation for neuromodulation, from June 2020 to June 2022. Participants completed standardized measures of pain intensity and interference, work and social adjustment, depression, and pain acceptance before and after treatment. Data from 2018 and 2019 for in-person residential ($n=561$), outpatient ($n=123$), and pre-neuromodulation ($n=207$) PMPs were also examined to provide an historical benchmark of performance. **Results:** The virtual high-intensity PMP ($n=294$) showed significant improvements on all variables, with small effects. There were significant improvements with small effects for pain interference, depression, and acceptance for the virtual pre-neuromodulation PMP ($n=129$). No statistically significant improvements were observed for the virtual low intensity PMP ($n=90$). The improvements associated with pre-pandemic in-person PMPs were generally larger relative to the virtual PMPs of comparable intensity delivered during the pandemic. **Discussion:** These data provide preliminary support for the potential benefits of high, but not low, intensity virtual ACT-based PMPs, including in the context of neuromodulation. Research is needed to maximize the impact of virtual PMPs and match patients with the most appropriate delivery format.

Key Word: Pain management, Acceptance and Commitment Therapy, virtual delivery, chronic pain, pandemic

Introduction

Interdisciplinary pain management programmes (PMPs) based on cognitive-behavioural therapy (CBT) are supported by meta-analyses of randomized-controlled trials (RCTs) and observational data.¹⁻⁵ Acceptance and Commitment Therapy (ACT) is a more recent form of CBT for which evidence for persistent pain is growing.⁶⁻⁹ CBT and ACT-based pain management programmes focus on helping people to manage the impact of persistent pain on their lives, rather than on reducing pain itself. Consistent with this, research indicates that these approaches generally produce larger benefits in physical, social, and emotional functioning than in pain intensity.^{5, 7}

ACT is increasingly used within interdisciplinary PMPs in routine clinical practice.¹⁰⁻¹² To address varying levels of patient need and complexity, different formats and intensities of ACT-based PMPs have been implemented within the UK's National Health Service.¹³ For example, an intensive residential ACT-based PMP has been running for more than 12 years for patients presenting with severe and complex pain-related disability or distress.^{14, 15} A less intensive outpatient format is also offered for people presenting with less pervasive impacts of pain on their lives.¹⁶ Finally, ACT-based PMPs have also been implemented for patients that are medically suitable for neuromodulation.¹⁷ ACT-based PMPs in this context help patients to make an informed decision about neuromodulation and to develop skills to respond more effectively to pain irrespective of the outcome of neuromodulation.¹⁷

The COVID-19 pandemic caused an unprecedented impact on healthcare delivery worldwide.¹⁸ Within this context, there was a need to rapidly adapt interdisciplinary PMPs for remote delivery to reduce service disruption. Increasing evidence from RCTs of Internet-delivered CBT for pain, including ACT, support the

potential benefits of remote delivery.¹⁹⁻²² Additionally, evidence from one non-inferiority trial suggests that in-person and remotely-delivered ACT for pain produce comparable outcomes.²³ Before the pandemic, however, remotely delivered PMPs were not widely implemented, with notable exceptions.²⁴ Research is therefore needed to understand the effectiveness of remotely-delivered PMPs implemented in real-world practice where patients present with greater complexity.²⁴ Crucially, implementation must consider the local context, including permitted technological platforms, staff resource, and support to sustainably deliver and continuously improve remote treatment.²⁵⁻²⁷

Remote delivery of PMPs is not without challenges. Key among these is maintaining patient engagement.¹⁸ Difficulties fostering a therapeutic alliance, privacy and security concerns, and poor digital literacy are potential challenges to address to optimize inclusion and engagement in this format.^{18, 28} Additionally, in-person PMPs are often delivered in a group and processes such as group cohesion are thought to impact on outcomes.²⁹ However, Internet-based treatments for pain are typically delivered individually. There is also a need to understand outcomes associated with varying intensities and formats of remote PMPs to improve understanding of how to best address varying complexity of patient need.

This study therefore investigated outcomes associated with ACT-based PMPs delivered for groups via video platform (“virtual PMPs”) in a specialty pain service during the pandemic. Prior to the pandemic, this service provided a range of in-person group-based PMPs to address varying needs including, as mentioned, intensive residential,¹⁵ outpatient¹⁶, and neuromodulation preparation PMPs.¹⁷ Virtual PMPs mirroring the content and intensity of these in-person programmes were developed during the pandemic. Thus, the service adapted each of the PMPs

that was delivered in-person before the pandemic into a virtual format to support a range of patient needs during the pandemic. It was hypothesized that each of the three formats of virtual ACT-based PMPs would be associated with significant improvements in pain interference, work and social adjustment, depression, and pain acceptance. Given that the virtual PMP formats varied as a way to address differing patient needs, we did not make specific hypotheses about the relative performance of the different treatment formats, nor was it our intention to directly compare these. Nonetheless, data from the virtual high and low intensity and pre-neuromodulation programmes are presented together in this manuscript to illustrate implementation in practice and to examine potential generality of results across treatment formats in the unique historical context of the pandemic. Although direct comparisons require cautious interpretation, pre-pandemic data from the in-person PMPs in this service are presented as a benchmark of previous performance.

Materials and Methods

Participants

This paper presents data from consecutive participants completing virtual PMPs during the COVID-19 pandemic from June 2020 to June 2022. This includes data from participants completing virtual high and low intensity and pre-neuromodulation programmes during this time. Data from consecutive participants completing in-person PMPs prior to the pandemic were also included (January 2018 to December 2019). This includes data from participants completing residential, outpatient, and pre-neuromodulation programmes. Figure 1 shows the data collection process and

the number of participants providing pre- and post-treatment data for each treatment programme. Portions of the pre-pandemic residential PMP data have been previously published;¹⁴ however, outcome data from the other programmes before and during the pandemic have not been published.

All participants were assessed by a Clinical Psychologist and Advanced Practitioner Physiotherapist in Pain Management to determine the suitability of a group ACT-based PMP. Across all treatment formats, the general inclusion criteria were: (1) being 18 years of age or older; (2) the presence of pain for three months or more which significantly impacted on daily function, mood and/or overall quality of life, as judged by the assessing clinicians; and (3) willingness to attend and participate in a treatment that focused on improving quality of life and personal goals rather than on pain reduction. For the pre-neuromodulation programmes, participants were willing to engage in treatment focused on these aims alongside learning technical information to make an informed decision about receiving neuromodulation, typically a spinal cord stimulator. The general exclusion criteria across treatment formats were: (1) significant ongoing medical treatments, investigations or procedures (with the exception of neuromodulation); (2) serious and poorly controlled psychiatric conditions (e.g. active psychosis, severe post-traumatic stress disorder, active suicidality); (3) inability to engage constructively in group treatment, such as due to interpersonal difficulties or cognitive impairments; and (4) use of liquid opioid medication whilst attending the programme (immediate release tablets below 200mg daily dose of morphine equivalence was acceptable).

There were additional inclusion and exclusion criteria depending on the specific delivery format and treatment pathway. These are presented in Table 1 for comparison. Clinicians' judgment, based on the assessment information, in

combination with consideration of patient preferences informed the recommendation for the specific PMP format. The frequency of specific reasons for exclusion/attrition were not systematically recorded for this study. However, an audit (separate to the current study) conducted within the same service identified that the most common reasons for exclusion from the programmes offered were the presence of serious and poorly controlled psychiatric conditions, not being ready for a self-management approach, and pain not significantly impacting on daily functioning.¹³

Procedure

All treatment participants were asked to complete a standardized and validated set of self-report measures at the start and end of their treatment programme. The pre-treatment measures gathered demographic information, including gender, age, ethnicity, pain location and duration, home situation, highest level of education, and work status. At pre-treatment, participants completing virtual programmes during the pandemic also responded to questions about whether they had experienced specific events related to COVID-19 and how the pandemic had affected their healthcare use, health, functioning, mood, pain, and social support. These data were collected for descriptive purposes to contextualise the outcome data. At both pre- and post-treatment, participants completed standardized measures of pain outcomes, namely, pain intensity, pain interference, work and social adjustment, and depressive symptoms. They also completed a measure of pain acceptance, a key treatment process variable at pre-and post-treatment. Additionally, at post-treatment participants provided ratings of their overall impression of change during treatment.

All measures are described in detail below. Written informed consent was obtained from participants to use their data for research purposes.

Participants doing a pre-pandemic in-person programme completed standard paper-based assessment measures in clinic. Participants completing a virtual programme were sent an email with a link to complete questionnaires online via 'Online Surveys' ([https:// www.onlinesurveys.ac.uk](https://www.onlinesurveys.ac.uk)). Trained service staff were on hand to provide support and answer questions for participants completing questionnaires in clinic and remotely. This process facilitated data completeness. This study was approved by the National Research Ethics Service Committee South Central – Oxford C (17/SC/0537) and was conducted in line with the Declaration of Helsinki.

Treatment approach applied across delivery formats

Prior to the pandemic, patients completed either a three-week residential PMP, an outpatient PMP, or a two-week residential pre-neuromodulation PMP depending on their needs, as discussed in the inclusion/exclusion criteria. During the pandemic, participants completed a virtual high or low intensity programme or a virtual pre-neuromodulation programme; these were developed to correspond to the content and intensity of the residential, outpatient, and pre-neuromodulation programmes, respectively. All treatment programmes and delivery formats were based on the ACT model and focused on enhancing psychological flexibility.^{7, 30} Programme types and delivery formats, including clinicians involved and contact time are summarised in Table 2.

Across all programme formats, the treatment approach included use of metaphors, experiential exercises, mindfulness practice (including mindful movement exercises), values clarification, values-based goal setting, and opportunities for practice and rehearsal. Treatment was aimed at broadening the behavioural strategies employed and increasing awareness of options for pursuing values-based action. Throughout the programme, clinicians applied ACT principles to highlight avoidance and applied goal achievement as a guide for action. ACT strategies helped participants become more aware of and respond more openly to challenging experiences (e.g., pain, fear, shame, guilt, anger, sadness, etc.) and to pursue their values. All clinicians received regular training and updating of pain management practices and ACT through regular clinical development meetings. Psychoeducation on pain medication was also provided.

For programmes where nurses were involved (see Table 2), one-to-one telephone contact was made by a nurse to discuss individual's pain medication consumption and explore goals for pain medication reduction. Psychoeducation on pain physiology, anatomy and allostatic loading and stress models were also applied flexibly as required. Additional home exercises, mindfulness practice and weekend goals were discussed during the treatment period. Regular inter-disciplinary team meetings to reflect, plan and formulate formed an integral part of the team's treatment strategy.

Adapting treatment for virtual delivery

The virtual programmes were delivered on a video platform called BlueJeans, which was approved for use by the hospital. Participants were offered an

appointment prior to the programme to ensure that they were able to use the BlueJeans platform successfully. To maximise focus and engagement, the virtual treatments had regular breaks, and employed group discussions, breakout rooms, multimedia resources (e.g., short videos, audio recordings), and screen displays. Due to concerns that patients would have difficulty maintaining engagement and concentration five days per week in the intensive virtual treatment programme, the overall number of days for this programme was reduced to 12 compared to the 15 days of the residential format. The number of days for the virtual low intensity and virtual pre-neuromodulation programmes were consistent with their in-person counterparts.

To foster group cohesion and openness in the virtual high intensity and pre-neuromodulation PMPs, an additional optional hour-long daily session was scheduled for patients to meet and talk with each other virtually without clinician involvement. This was not available in the virtual low intensity programme, but patients were encouraged to connect with each other outside of the formal programme hours if they were able to. To develop the therapeutic alliance and to mitigate challenges arising during virtual treatment, each patient was allocated to a named clinician who followed them up by phone. For the virtual high intensity and pre-neuromodulation programmes, patients were contacted by their allocated clinician a minimum of two times per week, while patients completing the virtual low intensity PMP were contacted by their clinician once per week on average. The implementation of these features was shaped in response to patient feedback. There were generally 8-10 participants per group in the virtual treatments.

Following the initial implementation of the virtual low intensity programme, patient and clinician feedback indicated that the duration was insufficient to deliver

sufficient content. Therefore, this programme was increased from 12.5 to 20 hours at the end of 2021. Due to the small numbers, it was not possible to compare outcomes associated with the 12.5- and 20-hour versions of this programme. Therefore, outcomes for patients completing either version of the virtual low intensity programme were combined for analysis.

Assessment Measures

Pain intensity: Participants rated their average pain intensity over the past week using a standard 11-point numerical rating scale with the end points 0 (no pain) to 10 (worst possible pain).

Brief Pain Inventory – Interference Subscale (BPI-IS): The BPI-IS was used to measure the impact of pain on daily functioning in seven domains: general activity, mood, walking ability, work (including housework) relationships with others, sleep, and enjoyment of life. Responses apply to the past week and require participants to rate the seven items on an 11-point scale, ranging from 0 (does not interfere) to 10 (completely interferes).³¹ BPI-IS average scores were used, with higher average scores reflecting greater pain-related interference. The BPI-IS is a widely used outcome measure in chronic pain studies and is considered a reliable and valid measure for assessing pain-related interference with daily functioning.³²⁻³⁴

Work and Social Adjustment Scale (WSAS): The WSAS was used to measure functional impairment associated with the participants' health condition in five

domains: work, home management, social leisure, and private leisure activities, and personal or familial relationships³⁵ Participants rated the five-items on an 8-point scale, ranging from 0 (no impairment) to 8 (very severe impairment). Higher scores indicate more severe impairment in work and social functioning. The WSAS is considered a reliable and valid measure for assessing functioning in people with long-term health conditions.^{35, 36}

Patient Health Questionnaire (PHQ-9): The PHQ-9³⁷ was used to assess participants' depressive symptom severity, as defined by the standard diagnostic criteria for depression. Participants rated the frequency with which they experience nine symptoms of depression over the past two weeks on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day). Higher scores indicate more severe depression symptoms. The PHQ-9 is considered a reliable measure for assessing the severity of depression symptoms and has been validated among patients with a broad range of physical health conditions, including chronic pain.³⁸

Chronic Pain Acceptance Questionnaire (CPAQ-8): The eight-item version of the CPAQ was used to measure participants' pain acceptance.³⁹ The CPAQ consists of items related to participation in valued activities in the presence of pain, and refraining from unsuccessful attempts to control, avoid or reduce pain.⁴⁰ Participants rated each item on a seven-point numerical scale ranging from 0 (never true) to 6 (always true). CPAQ-8 total scores were used, with higher scores indicating greater pain acceptance. There is evidence for the reliability and validity of the CPAQ-8 and it has shown good convergent validity with the original 20-item version of the CPAQ.

Patient Global Impression of Change (PGIC): At post-treatment, the PGIC was used to measure participants' overall impression of change over the course of treatment.⁴² Participants rated their overall improvement following the general stem "Compared to how you were before treatment, how are you doing overall" on the following seven-point scale: 1 (very much improved), 2 (much improved), 3 (minimally improved), 4 (no change), 5 (minimally worse), 6 (much worse), and 7 (very much worse). The PGIC has been widely used in clinical trials of analgesic medications for chronic pain,⁴³ and has been shown to capture change related to a number of important outcome domains following completion of an ACT-based PMP.⁴⁴ The following anchors were used to describe 'Meaningful improvement' (1- very much improved, 2- much improved), 'No meaningful change' (3- minimally improved, 4- no change, 5- minimally worse), and 'Meaningful worsening' (6- much worse, 7- very much worse).

Statistical Analysis

Preliminary statistical analyses were carried out using SPSS version 27 (SPSS Inc., Chicago, IL). Descriptive statistics were computed for all variables. Skewness, kurtosis, histograms, and Q-Q plots were examined for each variable to determine normality. Means and standard deviations were computed for continuous variables for descriptive purposes and frequencies and percentages were computed for categorical variables. Participants who did not complete post-treatment measures were compared to those who did on all demographic and outcome/process variables, using independent samples *t*-tests for continuous variables and Chi-square tests for categorical variables.

To examine change on the variables from pre- to post-treatment, intention-to-treat linear mixed models were run using restricted maximum likelihood estimation to maximize use of all available data and account for the repeated measures nature of the data. The mixed models included a fixed effect of time and a random intercept. The analyses were run with the Jamovi gamlj module. Cohen's d was computed using the adjusted mean change from each mixed model divided by the pooled observed standard deviations. The following benchmarks for interpreting d were used: small (≥ 0.20), medium (≥ 0.50), and large (≥ 0.80).⁴⁵ As a sensitivity analysis, missing post-treatment data were imputed using the baseline observation carried forward (BOCF) and the linear mixed models and effect sizes were re-computed. Frequencies and proportions were computed for the PGIC categories.

Results

Sample demographics and experience of COVID-related events

Descriptive statistics for participants' demographics according to treatment programme are summarised in Table 3. Briefly, across all programmes, the samples were comprised predominantly of women and white participants. The mean age of participants ranged from 45.26 (SD=13.17) in the virtual low intensity programme to 50.16 (11.92) in the residential pre-neuromodulation programme. Across the programmes, participants had pain of longstanding duration (all means/medians >9 years). Low back pain was the most frequently reported primary pain location across the programmes.

Across the virtual programmes, the majority of participants had not experienced a significant COVID-related event (Supplementary Table 1). However, a minority of participants experienced events such as losing their job, death of a family member or friend, a major financial change for the worse, and/or a change in their living situation. Across all virtual programmes, 27-41% of participants reported meaningful worsening in their health/functioning overall, and 29-56% reported worsening in the areas of physical activity, work, mood, social activities, and pain intensity due to the COVID-19 pandemic.

Pre-treatment differences between people who did and did not complete post-treatment questionnaires

Participants who completed post-treatment questionnaires did not differ significantly from those who did not complete these on any baseline variable, across all three virtual programmes. Within the three-week residential programme and the pre-neuromodulation residential programme, participants who completed post-treatment questionnaires did not differ significantly from those who did not complete these on any baseline variable. For the in-person outpatient programme, participants who completed post-treatment questionnaires were significantly younger ($M=43.74$, $SD=11.91$) than those who did not complete these ($M=49.86$, $SD=13.37$), $t(106)=2.38$, $p<0.05$. Outpatient programme participants who completed questionnaires also had significantly lower pre-treatment pain interference ($M=6.18$, $SD=1.97$) than those who did not ($M=6.87$, $SD=1.62$), $t(78.90)=2.00$, $p<0.05$. For this programme, white participants (75%) were significantly more likely to complete post-treatment questionnaires than participants from an ethnically minoritized background

(55%), $\chi^2=4.64$, $p<0.05$. Participants in the outpatient programme who did and did not complete post-treatment questionnaires did not differ on any other baseline variable.

Treatment outcomes: Three-week residential and virtual high intensity programmes

Table 4 shows pre- and post-treatment scores on outcome and process variables across the in-person residential (pre-pandemic) and virtual high intensity (during the pandemic) programmes. For the pre-pandemic residential programme, statistically significant improvements (all $ps<0.001$) were observed for all variables. Based on the effect sizes, these improvements were large for pain interference and depression, and small for work and social adjustment, pain intensity, and pain acceptance. Pain interference and depression reduced to medium effect size improvements when analysed using BOCF, while the effects for the other outcomes remained small when analysed with BOCF; all of these remained statistically significant (all $ps<0.001$). On the post-treatment PGIC, 44.6% of participants reported meaningful improvement overall, while 50.8% did not report a meaningful change, and 4.6% of participants reported that they were meaningfully worse overall at the end of treatment.

For the virtual high intensity programme during the pandemic, statistically significant improvements (all $ps<0.001$) with small effect sizes were also observed for all variables from pre- to post-treatment. A similar pattern of results was observed when analysed using BOCF. At the end of treatment, 35.1% of participants rated themselves as meaningfully improved overall, while 60.8% reported no meaningful change. Four percent rated themselves as meaningfully worse at post-treatment.

Treatment outcomes: Outpatient and virtual low intensity programmes

For the in-person outpatient programme, statistically significant improvements (all $ps < 0.01$) were observed from pre- to post-treatment for pain interference, depression, pain intensity, and pain acceptance, with small effects. When analysed with BOCF, pain interference and depression showed small effects, while pain intensity and pain acceptance reduced to less than small effects, although these remained statistically significant (all $ps \leq 0.01$). There was no significant change in work and social adjustment, and the effect size was less than small across analyses with and without BOCF. On the post-treatment PGIC, 20.2% of participants reported meaningful improvement, 76.2% reported no meaningful change, and 3.6% reported that they were meaningfully worse overall.

There were no statistically significant changes on any variable for the virtual low intensity programme (p -values ranged between 0.06 and 0.59). Although not statistically significant, a small effect size improvement was observed for pain interference, although this reduced to less than small in the analysis with BOCF. The effects for all other variables were less than small across analyses with and without BOCF. At the end of treatment, 21.8% of participants rated themselves as meaningfully improved overall and 78.2% reported no meaningful change. No participant rated themselves as meaningfully worse on the PGIC (Table 5).

Treatment outcomes: Two-week residential and virtual pre-neuromodulation programmes

For the residential two-week pre-neuromodulation programme, statistically significant improvements (all $ps<0.01$) were observed from pre- to post-treatment for all variables. The improvements were medium for pain interference, small for work and social adjustment, depression, and pain acceptance, and less than small for pain intensity. The pattern of results was similar when analysed with BOCF. On the PGIC, 31.1% of participants reported meaningful improvement, 64.2% reported no meaningful change, and 4.7% reported that they were meaningfully worse overall.

For the virtual pre-neuromodulation programme there were statistically significant improvements (all $ps<0.01$) with small effect sizes for pain interference, depression, and pain acceptance from pre- to post-treatment. Work and social adjustment ($p=0.12$) and pain intensity ($p=0.16$) did not significantly improve, and less than small effects were observed. The BOCF analyses showed a similar pattern of results. At post-treatment, 16.4% of participants rated themselves as meaningfully improved and 75.0% reported no meaningful change, while 8.6% rated themselves as meaningfully worse overall on the PGIC (Table 6).

Discussion

This study investigated outcomes associated with the implementation of a range of virtual ACT-based PMP formats in routine care during the pandemic. Post-treatment questionnaire completion rates suggest a small reduction in treatment completion (7-14%) for virtual compared to in-person programmes. High intensity ACT-based virtual programmes, including for patients awaiting neuromodulation, were associated with significant improvements in pain interference, depression, and pain acceptance. Work and social adjustment and pain intensity also improved after the virtual high intensity programme. No significant improvements were observed for

the low intensity virtual programme. This pattern of results across the virtual programmes was generally consistent when sensitivity analyses were conducted using BOCF imputation. Across virtual programmes, 16-35% of participants reported meaningful improvement overall, while only a small proportion, 0-9%, reported meaningful worsening on the global impression of change index. Taken together, the data provide preliminary support for the potential benefits of high, but not low, intensity virtual group delivery of ACT-based PMPs. The findings can inform future research and virtual treatment developments to optimize engagement and outcomes.

For the virtual high intensity programme, significant small effects were observed for all variables. This contrasts with large effects (medium when analysed with BOCF) for pain interference and depression for the residential programme. Direct comparison between outcomes for these programmes must be qualified given the observational design, different contexts of data collection, and different sample sizes. However, several plausible explanations for the relative magnitude of outcomes warrant consideration. Firstly, due to challenges with fatigue and concentration with remote delivery,²⁶ the treatment hours in the virtual high intensity programme was considerably reduced from the residential programme, which may have limited the magnitude of improvements. In-person programmes may also provide greater opportunities to foster the therapeutic alliance and sensitivity for detecting and engaging with therapeutic processes.^{18, 27} Notably, though, a previous noninferiority RCT showed that in-person and video conferencing delivery of ACT (individual rather than group-based) produced comparable outcomes for veterans with chronic pain.²³

The pandemic context may have limited the magnitude of change that was possible during virtual PMPs. Rates of psychological distress increased during the

pandemic, including in people with persistent pain.⁴⁶⁻⁴⁸ Similarly, social and physical functioning were limited for substantial periods due to lockdown restrictions and social distancing. Therefore, participants' capacity to make further gains on mood and functioning may have been limited by this context. Indeed, a number reported significant COVID-related events and worsening in functioning and mood because of COVID-19. Research is therefore needed to understand the impact of virtual PMPs beyond the pandemic.

Participants who completed a virtual PMP in preparation for receiving neuromodulation also showed significant improvements in pain interference, depression, and pain acceptance. Across residential and virtual formats of the pre-neuromodulation programme, improvements were generally small, except for a medium improvement for pain interference in the residential format. Given the unique context of the pre-neuromodulation programme, including specific concerns and worries that patients may have about the procedure itself, it is important to emphasize that the outcome data from this programme cannot be directly compared with the other ACT-based programmes reported here. However, these results add to previous findings showing that people can improve their functioning in the presence of pain while they await an intervention to control it.¹⁷ Research is needed to further maximise the impacts of psychologically-informed pre-neuromodulation treatment. Research is also needed to understand the extent to which improvements on such a programme contribute to improvements in post-stimulation outcomes.⁴⁹

The significant small effects observed for the in-person outpatient PMP are consistent with an RCT of four-session group-based ACT in primary care.¹⁶ These data support the utility of relatively brief ACT-based treatment for some people with pain. However, not all outcomes improved with the outpatient programme and there

were no significant improvements in the virtual low intensity programme. In-person and virtual treatment completion was relatively low for this group of patients, which further limited the sample size and makes interpretation of the effect estimates challenging. Most participants on the in-person outpatient and virtual low intensity PMPs were in some form of employment. Therefore, difficulties fitting treatment around work may partially account for lower treatment completion.⁵⁰ During implementation of the virtual low intensity programme, patients suggested the need to increase the overall treatment duration to reduce the frequency of sessions per week to facilitate their attendance alongside work, and this informed treatment refinements. There is evidence that cognitive-behavioural interventions targeting the person in pain and their employer improves healthcare utilisation and work absence.⁵¹ Therefore, further collaboration with employers may be needed as part of the low intensity treatment package given the relevance of employment-related issues for this cohort.

Another challenge of low intensity ACT-based PMPs is how to optimally target psychological flexibility processes within a relatively brief timeframe. Considering the relatively higher level of functioning of this group, of relevance is research indicating that some people with pain remain engaged in activities while being unwilling to experience pain.^{52, 53} This may reflect a tendency to distract from pain by 'keeping busy', which may come with costs in terms of increased distress.^{52, 53} Supporting people to acknowledge and make space for pain and related difficulties poses a challenge in a time-limited treatment, particularly when this requires practice with slowing down their approach to activities and movement rather than 'pushing through'. This may be especially challenging in a virtual context where people remain in their usual environment for treatment. Therefore, research is needed to

understand how psychological flexibility processes can best be targeted within this context.

If future research provides additional support for virtual PMPs, ongoing implementation of in-person and virtual PMP delivery options can increase inclusivity. Beyond the pandemic, virtual treatments have advantages for enabling patients from wider geographic areas to participate and potentially reducing costs.¹⁸ ⁵⁴ However, remote delivery is not accessible to all, including those without Internet, sufficient digital literacy, or an appropriate home environment.⁵⁵⁻⁵⁷ Therefore, despite the proliferation of remotely-delivered PMPs during the pandemic, in-person delivery remains important. Where services rely heavily on remote delivery, it is important to consider strategies to widen accessibility, such as loaning required technology and up-skilling patients to use this.

With the range of in-person and virtual PMPs now available, a key challenge is to match patients with the most appropriate treatment option. Incorporating patient preferences into the treatment recommendation process may have motivated engagement with treatment programmes in the current study, although the impact of this is difficult to ascertain within the current observational design.^{58, 59} Further understanding of predictors of treatment outcomes by delivery format may enhance our ability to match patients with the most suitable treatment format. To date, research on cognitive-behavioural pain management approaches, including ACT, has struggled to identify consistent predictors of treatment outcomes.^{14, 60, 61} The reliance on aggregate group-level data may contribute to the difficulty identifying predictors, as treatment response is likely to be highly individual. Idiographic methods, such as single-case experimental designs, may facilitate more nuanced understanding of treatment predictors and outcomes for in-person and virtual

formats.^{62, 63} An idiographic focus may ultimately enable researchers and treatment providers to better match patients with the most appropriate treatment format.

This study had several limitations. This was not an RCT, which limits conclusions about the causal impact of the treatments. Additionally, the in-person and virtual programmes cannot be unequivocally compared given the study design and differing contexts of data collection. Experimental designs are needed to directly compare the delivery formats examined. Furthermore, the sample sizes differed considerably which limits interpretation of the outcomes across the treatment programmes. In particular, the sample for the virtual low intensity programme was relatively small, reducing power and limiting certainty around the reported effects. Relatedly, the duration of the virtual low intensity programme was increased in response to feedback during initial implementation. Anecdotally, patients indicated that the 20-hour version was more acceptable than the 12.5-hour version. However, due to the small number of patients receiving these different versions, a comparison was not made and these data were combined. The programmes were delivered by clinicians in one speciality centre and replication across other centres is needed. Finally, although there was better representation of people from ethnically minoritized backgrounds in the virtual high (34%) and low intensity (33%) programmes, participants completing the virtual pre-neuromodulation programme were predominantly white (92%). Therefore, lack of generalizability to ethnically minoritized participants is a key limitation of data from the pre-neuromodulation programmes. To mitigate the risk of perpetuating inequities,⁶⁴ research is needed to understand the barriers to ethnically minoritized patients being referred for neuromodulation and this form of preparatory treatment.

Despite these limitations, this study provides preliminary support for the potential benefits of higher intensity virtual PMPs, although research is needed to maximise treatment engagement and outcomes. The availability of virtual programmes in addition to in-person options can facilitate greater inclusivity of services to meet the needs of a broad spectrum of patients. A key challenge moving forward is to match patients with the delivery format that best meets their needs.

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Table 1. Additional inclusion and exclusion criteria according to treatment format.

Specific criteria for in-person programmes (2018-2019)	
Residential	<ul style="list-style-type: none"> • Ability to manage all aspects of their own self-care and manage the physical requirements necessary to attend and participate in the programme staying on site.
Outpatient	<ul style="list-style-type: none"> • Ability to manage the physical requirements necessary to commute twice per week to and from the hospital and still actively participate in the programme. • Patients recommended for the outpatient PMP generally have a higher level of physical/emotional/social functioning warranting less intensive treatment as compared to those recommended for the residential programme.
Residential pre-neuromodulation	<ul style="list-style-type: none"> • Deemed medically suitable for neuromodulation after review by a neuromodulation consultation (e.g., has a condition such as complex regional pain syndrome or localised neuropathic signs and symptoms). • Ability to manage all aspects of their own self-care and manage the physical requirements necessary to attend and participate in the programme whilst staying on site.
Specific criteria for virtual programmes (2020-2022)	
High intensity virtual	<ul style="list-style-type: none"> • Suitable computing facilities (i.e., a tablet, laptop, or desktop computer)*, Wi-Fi access, and a private space with which to engage in the virtual programme.
Low intensity virtual	<ul style="list-style-type: none"> • Suitable computing facilities (as above)*, Wi-Fi access and a private space with which to engage in the virtual programme • Patients recommended for the low intensity virtual PMP generally have a higher level of physical/emotional/social

	functioning warranting less intensive treatment as compared to those recommended for the high intensity virtual programme.
Virtual pre-neuromodulation	<ul style="list-style-type: none"> • Deemed medically suitable for neuromodulation (as above) • Suitable computing facilities (as above)*, Wi-Fi access, and a private space with which to engage in the virtual programme

* From December 2020, the option of being loaned a tablet was available to participants so they could attend if they had Wi-Fi access but no suitable device.

Table 2. Details of format and delivery across the in-person and virtual programmes.

Type of Pain Management Programme	Treatment days	Treatment duration	Hours of contact	Clinical staff involved
Virtual high intensity	12 days	3 weeks	36 *12 **	φ, P, OT & N
Residential	15 days	3 weeks	75	φ, P, OT & N
Virtual low intensity	5 days	3 weeks (4 weeks from end of 2021)	12.5 (20 from end of 2021) †	φ & P
Outpatient	5 days	3 weeks	20	φ & P
Virtual pre-neuromodulation	8 days	2 weeks	27 *4 **	φ, P, OT & N
Residential pre-neuromodulation	8 days	2 weeks	40	φ, P, OT & N

Note: Clinical Psychologist (φ), Advanced Practitioner Physiotherapist in Pain

Management (P), Specialist Occupational Therapist (OT) & Specialist Pain Nurse

(N).

*Signifies additional hours available for patients to meet and talk with other participants in the group online without clinician input.

**Signifies twice weekly 1:1 telephone calls for therapeutic input with patients by a named clinician.

†Signifies once weekly 1:1 telephone calls for therapeutic input with patients by a named clinician.

Table 3. Demographic characteristics for all participants who started treatment across treatment programmes before and during COVID-19.

	Virtual High Intensity M(SD) or n(%) Pre-treatment n= 294	Residential M(SD) or n(%) Pre-treatment n=561	Virtual Low Intensity M(SD) or n(%) Pre-treatment n= 90	Outpatient M(SD) or n(%) Pre-treatment n=123	Virtual NM M(SD) or n(%) Pre-treatment n=129	Residential NM M(SD) or n(%) Pre-treatment n=207
Gender						
Women	238 (80.9)	437 (77.9)	71 (78.8)	95 (77.2)	67 (52.0)	121 (58.5)
Men	54 (18.4)	121 (21.6)	19 (21.2)	28 (22.8)	62 (48.1)	86 (41.5)
Missing	2 (0.7)	3 (0.5)	0 (0)	0 (0)	0 (0)	0 (0)
Age	47.21 (12.35)	48.12 (12.87)	45.26 (13.17)	45.66 (12.65)	49.18 (11.98)	50.16 (11.92)
Ethnicity						
Asian	23 (7.8)	40 (7.1)	5 (5.6)	8 (6.5)	5 (3.9)	1 (0.5)
Black	50 (17.0)	67 (11.9)	13 (14.4)	13 (10.6)	3 (2.3)	2 (1.0)
Mixed	13 (4.4)	26 (4.6)	5 (5.6)	7 (5.7)	4 (3.1)	5 (2.4)
Other	10 (3.4)	11 (2.0)	5 (5.6)	8 (6.5)	3 (2.3)	0 (0)
White	198 (67.3)	404 (72.0)	61 (67.8)	85 (69.1)	114 (88.4)	196 (94.7)
Missing	0 (0)	13 (2.3)	1 (1.1)	2 (1.6)	0 (0)	3 (1.4)
Education (years)		13.50 (3.58)		16.00 (5.00)*		12.00 (4.00)*
Primary	16 (5.4)		2 (2.2)		8 (6.2)	
O-Levels/GCSEs	80 (27.2)		22 (24.4)		55 (42.6)	

A-Levels	68 (23.1)		17 (18.9)		27 (20.9)	
Uni. Bachelor's	63 (21.4)		20 (22.2)		17 (13.2)	
Uni. Post-grad.	41 (13.9)		21 (23.3)		10 (7.8)	
Doctoral degree	1 (0.3)		3 (3.3)		1 (0.8)	
Other	25 (8.5)		5 (5.6)		11 (8.5)	
Employed						
Unemployed	174 (59.1)	308 (54.9)	12 (13.3)	28 (22.8)	69 (53.5)	90 (43.5)
Part/Full-time	79 (26.8)	142 (25.3)	64 (71.1)	70 (56.9)	38 (29.5)	66 (31.9)
Volunteer	1 (0.3)	8 (1.4)	0 (0)	5 (4.0)	1 (0.8)	4 (1.9)
Carer	1 (0.3)	3 (0.5)	1 (1.1)	3 (2.4)	0 (0)	3 (1.4)
Homemaker	3 (1.0)	14 (2.5)	1 (1.1)	0 (0)	0 (0)	7 (3.4)
Student	4 (1.3)	9 (1.6)	3 (3.3)	4 (3.3)	0 (0)	0 (0)
Retired	32 (10.9)	60 (10.7)	9 (10.0)	9 (7.3)	21 (16.3)	29 (14.0)
Missing	0 (0)	17 (3.0)	0 (0)	4 (3.3)	0 (0)	8 (3.9)
Pain Duration (years)	14.06 (10.65)	10.23 (13.24)*	11.00 (12.02)*	9.01 (11.34)*	12.03 (8.98)	9.01 (14.52)*
Main Pain						
Back	129 (43.9)	211 (37.6)	36 (40.0)	57 (46.3)	56 (43.4)	113 (54.6)
Widespread	40 (13.6)	102 (18.2)	8 (8.8)	11 (8.9)	4 (3.1)	4 (1.9)
Lower limbs	41 (13.9)	65 (11.9)	10 (11.1)	18 (14.6)	36 (27.9)	46 (22.2)
Upper limbs	23 (7.8)	30 (5.3)	16 (17.7)	12 (9.7)	12 (9.3)	10 (4.8)
Neck	22 (7.5)	32 (5.7)	5 (5.5)	7 (5.7)	2 (1.5)	5 (2.4)
Head/face	6 (2.0)	23 (4.1)	2 (2.2)	4 (3.2)	3 (2.3)	6 (2.9)
Abdominal	9 (3.1)	20 (3.6)	4 (4.4)	4 (3.2)	5 (3.9)	4 (1.9)
Pelvic	24 (8.2)	14 (2.5)	8 (8.8)	3 (2.4)	7 (5.4)	6 (2.9)
Anal/genital	0 (0)	3 (0.5)	0 (0)	0 (0)	4 (3.1)	4 (1.9)
Chest	0 (0)	6 (1.1)	1 (1.1)	3 (2.4)	0 (0)	0 (0)

Missing	0 (0)	55 (9.8)	0 (0)	4 (3.9)	0 (0)	9 (4.3)
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*Median and Interquartile Range

Note – education was assessed in years from 2018-2019. From 2020 onwards, this was assessed as the highest level of education.

NM, pre-neuromodulation

Table 4. Treatment outcomes for virtual high intensity (during COVID) and in-person residential programmes (pre-COVID).

Variable Programme	Pre Mean* (SE)	Post Mean* (SE) or frequency (%)	<i>t</i> (df) and <i>p</i>	Effect size (d)	BOCF Pre Mean* (SE)	BOCF Post Mean* (SE) or frequency (%)	BOCF <i>t</i> (df) and <i>p</i>	BOCF Effect size (d)
Pain Interference Virtual High Intensity	7.51 (0.11)	6.68 (0.11)	-8.74 (234), <i>p</i> <0.001	0.46	7.51 (0.11)	6.89 (0.11)	-8.13 (291), <i>p</i> <0.001	0.33
Pain Interference Residential	7.82 (0.07)	6.38 (0.08)	-20.10 (514), <i>p</i> <0.001	0.83	7.82 (0.07)	6.60 (0.07)	-18.5 (559), <i>p</i> <0.001	0.71
Work/Social Adjustment Virtual High Intensity	31.30 (0.43)	29.00 (0.46)	-5.81 (240), <i>p</i> <0.001	0.31	31.30 (0.43)	29.60 (0.43)	-5.60 (292), <i>p</i> <0.001	0.23
Work/Social Adjustment Residential	32.50 (0.30)	29.10 (0.31)	-11.20 (509), <i>p</i> <0.001	0.48	32.50 (0.30)	29.60 (0.30)	-10.70 (556), <i>p</i> <0.001	0.41
Depression Virtual High Intensity	16.30 (0.35)	13.40 (0.39)	-8.26 (242), <i>p</i> <0.001	0.48	16.30 (0.36)	14.10 (0.36)	-7.68 (293), <i>p</i> <0.001	0.35
Depression Residential	18.10 (0.25)	13.00 (0.26)	-20.30 (506), <i>p</i> <0.001	0.87	18.1, (0.25)	13.70 (0.25)	-18.70 (552), <i>p</i> <0.001	0.73

Pain Intensity			-7.34 (238),				-6.87 (293),	
Virtual High Intensity	7.51 (0.09)	6.81 (0.10)	$p<0.001$	0.44	7.51 (0.10)	6.99 (0.10)	$p<0.001$	0.32
Pain Intensity			-11.30 (515),				-10.70 (556),	
Residential	7.80 (0.07)	6.98 (0.07)	$p<0.001$	0.49	7.80 (0.07)	7.11 (0.07)	$p<0.001$	0.42
Pain Acceptance			5.87 (245),				5.74 (288),	
Virtual High Intensity	16.30 (0.43)	18.80 (0.46)	$p<0.001$	0.34	16.30 (0.43)	18.20 (0.42)	$p<0.001$	0.27
Pain Acceptance			10.30 (501),				9.67 (548),	
Residential	16.40 (0.35)	20.10 (0.37)	$p<0.001$	0.46	16.40 (0.36)	19.50 (0.35)	$p<0.001$	0.38
PGIC: Virtual High Intensity (n=225)								
Meaningful Improvement		79 (35.1)						
No Meaningful Change		137 (60.8)						
Meaningful Worsening	--	9 (4.0)	--	--	--	--	--	--
PGIC Residential (n=480)								
Meaningful Improvement		214 (44.6)						
No Meaningful Change		244 (50.8)						
Meaningful Worsening	--	22 (4.6)	--	--	--	--	--	--

Note: *Estimated marginal mean; BOCF, Imputation using baseline observation carried forward; PGIC, Patient Global Impression of Change rating; SE, standard error. Effects sizes (Cohen's d) interpreted as 0.20=small, 0.50=medium, 0.80=large.

Table 5. Treatment outcomes for virtual low intensity (during COVID) and in-person outpatient programmes (pre-COVID).

Variable Programme	Pre Mean* (SE)	Post Mean* (SE) or frequency (%)	<i>t</i> (df) and <i>p</i>	Effect size (d)	BOCF Pre Mean* (SE)	BOCF Post Mean* (SE) or frequency (%)	BOCF <i>t</i> (df) and <i>p</i>	BOCF Effect size (d)
Pain Interference Virtual Low Intensity	6.44 (0.20)	6.01 (0.24)	-1.93 (65.3), <i>p</i> =0.06	0.22	6.44 (0.20)	6.21 (0.20)	-1.64 (88.2), <i>p</i> =0.10	0.12
Pain interference Outpatient	6.38 (0.17)	5.80 (0.18)	-4.55 (91.5), <i>p</i> <0.001	0.30	6.38 (0.17)	6.00 (0.17)	-4.04 (121), <i>p</i> <0.001	0.20
Work /Social Adjustment Virtual Low Intensity	24.20 (0.99)	24.80 (1.09)	0.85 (57.5), <i>p</i> =0.40	0.07	24.20 (0.99)	24.70 (0.99)	1.13 (89), <i>p</i> =0.26	0.06
Work/Social Adjustment Outpatient	25.10 (0.77)	24.20 (0.81)	-1.73 (89.7), <i>p</i> =0.09	0.10	25.10 (0.77)	24.50 (0.76)	-1.58 (120), <i>p</i> =0.12	0.07
Depression Virtual Low Intensity	13.10 (0.62)	13.40 (0.73)	0.55 (59.1), <i>p</i> =0.59	0.11	13.10 (0.63)	13.30 (0.63)	0.45 (89), <i>p</i> =0.65	0.03
Depression Outpatient	13.00 (0.55)	11.20 (0.59)	-4.27 (88.9), <i>p</i> <0.001	0.32	13.00 (0.56)	11.80 (0.55)	-3.90 (121), <i>p</i> <0.001	0.20

Pain Intensity			-0.55 (75.7),				0.238 (89),	
Virtual Low Intensity	6.81 (0.20)	6.66 (0.25)	$p=0.58$	0.08	6.81 (0.20)	6.86 (0.20)	$p=0.81$	0.10
Pain Intensity			-2.83 (92.6),				-2.50 (121),	
Outpatient	6.87 (0.17)	6.48 (0.19)	$p<0.01$	0.20	6.87 (0.17)	6.62 (0.17)	$p=0.01$	0.13
Pain Acceptance			0.81 (60.5),				0.57 (87),	
Virtual Low Intensity	21.80 (0.78)	22.40 (0.90)	$p=0.42$	0.12	21.80 (0.78)	22.00 (0.78)	$p=0.57$	0.04
Pain Acceptance			3.47 (87.4),				3.21 (120),	
Outpatient	22.60 (0.69)	24.50 (0.74)	$p<0.001$	0.26	22.6 (0.69)	23.90 (0.68)	$p<0.01$	0.17
PGIC: Virtual Low Intensity (n=55)	--	12 (21.8)	--	--	--	--	--	--
Meaningful Improvement		43 (78.2)						
No Meaningful Change		0 (0.0)						
Meaningful Worsening								
PGIC Outpatient (n=84)								
Meaningful Improvement	--	17 (20.2)	--	--	--	--	--	--
No Meaningful Change		64 (76.2)						
Meaningful Worsening		3 (3.6)						

Note: *Estimated marginal mean; BOCF, Imputation using baseline observation carried forward; PGIC, Patient Global Impression of Change rating; SE, standard error. Effects sizes (Cohen's d) interpreted as 0.20=small, 0.50=medium, 0.80=large.

Table 6. Treatment outcomes for virtual pre-neuromodulation (during COVID) and in-person two-week residential pre-neuromodulation programmes (pre-COVID)

Variable	Pre	Post	<i>t</i> (df) and <i>p</i>	Effect size	BOCF Pre	BOCF Post	BOCF	BOCF
Programme	Mean* (SE)	Mean* (SE) or frequency (%)		(d)	Mean* (SE)	Mean* (SE) or frequency (%)	<i>t</i> (df) and <i>p</i>	Effect size (d)
Pain Interference								
Virtual Neuromodulation	7.89 (0.15)	7.11 (0.16)	-6.18 (109), <i>p</i> <0.001	0.46	7.89 (0.15)	7.27 (0.15)	-5.83 (128), <i>p</i> <0.001	0.36
Pain interference								
Residential Neuromodulation	7.60 (0.11)	6.70 (0.11)	-10.90 (194), <i>p</i> <0.001	0.56	7.60 (0.11)	6.76 (0.11)	-10.70 (205), <i>p</i> <0.001	0.51
Work/Social Adjustment								
Virtual Neuromodulation	31.70 (0.70)	30.70 (0.74)	-1.59 (112), <i>p</i> =0.12	0.13	31.70 (0.70)	30.90 (0.69)	-1.48 (128), <i>p</i> =0.14	0.10
Work/Social Adjustment								
Residential Neuromodulation	31.0 (0.44)	29.60 (0.45)	-3.83 (195), <i>p</i> <0.001	0.22	31.00 (0.44)	29.70 (0.45)	-3.78 (206), <i>p</i> <0.001	0.20
Depression								
Virtual Neuromodulation	16.60 (0.55)	14.60 (0.58)	-4.22 (109), <i>p</i> <0.001	0.32	16.60 (0.55)	15.00 (0.55)	-4.06 (128), <i>p</i> <0.001	0.25

Depression			-7.62 (198),				-7.52 (204),	
Residential Neuromodulation	15.70 (0.43)	12.70 (0.44)	$p<0.001$	0.49	15.70 (0.43)	12.90 (0.43)	$p<0.001$	0.46
Pain Intensity			-1.42 (104),				-1.63 (128),	
Virtual Neuromodulation	7.83 (0.12)	7.68 (0.12)	$p=0.16$	0.12	7.83 (0.12)	7.69 (0.12)	$p=0.11$	0.10
Pain Intensity			-3.09 (200),				-3.02 (205),	
Residential Neuromodulation	7.77 (0.10)	7.50 (0.10)	$p<0.01$	0.19	7.77 (0.10)	7.51 (0.10)	$p<0.01$	0.18
Pain Acceptance			3.34 (110),				3.14 (127),	
Virtual Neuromodulation	14.80 (0.69)	17.00 (0.74)	$p=0.001$	0.29	14.80 (0.69)	16.50 (0.69)	$p<0.01$	0.22
Pain Acceptance			4.85 (193),				4.81 (202),	
Residential Neuromodulation	17.80 (0.60)	20.00 (0.60)	$p<0.001$	0.26	17.80 (0.60)	19.90 (0.60)	$p<0.001$	0.27
PGIC: Virtual								
Neuromodulation (n=104)	--	17 (16.4)	--	--	--	--	--	--
Meaningful Improvement		78 (75.0)						
No Meaningful Change		9 (8.6)						
Meaningful Worsening								
PGIC Residential								
Neuromodulation (n=193)	--	60 (31.1)	--	--	--	--	--	--

Meaningful Improvement		124 (64.2)						
No Meaningful Change		9 (4.7)						
Meaningful Worsening								

Note: *Estimated marginal mean; BOCF, Imputation using baseline observation carried forward; PGIC, Patient Global Impression of Change rating; SE, standard error. Effects sizes (Cohen's *d*) interpreted as 0.20=small, 0.50=medium, 0.80=large.

Table S1. COVID-19 events experienced and impact.

	Virtual High Virtual pain management programmes Intensity M(SD) or <i>n</i> (%) Pre-treatment <i>n</i> = 294	Virtual Low Intensity M(SD) or <i>n</i> (%) Pre-treatment <i>n</i> = 90	Virtual Pre-50 NM M(SD) or <i>n</i> (%) Pre-treatment <i>n</i> = 129
COVID-19 Events (not mutually exclusive)			
I have been ill with COVID	59 (20.5)	17 (19.5)	15 (11.7)
Caring for a friend/flatmate with COVID	1 (0.3)	0 (0)	0 (0)
Caring for family/partner with COVID	12 (4.2)	4 (4.6)	2 (1.6)
Death of spouse/partner	1 (0.3)	0 (0)	0 (0)
Separation/divorce	3 (1.0)	1 (1.1)	2 (1.6)
Being fired/lost job	20 (6.9)	4 (4.5)	6 (4.7)
Death of a friend/family member	45 (15.6)	10 (11.4)	9 (7.0)
Major financial change (better)	4 (1.4)	1 (1.1)	0 (0)
Major financial change (worse)	52 (18.1)	13 (14.9)	21 (16.4)
Major change in living conditions	49 (17.0)	9 (10.3)	8 (6.3)
None of the above	149 (51.7)	52 (59.1)	84 (65.6)
Change in healthcare use			
Reduced	155 (52.8)	37 (41.1)	63 (48.9)
No change	102 (34.6)	47 (52.3)	56 (43.5)
Increased	30 (10.2)	4 (4.4)	9 (7.0)
Missing	7 (2.4)	2 (2.2)	1 (0.8)
Change in health/functioning overall			
Meaningful Improvement	13 (4.4)	5 (5.5)	2 (1.6)
No Meaningful Change	153 (52.0)	58 (64.5)	90 (69.8)

Meaningful Worsening	121 (41.2)	24 (26.7)	36 (27.9)
Missing	7 (2.4)	3 (3.3)	1 (0.8)
Change in physical activities			
Meaningful Improvement	10 (3.4)	5 (5.5)	1 (0.8)
No Meaningful Change	144 (49.0)	45 (50.0)	78 (60.4)
Meaningful Worsening	133 (45.2)	38 (42.2)	49 (38.0)
Missing	7 (2.4)	2 (2.2)	1 (0.8)
Change in social activities			
Meaningful Improvement	4 (1.3)	1 (1.1)	1 (0.8)
No Meaningful Change	118 (40.2)	45 (50.0)	65 (50.4)
Meaningful Worsening	165 (56.2)	42 (46.6)	62 (48.1)
Missing	7 (2.4)	2 (2.2)	1 (0.8)
Change in work-related activities			
Meaningful Improvement	6 (2.0)	1 (1.1)	2 (1.6)
No Meaningful Change	162 (55.2)	60 (66.7)	84 (65.2)
Meaningful Worsening	119 (40.5)	26 (28.9)	42 (32.6)
Missing	7 (2.4)	3 (3.3)	1 (0.8)
Change in mood			
Meaningful Improvement	13 (4.4)	3 (3.3)	1 (0.8)
No Meaningful Change	155 (52.7)	56 (62.2)	78 (60.5)
Meaningful Worsening	119 (40.5)	29 (32.2)	49 (38.0)
Missing	7 (2.4)	2 (2.2)	1 (0.8)
Change in pain			
Meaningful Improvement	4 (1.4)	4 (4.4)	2 (1.6)
No Meaningful Change	128 (43.6)	49 (54.4)	55 (58.9)
Meaningful Worsening	155 (52.7)	34 (37.8)	50 (38.7)

Missing	7 (2.4)	3 (3.3)	1 (0.8)
Social support satisfaction			
Meaningful Improvement	55 (18.7)	10 (11.2)	17 (13.2)
No Meaningful Change	168 (57.1)	69 (76.6)	94 (72.9)
Meaningful Worsening	64 (21.7)	8 (8.9)	17 (13.2)
Missing	7 (2.4)	3 (3.3)	1 (0.8)

Note: NM, Pre-neuromodulation

¹ Percentages may not sum 100% because of rounding.

² Anchors:

- Meaningful improvement = 1- very much improved, 2- much improved
- No meaningful change = 3- minimally improved, 4- no change, 5- minimally worse
- Meaningful worsening = 6- much worse, 7- very much worse.

Figure 1. Participant flow diagram across treatment programmes

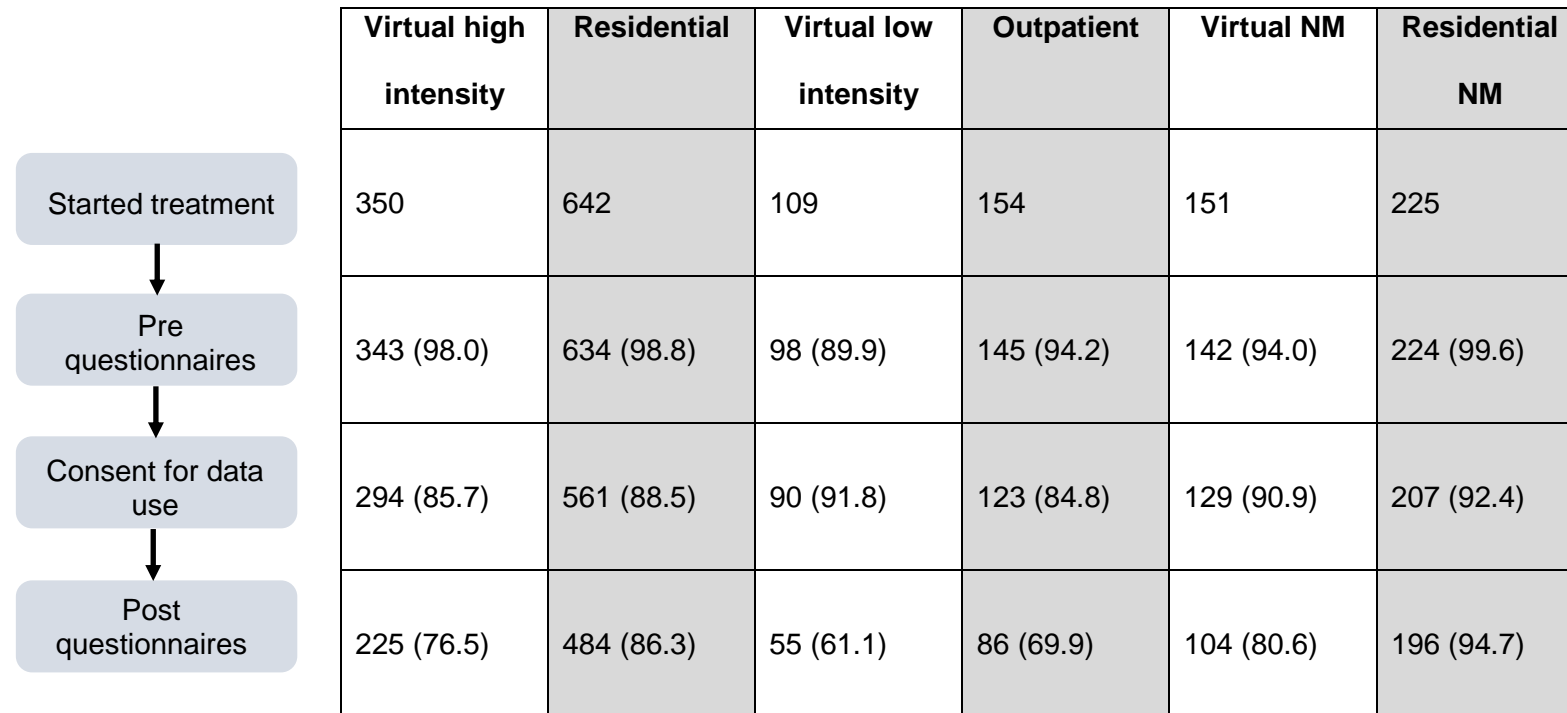


Figure legend. NM, pre-neuromodulation.