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# A Preliminary Study Looking at the Use of Mindful Compassion and Cannabis Suppositories for Anodyspareunia among Men Who Have Sex with Men (MSM)

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**Abstract:** Research on the use of cannabis rectal suppositories for analgesia is limited. Few trials have evaluated the combined use of mindfulness and cannabis suppositories for anodyspareunia in men who have sex with men (MSM). This preliminary study, including a randomised control trial (RCT) and content analysis, assessed the effectiveness of an online mindful-compassion and cannabis suppository intervention among 52 British MSM (aged 18–50) who predominantly identified as bottoms (recipients of anal sex). Participants were randomly allocated to one of four groups based on whether they were using cannabis suppositories: adjunct cannabis suppository and mindful-compassion (CSMF), cannabis suppository-only (CS), mindful-compassion-only (MF) and care-as-usual/control (CAU). Assessments measuring mindful compassion, sexual functioning, sexual self-efficacy, well-being, and anodyspareunia levels were completed at weeks 0, 4, and 12. Anodyspareunia levels were lower in the CSMF group compared to the other groups (CS/MF/CAU),  $p = 0.031$ . Feedback revealed that participants felt mindful compassion potentiated the effects of cannabis suppositories during sexual intimacy, reducing pain and enhancing sexual self-efficacy, sexual functioning, and well-being. This preliminary study warrants larger-scale investigation to establish the role of cannabis suppositories and mindful compassion in reducing anodyspareunia.

**Keywords:** anodyspareunia; MSM; cannabis suppositories; mindful-compassion sexual self-efficacy; psychosexual services

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## 1. Introduction

Anodyspareunia is pain experienced in the anus during anal penetration [1,2]. Mindfulness has been anecdotally reported to reduce anodyspareunia symptoms in men who have sex with men (MSM). For example, mindfulness was more effective than cognitive behavioral therapy (CBT) for pain reduction in a study comparing CBT with a mindfulness-based cognitive intervention for provoked vestibulodynia [3]. Mindfulness-based therapies are subsequently becoming more popular in National Health Service (NHS) services for bio-psychological problems [4]. A growing body of evidence now supports using compassion-focused therapy for general pain [5] and sexual pain, including generalised pelvic pain disorder (GPPD) [6].

Medical cannabis (MedC) is a novel approach to pain management. In 2018, MedC products were rescheduled for prescription use in the UK [7]. NHS prescriptions are available, but limited to severe forms of epilepsy, chemotherapy and multiple sclerosis [8]. The clinical literature on MedC is subject to numerous limitations and vast heterogeneity, yet evidence does suggest that certain doses and formulation MedC may be an effective therapies for chronic

pain [9,10]. In an open-label study looking at the long-term effects of MedC among 176 treatment-resistant participants experiencing long-term pain, the pain severity median score reduced from 7.50 [95% CI, 6.75–7.75] to 6.25 [95% CI, 5.75–6.75] with MedC [9].

There is a paucity of research focusing on the effects of MedC on dyspareunia. Yet, available research suggests that dyspareunia symptoms may decrease when patients consume cannabis before intercourse [11]. In a study of 38 women with vulvodynia with long-term cannabis use, cannabis treatment expectation, cannabis use, and levels of vulvodynia pain symptom severity had moderate to large effects on vulvodynia symptoms ( $d = 0.63$ – $1.19$ ) [12]. Similar to other studies on the effects of MedC, participants who reported more severe symptoms expected higher levels of relief from cannabis use [12–14]. However, cannabis-induced analgesia did not increase the frequency of cannabis misuse or psychiatric adverse events [12]. In addition to effects on pain, doses between 50 to 525mg per unit of CBD/THC have also been observed to reduce the anxiety associated with anticipated pain during anal sex [2].

Cannabis suppositories are oil-based extracts from the cannabis plant and are inserted into the anus, urethra, or vagina. These can contain cannabidiol (CBD), delta-9-tetrahydrocannabinol (THC), or a mixture of both in combination with other minor cannabinoids, terpenes, and flavonoids. Suppositories increase increasing drug absorption and delivery to local tissues while minimizing off-target side effects [15]. For cannabis suppositories used for dyspareunia, the potential benefit may include a reduction in **eu-phoria** compared to inhaled or oral use at sufficient doses. Hence, larger doses may be tolerated without the effects associated with systemic cannabis.

When comparing the use of oral cannabis with suppositories concerning pain, Brenneisen et al. [16] conducted an RCT administrating nine THC capsules (Marinol) and hemisuccinate rectal suppositories in 24-h intervals to two patients for spasticity. Both oral and rectal THC reduced pain; however, rectal administration reduced pain by up to 50% compared to 20% for oral THC.

The use of cannabis, particularly in supporting chronic non-cancer pain and neuropathic pain, appears promising [17]. However, most systematic reviews and meta-analyses comprising suggest the effect size is uncertain and likely small. Moreover, there is limited evidence on the efficacy of inhaled formulations [10,18].

Research on mindfulness-based interventions or MedC for sexual pain is limited, and sexual pain often goes unreported, potentially compromising psychological well-being [19]. This research aims to establish the effectiveness of an online mindful compassion intervention combined with cannabis suppositories to minimise sexual pain among MSM and increase well-being. The mindful compassion was delivered online to reach a more comprehensive and diverse group. This preliminary study examined how a mindful compassion intervention combined with cannabis suppositories might help minimise anodyspareunia whilst improving sexual function, well-being, and sexual self-efficacy (SSE).

Based on the literature review, the following hypotheses were assessed:

1. There will be a significant effect of time on sexual self-efficacy, mindful compassion, sexual functioning, well-being and sexual pain during the delivery of mindful-compassion among groups using cannabis suppositories and/or mindfulness.
2. There will be no significant effect of time for sexual efficacy, mindful compassion, sexual functioning and well-being in the control group (see methods).
3. Levels of anodyspareunia might vary between CBD, THC and combined. CBD/THC suppositories in CS and CSMF groups.

## 2. Methodology

### 2.1. Design

This was a four-arm RCT with care-as-usual/control (CAU), cannabis suppository-only (CS), mindful-compassion-only (MF) and adjunct cannabis suppository and mindful-compassion (CSMF) groups. Individuals were randomly allocated to a group based on

whether they were already taking cannabis suppositories. The research was conducted online, and the intervention lasted four weeks with a 12-week follow-up. All groups were compared for differences in mindful compassion, sexual functioning, well-being, sexual self-efficacy, and sexual pain.

The four groups were defined as:

1. Cannabis-only group (cannabis suppositories used for sexual pain). This could be the control group, but long-term cannabis use has been associated with continuing pain reduction. Though this variable could be controlled, it was decided to have a care-as-usual group as the control [20]. [CS].
2. Mindful compassion group. [MF].
3. Combined group—Cannabis (suppositories used for sexual pain) and mindful compassion group adjunct. [CSMF].
4. Care as usual (no mindful compassion or cannabis) [CAU].

## 2.2. Participants

The Inclusion criteria are as follows:

1. Identify as MSM
2. Use cannabis suppositories (for CS and CSMF groups). This study did not prescribe or distribute cannabis to participants
3. Engaged in anal sex (within the last month)
4. Based in the UK
5. Experience anodyspareunia
6. An absence of co-occurring difficulties
7. Aged 18 years or older
8. Read and write English
9. Patient Health Questionnaire-9 (PHQ-9) score between 0–9 (no/mild depression) [21].
10. Generalised Anxiety Disorder-7 (GAD-7) score between 0–9 (no/mild generalised anxiety) [22].

The Exclusion criteria are as follows:

1. Do not identify as MSM
2. Had not attempted anal intercourse in the last month
3. Had co-occurring difficulties
4. Aged below 18 years
5. Reading and writing English difficulties
6. Not experiencing anodyspareunia
7. PHQ-9 score  $\geq 10$  (moderate to severe depression)
8. GAD-7 score  $\geq 10$  (moderate to severe anxiety)

Fifty-nine participants were interested in the study and were assessed on eligibility based on the inclusion and exclusion criteria. Of these, 7 did not meet the eligibility criteria, where 52 consenting participants (n = 15 group CS; n = 9 group MC; n = 18 group CSMF and n = 10 group CAU) contributed to this study. Of these, 33 were using cannabis suppositories, and 19 did not use cannabis suppositories during this study. Attrition rates were low at week 12 (n = 12 CS, n = 7 MF, n = 15 CSMF and n = 6 CAU). The highest attrition rate was among the CAU group. Participant numbers at week 12 were n = 40.

Concerning demographics, 11.5% (n = 6) were aged between 18 and 30, 55.7% (n = 29) between 31 and 50, and 32.5% (n = 17) above 50. Of the sample, 21.2% (n = 11) were using THC suppositories (It was difficult to establish whether all THC suppositories were MedC), 26.7% (n = 14) CBD 15.4% (n = 8) combined THC/CBD and 36.5% (n = 19) not applicable.

In terms of cannabis suppository use, 34.6% (n = 18) reported less than once-a-week usage, 17.3% (n = 9) over a month, 7.7% (n = 4) 1–3 weekly, 3.8% (n = 2) approximately 4 weeks and 36.5% (n = 19) not applicable. Regarding the duration of suppositories, 44.2% (n = 23) reported less than 6 months, 7.7% (n = 4) between 6–12 months, 11.5% (n = 6) > 12

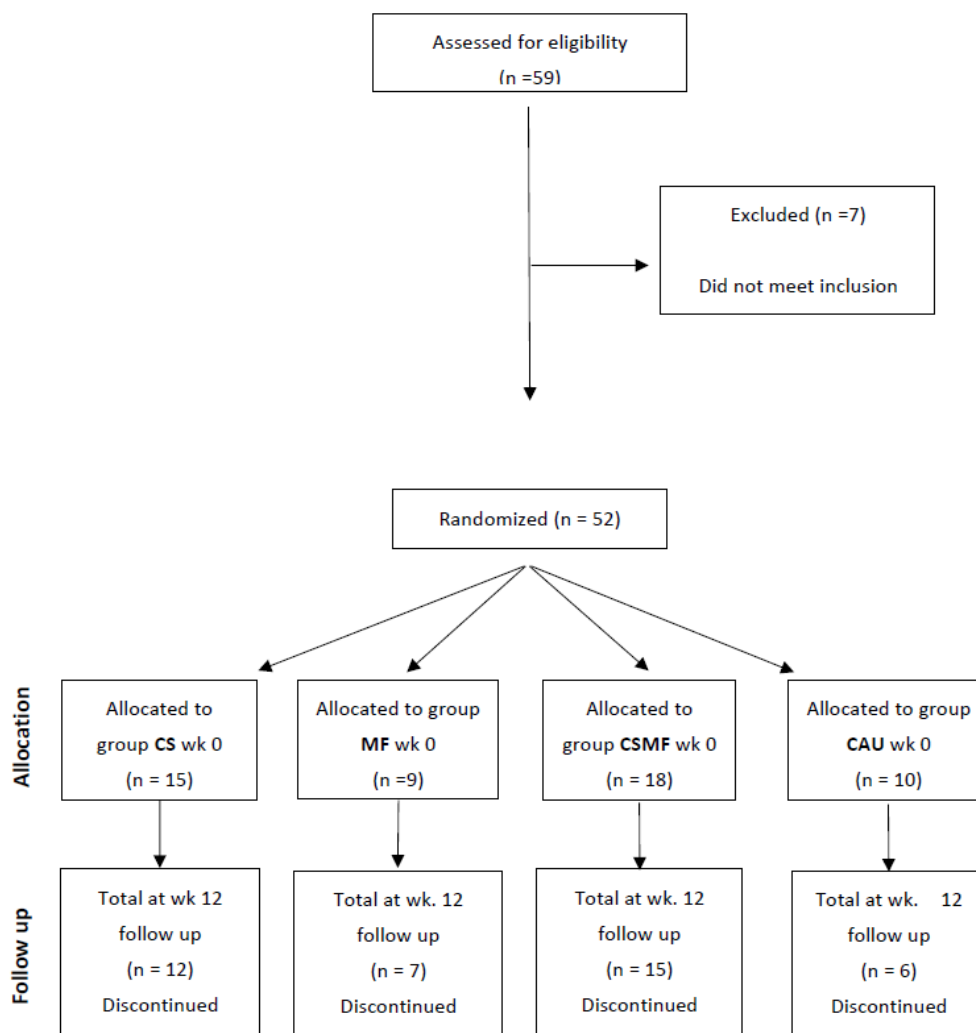
months, and 36.5% (n = 19) not applicable. Suppository dosages varied, with 36.5% (n = 19) not applicable), 26.9% (n = 14) reporting uncertainty about how much cannabis was being used, 13.5% (n = 7) 100 mg, 11.5% (n = 6) 500 mg, 7.7% (n = 4) between 10 to 50 mg and 3.8% (n = 2) 1000 mg. The duration of which the cannabis suppository was inserted prior to sexual intercourse approximated between 30–60 min (32.7%, n = 17), 25.0% (n = 13) reported over 60 min, 5.8% (n = 3) 30 min and 36.5% (n = 19) not applicable.

Regarding condom use, 71.2% (n = 37) reported not using condoms, 15.4% (n = 8) latex-free/polyurethane condoms, and 13.5% (n = 7) reported using “regular” condoms (waited for cannabis oil to dissipate prior to anal intercourse).

The preferred sexual positions included 55.8% (n = 29) reporting being a bottom (recipient of anal sex), 19.2% (n = 10) side (not always including penetration), 13.5% (n = 7) versatile (mixed recipient or insertive role during anal sex) and 11.5% (n = 6) a top (sexually insertive role).

Most of the sample took PrEP (pre-exposure prophylaxis) prior to sexual intercourse (65.4%, n = 34), 19.2% (n = 10) were using PEP (post-exposure prophylaxis for HIV), 9.6% (n = 5) PREP/PEP and 5.8% (n = 3) non-use.

Non-prescribed substances/medications included 28.8% (n = 15) smoking cannabis (additionally to suppositories), 25.0% (n = 13) no substances, 21.1% (n = 11) speed/methamphetamine, 9.6% (n = 5) cocaine, 7.7% (n = 4) gamma-hydroxybutyrate (GHB) and 7.7% (n = 4) combined GHB, methamphetamine and cocaine.



**Figure 1.** CONSORT diagram showing the flow of participants through each stage of a combined cannabis suppository and mindful compassion RCT.

### 2.3. Mindful Compassion Intervention

Briefly, a Behaviour Change Technique (BCT) is a reliable component of an intervention designed to regulate/change behaviour, such as reducing sexual pain via, for example, using graded tasks until the desired behaviour is achieved. This is hoped to increase one's beliefs about one's capabilities by increasing levels of self-efficacy [23]. The BCTs consist of 93 behaviour change techniques for selecting relevant taxonomies for this intervention (BCTTv1) [24]. In total, 12 domains have been included in the development of this Intervention. Of these, 23 of the 93 BCTs listed in the BCTv1 taxonomy were identified. Prior mindfulness interventions using these behaviour-change techniques were previously tested for MSM engaged in chemsex [25] and African Caribbean men with erectile dysfunction [26].

Mindful compassion exercises are hoped to support increased sexual desire, well-being and SSE [25]. The main exercises included mindfulness, breathing, relaxation techniques, Mindfulness of the senses and body, and understanding the self. These exercises incorporated the 3-model system of emotions, how to attend to the cognitive and physical patterns associated with painful sex, and towards acceptance and self-compassion with fewer symptoms.

### 2.4. Structuring of Intervention (Online Once a Week for 1–2 h)

- Wk 0—Baseline measurements taken for all groups
- Wk 1—Introduction—psychosexual education and anodyspareunia
- Wk 2—The 3-model system of emotions and anodyspareunia
- Wk 3—Practising mindful compassion and graded practice
- Wk 4—Self-care, efficacy, and your relationship with your anatomy

### 2.5. Self-Report Measures

#### 2.5.1. Preliminary Screening Tool PHQ-9 for Inclusion/Exclusion Criteria

The PHQ-9 was used to measure levels of depression, with internal reliability within the range of 0.86–0.89 [21]. The 9-item measure requests participants to rate the regularity of present difficulties during the past 2 weeks (e.g., “Trouble falling or staying asleep or sleeping too much”). Scores indicate the presence and the severity of the depression, with a maximum score of 27 and a minimum score of 0. Scores of 0, 5, 10, 15, and 20 indicate minimal, mild, moderate, moderately severe, and severe depression, respectively.

#### 2.5.2. Preliminary Screening Tool GAD-7 for Inclusion/Exclusion Criteria

The GAD-7 was used to measure anxiety levels, with an internal reliability 0.85 [22]. The 7-item measure requests participants to rate the regularity of difficulties during the past 2 weeks (e.g., “Not being able to stop or control worrying”). Scores indicate the presence of the severity of anxiety, with a maximum score of 21 and a minimum score of 0. Scores of 0, 5, 10, and 15 indicate minimal, mild, moderate, or severe anxiety.

### 2.6. Demographic Information

Demographic information included ethnicity, partnered status, sexuality, age, gender, sexual pain issues, number of sexual intercourse attempts in the last month, whether sexual pain is acquired or lifelong, other health concerns, the dose and type of MC, prescription medications (e.g., PrEP/PEP), condom use/type of condoms used, sexual preferences (bottom, top, versatile) substance use, alcohol consumption and smoking, along with levels of exercise.

### 2.7. Anodyspareunia

Based on Damon and Rosser's [26] pain on the frequency and severity of pain during anal sex, this is a 5-point Likert-type scale which ranges from "never" (5) to "all the time" (1) and "no anal pain" (5) to "severe anal pain" (1). The Cronbach alpha in this study = 0.70.

### 2.8. Brief Sexual Function Inventory (BSFI) [27]

This is an 11-item questionnaire which focuses on sexual functioning including sexual desire, arousal and satisfaction and erectile functioning. The response categories include 0 = not at all to 5 = always or 0 = no problem to 5 = big problem (this varied pending question). The Cronbach alpha in this study = 0.75.

### 2.9. Adapted Sexual Self-Efficacy Scale [28]

This is a 10-item questionnaire which focuses on sexual confidence and behaviour. The response categories include: 1 is the lowest level of self-efficacy and 10 is the highest. There are no reverse questions. Cronbach's alpha is  $\alpha = 0.88$  (high). This questionnaire has been adapted to reflect the participants in a study looking at sexual self-efficacy and sexual function. Less than 5% of the original questionnaire remains. The Cronbach alpha in this study = 0.83.

### 2.10. The Short Warwick–Edinburgh Mental Wellbeing Scale (SWEMWBS) [29]

This is a 7-item questionnaire with 5 response categories looking at functioning and feeling aspects of well-being. The response categories include 1 = none of the time to 5 = all of the time. Cronbach alpha = 0.89–0.91. There is no reverse scoring. Scores range from 7 to 35, with the latter having the highest level of well-being. Example questions include, "I've been feeling close to other people" and "I've been feeling relaxed". The Cronbach alpha in this study = 0.85.

### 2.11. State Self-Compassion Short Form [30]

This is a 12-item measure with 5 response categories, 1 = almost never to 5 = almost always, with higher scores indicating higher levels of self-compassion. The questionnaire measures self-kindness vs. self-judgement, common humanity vs. isolation, and mindfulness vs. over-identification with painful thoughts and emotions. Reliability Cronbach's alphas range between 0.68 and 0.78. The Cronbach alpha in this study was 0.73.

### 2.12. Qualitative Measures

A content analysis using Mentimeter of participants' experiences with this intervention was conducted at weeks 0, 4, and 12. A content analysis was conducted on this data. Mentimeter is a software app used to create anonymous participant input, providing real-time feedback to the authors. Participants were encouraged to voice their views about the intervention in weeks 0, 4 and 12 of this study. This included the MC and the CAU group, in which a series of adapted questions were provided. The principal researcher, a trained psychosexual therapist, supported the MC and the CAU group at weeks 0, 4 and 12 for approximately 1 h via Microsoft Teams. The importance of being allocated to the MC or CAU group was communicated at these meetings to reinforce the participants' critical role in this study.

### 2.13. Procedure

The intervention has been registered with [clinicaltrials.gov](https://clinicaltrials.gov) (NCT06435650) and was ethically approved on 16 June 2023 by a university ethics review panel. This study was conducted under the British Psychological Society (BPS) Code of Ethics and Conduct [31]. The study was advertised on social media, including LinkedIn and TikTok, using a snowballing sampling method, targeting those experiencing sexual pain. An advertisement

recruiting participants was placed on LinkedIn and TikTok. Social media sites are becoming increasingly popular in participant recruitment among diverse groups [32]. The researcher's prior use of social media suggested higher recruitment numbers were evident on sites like LinkedIn and TikTok. A study recording was made available on TikTok with contact details to the principal investigator, and it was snowballed across TikTok users. However, this may vary depending on connections and topics across different social media sites.

The study link included an information sheet and consent form. Once the consent form had been signed, the file was downloaded and encrypted using a basic split-encrypt procedure and stored in OneDrive. Mental health was screened (depression) using the PHQ-9 and anxiety using the GAD-7 to determine participants' eligibility.

Eligible participants ( $n = 52$ ) were randomly allocated to a group based on whether they were using cannabis suppositories. All participants completed baseline assessments before the commencement of the study at week 0. Further measurements were taken at weeks 4, and 12. The ordering of the online Microsoft Forms [Microsoft, Redmond, WA, USA] survey was as follows: The anal pain frequency and severity Likert scales [26]; Brief Sexual Function Inventory (BSFI) [27]; adapted Sexual Self-efficacy [28]; Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) [29]; and State Self-compassion Short Form [30] followed by the debrief including additional support services and a complaints contact.

Those randomly allocated to the MF or CSMF groups attended online mindful compassion groups (approximately 5 in each group) for 1–2 h for 4 weeks. These were under the guidance of a qualified mindfulness practitioner who provided psychosexual education and mindful-compassion exercises, including a graded response to sexual intimacy (please see the structuring of the intervention).

All data was stored in OneDrive [Microsoft, Redmond, WA, USA] based at the Principal Investigator's university, according to the Data Protection Act (2018) and General Data Protection Regulation [33].

#### 2.14. Statistical Analysis

A repeated measures ANOVA was conducted to assess changes in sexual functioning, quality of life, and well-being across these variables at 0, 4, and 12 weeks (follow-up) for all groups. A Bonferroni post hoc test was conducted on significant interaction outcomes. Owing to insufficient power in the sample coupled with an assumption testing violation (small and irregular sample), it was decided to utilise a non-parametric related K Friedman's analysis (ANOVA) to compare levels of sexual pain, mindful-compassion, well-being, sexual self-efficacy and sexual functioning between groups at week 12. A post hoc test (Friedman's 2-way ANOVA K samples) was conducted on any statistically significant outcomes. An independent Kruskal Wallis H test compared pain reduction levels with the use of THC, CBD, and combined THC/CBD suppositories in the CS and CSMF groups. Using Mentimeter, feedback was taken from participants at weeks 0, 4, and 12 of the intervention. A summative content analysis using nonparametric data analysis was conducted on week 12 responses. A  $p$ -value  $< 0.05$  was considered statistically significant. SPSS version 28.0 [IBM, Armonk, NY, USA] was used to conduct the statistical analysis.

### 3. Results

#### 3.1. The Impact of Time on Levels of Sexual Pain, Well-Being, Mindful Compassion, Sexual Self-Efficacy and Sexual Functioning

The effect size was partial eta squared combined with 95% confidence intervals (95% CI). All analysis was performed using Repeated measures ANOVA. Table 1 provides the means and standard deviations for all groups pre-and post-intervention for ano-dyspareunia, sexual functioning, mindful compassion, sexual self-efficacy and well-being.

**Table 1.** The means (M) and standard deviations (SD) of the group’s CS, MF, CSMF, and CAU before (week 0) and after (weeks 4 and 12) intervention for anodyspareunia. Significant differences have been highlighted between weeks 0 to 12.

Week	CS		MF		CSMF		CAU	
	M	SD	M	SD	M	SD	M	SD
<b>Pain</b>								
0	6.42	0.793	3.14	0.900	6.11	1.231	3.17	0.983
4	7.00	1.04	4.00	1.118	6.78	1.093	3.00	1.095
12	7.17	1.193	4.67	1.033	7.00	1.549 *	3.17	0.983
<b>Sexual function</b>								
0	11.53	2.031	7.22	0.972	11.11	2.111	9.3	1.497
4	11.6	2.028	8	1.732	13.44	2.791	9.28	0.976
12	17.08	2.021	15.57	2.299 **	17.33	2.024 **	9.83	1.169
<b>Mindful compassion</b>								
0	22.8	5.545	25.67	5.385	23.39	6.05	26.3	5.458
4	23.47	5.527	35.56	3.575	23.56	5.261	26.3	5.458
12	22.17	5.606	37.57	3.552 **	28.2	4.459 *	25.67	3.67
<b>Sexual self efficacy</b>								
0	16.53	3.502	14.33	2.55	16.28	3.25	14.5	2.461
4	16.93	3.474	45.33	5.701	16.94	3.28	15.3	2.312
12	17.08	3.801 *	59.14	5.928 **	17.60	3.542 *	14.83	2.317
<b>Well being</b>								
0	18.4	3.924	12.	3.775	17.50	4.134	12.1	3.573
4	18.93	3.674	27.56	2.007	18.84	3.506	12.4	3.438
12	27.42	1.505 **	27.86	1.773 **	27.4	4.459 **	10.5	2.168

\* Significant at  $p < 0.05$ ; \*\* Significant at  $p < 0.001$ .

Concerning the CS group, there was no effect of time on anodyspareunia at weeks 0, to 12,  $F(2, 10) = 4.130, p = 0.049, \eta^2 = 0.452, 95\% \text{ CI: } 6.266\text{--}7.456$ . There was a significant effect of time on well-being,  $F(2, 10) = 16.881, p < 0.001, \eta^2 = 0.771$  with confidence intervals between 20.263–23.237. There was no time effect on mindful compassion,  $F(2, 10) = 3.044, p = 0.093, \eta^2 = 0.378$  with narrow confidence intervals between 18.603–18.751. Sexual self-efficacy increased across weeks 0, 4 and 12,  $F(2, 10) = 10.000, p = 0.004, \eta^2 = 0.667$  with narrow confidence intervals between 14.047–14.668. Overall sexual functioning (the assessment tool excluded pain) was non-significant,  $F(2, 10) = 1.027, p = 0.393, \eta^2 = 0.181, 95\% \text{ CI: } 34.845\text{--}35.883$ . There was an interaction effect with sexual pain, well-being, mindful compassion, sexual self-efficacy and sexual functioning,  $F(1, 11) = 83.872, p < 0.001, \eta^2 = 0.898, 95\% \text{ CI: } 7.286\text{--}8.052$ . Post hoc pairwise comparisons yielded significant outcomes for anodyspareunia and well-being, mindful compassion, sexual self-efficacy and sexual functioning,  $p < 0.001$ .

Regarding the MF group, there was no significant effect of time on anodyspareunia at weeks 0 to 12,  $F(2, 5) = 4.640, p = 0.073, \eta^2 = 0.655, 95\% \text{ CI: } 3.104\text{--}4.518$ . There was a significant outcome on time on wellbeing,  $F(2, 5) = 69.747, p < 0.001, \eta^2 = 0.965, 95\% \text{ CI: } 20.555\text{--}24.683$ . Levels of mindful compassion increased from weeks 0, 4 to 12,  $F(2, 5) = 98.620, p < 0.001, \eta^2 = 0.975, 95\% \text{ CI: } 30.106\text{--}36.370$ . Sexual self-efficacy was also significant,  $F(2, 5) = 95.588, p < 0.001, \eta^2 = 0.975, 95\% \text{ CI: } 36.918\text{--}42.701$ . Overall sexual functioning improved (this assessment tool excludes sexual pain),  $F(2, 5) = 151.901, p < 0.001, \eta^2 = 0.984, 95\% \text{ CI: } 17.989\text{--}20.964$ . There was an interaction effect between variables,  $F(3, 4) = 546.268, p < 0.001, \eta^2 = 0.995, 95\% \text{ CI: } 27.514\text{--}30.366$ . Post hoc pairwise comparisons yielded significant outcomes for anodyspareunia and well-being, mindful compassion, sexual self-efficacy and sexual functioning,  $p < 0.001$ .



Within the CSMF group, there was a significant effect of time on anodyspareunia between weeks 0 to 12,  $F(2, 13) = 4.580, p = 0.031, \eta^2 p = 0.413, 95\% \text{ CI: } 6.412\text{--}7.366$ . Levels of wellbeing increased,  $F(2, 13) = 27.827, p < 0.001, \eta^2 p = 0.811, 95\% \text{ CI: } 20.147\text{--}22.190$ . Mindful compassion was significant,  $F(2, 13) = 5.747, p = 0.016, \eta^2 p = 0.469, 95\% \text{ CI: } 22.412\text{--}27.233$ . Levels of sexual self-efficacy increased from weeks 0 to 12,  $F(2, 13) = 8.500, p = 0.004, \eta^2 p = 0.567, 95\% \text{ CI: } 15.122\text{--}18.922$ . Overall sexual functioning improved,  $F(2, 13) = 483.573, p < 0.001, \eta^2 p = 0.987, 95\% \text{ CI: } 21.177\text{--}22.820$ . There was an interaction effect between variables,  $F(4, 11) = 836.123, p < 0.001, \eta^2 p = 0.997, 95\% \text{ CI: } 18.820\text{--}20.300$ . Post hoc pairwise comparisons yielded significant outcomes for anodyspareunia and well-being, mindful compassion, sexual self-efficacy and sexual functioning,  $p < 0.001$ .

Regarding the CAU group, there was no significant difference in time on anodyspareunia between 0 to 12 weeks,  $F(1, 5) = 1.000, p = 0.363, \eta^2 p = 0.167, 95\% \text{ CI: } 2.058\text{--}4.164$ . For well-being,  $F(2, 4) = 2.000, p = 0.250, \eta^2 p = 0.500, 95\% \text{ CI: } 7.507\text{--}15.048$ . Levels of mindful compassion remained non-significant,  $F(1, 5) = 2.500, p = 0.175, \eta^2 p = 0.333, 95\% \text{ CI: } 21.554\text{--}29.325$ . Sexual self-efficacy was non-significant,  $F(2, 4) = 3.400, p = 0.137, \eta^2 p = 0.630, 95\% \text{ CI: } 11.782\text{--}17.551$ . Sexual dysfunction was non-significant,  $F(2, 4) = 1.000, p = 0.444, \eta^2 p = 0.333, 95\% \text{ CI: } 27.962\text{--}30.149$ . Pairwise comparisons were non-significant between weeks 0 to 12,  $p > 0.05$ . There was an interaction effect between variables,  $F(2, 4) = 40.912, p = 0.024, \eta^2 p = 0.988$ . Post hoc pairwise comparisons yielded significant outcomes for anodyspareunia and mindful compassion, sexual self-efficacy and sexual functioning,  $p < 0.001$  and well-being,  $p = 0.004$ . Pairwise comparisons for anodyspareunia between groups were significant for CS, MF, CSMF with CAU,  $p = 0.014$ .

### 3.2. Comparisons across Groups

With regard to anodyspareunia, the mean rank for CS and CSMF = 3.50, MF = 1.72 and CAU = 1.28,  $X^2(3) = 26.211, p < 0.001$ . Looking closer at CSMF and CAU, there was a significant difference in sexual pain,  $X^2(1) = 4.00, p = 0.042$ . A post hoc test was significant for the hypothesis test summary,  $p > 0.001$ . Pairwise outcomes were significant for CAU and CSMF,  $p = 0.003$ .

Concerning well-being, the mean rank for CS, MF, CSMF = 3.00 and CAU = 1.00,  $X^2(3) = 18.000, p < 0.001$ . The post hoc hypothesis test summary was significant,  $p > 0.001$ . Pair-wise outcomes were significant for CSMF, CS and MF with CAU,  $p = 0.007$ . Concerning mindful compassion, the mean rank for MF = 3.92, CSMF = 2.75, CS = 2.25 and CAU = 1.08,  $X^2(3) = 15.684, p < 0.001$ . The post hoc hypothesis test summary was significant,  $p < 0.001$ . Pairwise comparisons were significant for CS and CSMF,  $p = 0.013$ ; MF and CS,  $p < 0.001$  and CAU and MF,  $p = 0.013$ .

Concerning sexual self-efficacy, the mean rank of MF = 4.00, CS and CSMF = 2.21 and CAU = 1.57,  $X^2(3) = 15.286, p = 0.002$ . Concerning sexual function, the mean rank of CS and CSMF = 3.50, MF = 2.00 and CAU = 1.00,  $X^2(3) = 18.000, p < 0.001$ . The post hoc hypothesis test summary was significant,  $p = 0.005$ . Pairwise outcomes were significant for CAU and MF,  $p = 0.003$ ; MF and SC,  $p = 0.014$  and MF and CSMF,  $p = 0.014$ . Concerning sexual function, the mean rank of MF = 2.08, CS = 2.92, CSMF = 1.0 and CAU = 4.0,  $X^2(3) = 17.776, p < 0.001$ . A post hoc test was significant for the hypothesis test summary,  $p < 0.001$ . Pairwise outcomes were significant for CAU and MF,  $p = 0.010$ ; MF and CSMF,  $p < 0.001$  and MF and CS,  $p = 0.005$ .

### 3.3. Levels of Anodyspareunia with the Use of THC, CBD and Combined THC/CBD Suppositories

Concerning the MC group, the differences between the rank totals of 4.68 (THC), 4.17 (GHB) and 1.50 (THC/GHB) were non-significant,  $H(2, n = 7) = 1.804, p = 0.406$ . Concerning the CSMF group, the difference between the rank totals of 5.50 (THC), 5.50 (GHB) and 1.50 (GHB/THC) were non-significant,  $H(2, n = 9) = 2.044, p = 0.360$ .

### 3.4. Content Analysis

Feedback from the participants throughout this study played a critical role in being co-collaborators of the research (experts by experience) and mitigating any distress that might have been experienced. A code was provided, and each participant was encouraged to give one response per question. This encouraged all participants to contribute. Whilst responses were obtained at weeks 0, 4, and 12, only week 12 follow-up feedback was provided as we felt that follow-up would indicate whether participants continued mindful-compassion practices and had given participants time to consider the impact of the intervention in terms of its sustainability.

**Table 2.** Content analysis of feedback at week 12 completion.

<b>Week 12:</b>				
Category/Themes of words used by:				
	<b>CS group, %</b>		<b>CSMF group, %</b>	
Question 1:	How is your sexual pain at follow-up?			
	Unsure	28.6	The same	40.0
	More manageable	28.6	Alright	33.3
	A bit better	28.6	A bit better	26.7
	No better	14.3		
Question 2:	Any thoughts about whether you will continue to practise mindfulness to help your sexual pain?			
	Sometimes if stressed	57.1	Using mindfulness increases cannabis	53.3
	Yes, for sexual experiences	14.3	Yes	33.3
	Probably not	14.3	Unlikely	13.3
	Unsure/don't know	14.3		
Question 3:	If you could receive this intervention again, would you prefer it delivered online or in person?			
	In person	42.9	Only if THC suppositories are available	40.0
	Online or in person	28.6	Either	33.3
	Online	14.3	Unsure	26.7
	Neither	14.3		
Question 4:	What were your overall experiences of receiving this intervention?			
	Fun	28.6	Relaxed	33.3
	Positive	28.6	Pleasant	26.7
	Enjoyed	28.6	Interesting	26.7
	Not bad	14.3	Helped with partner	13.3
Question 5:	It was noticed that condoms do not tend to be used with cannabis suppositories. Is there any reason for this?			
	PrEP	42.9	Lack of information	66.7
	Lack of information	42.9	PrEP	33.3
	Don't like using condoms	14.3		
Question 6:	Is there anything else you would like to add about your experiences with this intervention?			
	Mindfulness is great for relaxation	42.9	Cannabis is a natural form of mindfulness	40.0
	Mindfulness is less effective for pain	28.6	Mindfulness is less effective for pain	33.3
	Want to try cannabis suppositories	28.6	Cannabis should be legalised	26.7
<b>Week 12:</b>				
Category/Themes of words used by:				
	<b>CS group, %</b>		<b>CAU group, %</b>	
Question 1:	How is your sexual pain at follow-up?			

	The same	66.6	The same	66.6
	Bit better	33.3	Sometimes worse	33.3
Question 2:	Any thoughts about whether you will continue to practise mindfulness to help your sexual pain?			
	Nice to chat	41.7	Nice to chat	33.3
	Okay	41.7	Alright	33.3
	No point	16.6	Would prefer mindfulness	33.3
Question 3:	Should this study become available again, would you be interested in receiving mindful compassion and/or cannabis suppositories for sexual pain?			
	Cannabis reduces pain	75.0	If cannabis suppositories don't cause sleepiness or have side effects	33.3
	Maybe	16.7	Mindfulness online	33.3
	No mindfulness	8.3	Mindfulness in person	16.7
			Mindfulness and suppositories	16.7
Question 4:	It was noticed that condoms do not tend to be used with cannabis suppositories. Is there any reason for this?			
	PrEP	50.0	No information on oil friendly condoms	66.7
	Condoms will not work	16.7	PrEP	33.3
	Lack of information	8.3		
Question 5:	Is there anything else you would like to add about being the control group in this study?			
	Cannabis should be available in NHS	75	There should be options available to reduce sexual pain	50.0
	Nothing to add	25	Talking about this is important	33.3
			It was nice to chat about this	16.7

#### 4. Discussion

This research aimed to determine whether an online mindful-compassion compassion intervention adjunct with cannabis suppositories helped minimise anodyspareunia and increase well-being, sexual self-efficacy and sexual functioning. Regarding anodyspareunia, it was hypothesised that there would be a significant effect of time on anodyspareunia, well-being, mindful-compassion, sexual self-efficacy and sexual functioning among groups MF, CS and CSMF. Further, time would not have a significant effect on anodyspareunia, sexual self-efficacy, well-being and mindful-compassion in the CAU group. A series of post hoc tests examined the interaction effects among these variables to identify the significant outcomes. The hypotheses were partially supported. There was a significant effect of time on anodyspareunia among the CSMF group and no significant effect of time on anodyspareunia in the MF, CS and CAU groups. Compared to CS, MF and CAU groups, there was a significant effect of time on sexual self-efficacy, well-being, mindful-compassion and sexual functioning throughout the delivery of the intervention in group CSMF. It was further hypothesised that differences in pain reduction would be identified between CBD, THC and combined CBD/THC suppositories. However, the CS and CSMF groups were non-significant.

In the CS group, it was unsurprising that levels of anodyspareunia did not significantly reduce pre- and post-intervention outcomes. The use of suppositories over 12 weeks would not be long enough for further pain reduction to be observed, and tolerance is unlikely [34]. The effects of cannabis suppositories take place approximately 20 to 60 min following insertion [35], and participants in the cannabis groups had been using cannabis suppositories for at least one month before this research. Arguably, the pain reduction threshold had already been reached as cannabis suppository use was per sexual

activity rather than continuously being used. Nonetheless, the cannabis groups reported lower levels of anodyspareunia compared to the CAU group.

Indeed, MedC is often requested for chronic pain. In part, this is due to being a natural alternative to opiates, which have additional and unwanted side effects [36,37]. Numerous systematic reviews, including randomised placebo-controlled trials, have suggested that MedC does reduce pain [36]. According to Hill et al. (2017), the endocannabinoid system can regulate the transmission of nociceptive signals and the emotional regulation of pain. However, research is limited in how MedC is used, and the types of pain targeted. A Cochrane review suggested a lack of high quality evidence that MedC can reduce chronic neuropathic pain [37].

The current study aimed to establish whether levels of sexual pain varied between those using CBD, THC or combined CBD/THC suppositories. Outcomes in this study were inconclusive, with non-significant levels of sexual pain being reported between THC and CBD groups. The pharmacodynamic properties of THC and CBD are variable, despite sharing similar chemical characteristics [38]. THC is a partial agonist of cannabinoid type receptors, whilst CBD does not directly bind to CB1. Instead, it acts to inhibit breakdown of the endogenous CB1 agonist anandamide, whilst also acting as a negative allosteric modulator.

Outcomes were disappointing among the MF group in this study, where pain reduction was expected to be significant across the intervention delivery. Indeed, prior research looking at mindfulness for sexual pain has shown more promising results with higher effect sizes in pain reduction [3]. Nonetheless, a pairwise analysis yielded a significant outcome between weeks 0 and 12, and the reduction in pain was significant for the CSMF group. Similarly to the outcomes in this study with mindfulness and sexual pain reduction studies, moderate effect sizes have been reported in the literature. For example, Pernilla et al. [39], in a sample of 318 women experiencing sexual pain (42.1%), and women without sexual pain (57.9%) were compared post-mindfulness intervention. Initial effect size comparisons between groups suggested that higher levels of sexual pain and distress were experienced by the women in the pain group ( $g = 0.68$  and  $g = 0.90$ , respectively). Results show that higher levels of mindfulness during sexual activity were associated with higher levels of sexual functioning (reduction in pain and sexual distress) among women without sexual pain ( $r = 0.60$ ) and with pain ( $r = 0.62$ ). Similar outcomes have been reported by Brotto in which mindfulness looks promising in reducing sexual discomfort [3,40].

Interestingly, the content analysis revealed that mindfulness was part of using cannabis. In other words, it helped participants reach a mindful state. Indeed, participants suggested that mindful compassion potentiated the effects of the cannabis suppository. Research looking at the bidirectional nature of this association would help understand the therapeutic role these combined variables have. In one such study, 47 participants used oral cannabis and engaged in 45 min of yoga post-consumption, with significant improvements in the mysticality of experience [41]. This holds important clinical implications for supporting well-being among cannabis users. Indeed, in this study, well-being, sexual self-efficacy and sexual functioning were significant among the cannabis and mindful compassion groups. This is consistent with the literature where mindfulness and mindful compassion have been shown to increase levels of sexual self-efficacy, well-being and sexual functioning [25,26,45].

The limitations of this study centred on the legalities of THC in the UK and other territories. It has been noted that legislation has inhibited research on the potential medicinal use of cannabis [42]. Therefore, randomisation was limited to those already using this product to bypass the legal and ethical constraints of THC research. Participant dose variations and use further limited this research on establishing the analgesic properties associated with the dosages used, whether using THC or CBD suppositories varied concerning pain reduction. Whilst the logical way forward would be to control for dose variations, owing to the small sample size in this study, a non-parametric evaluation was made between groups. This extended into whether participants were prescribed MedC where

there was a lack of clarity on where the THC suppositories were obtained. Perhaps owing to the limited and restricted access to MedC on the NHS [8] coupled with the legalities of THC might have deterred MSM who use cannabis suppositories from participating in this study. Indeed, recruitment was challenging. Social media has proven useful in recruiting, but it could be argued that this has restricted recruitment since alternate recruiting strategies were not employed. Therefore, this may have resulted in volunteer bias [43] Strassberg and Lowe [44] found that volunteers in sex research were more positive towards sexuality and experiences than non-volunteers, therefore the current study may have a group of participants that are more likely to be respond to the intervention. Outcomes in this study cannot be generalisable to the broader population experiencing anodyspareunia and using cannabis suppositories for this purpose. Therefore, outcomes are to be interpreted with caution. Randomisation to groups prescribed varied doses of THC, CBD and combined dose variations suppositories might provide a better understanding of the role cannabis suppositories have for sexual pain and the choice of suppositories made. This holds important implications for psychosexual services in how this might be utilised as a pain reduction treatment adjunct option for varied sexual pain presentations. Despite the limitations, the outcomes in this study look promising as levels of anodyspareunia appeared higher in the control group compared to the experimental groups, and the localised use of cannabis minimised the level of intoxication experienced.

Future research needs to address public health aspects associated with the use of cannabis suppositories. Concerningly, most participants in this study did not use condoms. The ingredients of suppositories are oil-based, as cannabis is not water-soluble. This would necessitate the use of condoms, which are oil-compatible (latex-free/polyurethane). The existing team had contacted the leading cannabis manufacturers and practitioners concerning condoms, which are oil-compatible. Limited information, knowledge and understanding of oil-resistant condoms was evident. This was further voiced by participants who felt that there was a lack of information available on latex-free condoms. There are several manufacturers of latex-free condoms, and this would need to be part of psychosexual education supporting sexual health. Additionally, participants suggested PrEP as a reason for non-condom use. PrEP can reduce HIV transmission and is highly effective in preventing HIV. However, it does not prevent STIs. Routine check-ups and information on latex-free condoms are needed among this cohort. If this is a minority MSM group engaging in this, the stigma associated with PrEP use and STIs must be managed with awareness. If medical cannabis suppositories become part of a healthcare system, irrespective of sexuality or gender, routine checks and knowledge about different types of oil-resistant condoms are critical, which appears to be lacking in psychosexual services in the UK. The demographics revealed the use of chemsex drugs (methamphetamine/GHB). Research would need to explore whether cannabis suppositories are part of the chemsex scene, particularly since a significant proportion of the sample did not know the dose of cannabis they had been using, which is unregulated and raises possible health concerns.

In conclusion, THC and CBD cannabis suppositories appeared to reduce sexual pain among MSM. Compared to the CAU group, those engaged in mindful compassion and using cannabis suppositories reported higher levels of sexual self-efficacy, mindful compassion, sexual functioning and well-being. As a preliminary study, outcomes look promising but require a larger sample to establish the role cannabis and mindful compassion might have in supporting psychosexual presentations. It is essential to provide options in healthcare for reducing sexual pain. Not everyone would want to take or use cannabis suppositories where mindful compassion/mindfulness interventions also look promising. Many participants in this study were not using condoms, attributing this to a lack of knowledge of oil-resistant condoms and the use of PrEP. Regardless of sexuality or gender, it is imperative that a better understanding of oil-resistant condoms is conveyed to those engaged in cannabis suppository use and among sexual health and psychosexual services. We hope this research provides a foundation for further research to be conducted.

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