A randomized-controlled pilot trial of an online compassionate mind training intervention to help people with chronic pain avoid analgesic misuse

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Abstract

Problematic use of prescribed and over-the-counter analgesics is widespread and increasing among people with chronic pain, but the availability of preventative and treatment services is limited. We evaluated a 21-day online intervention based on compassionate mind training in a prospective, randomized-controlled trial. The participants were 73 adults with concerns about their use of analgesics for chronic pain conditions. Participants completed measures of analgesic use, misuse and dependence, plus self-criticism and self-reassurance (self-inadequacy, self-reassurance and self-hate), cognitive impulsivity (negative urgency, lack of perseverance, lack of premeditation, sensation-seeking and positive urgency) and behavioral impulsivity (delay discounting) at baseline, post-intervention and 1-week post-intervention follow-up. Following baseline assessment, participants were randomized to compassionate mind training (CMT; n=38) or relaxation music (RM; n=35), both delivered online. No adverse events or safety issues were reported and high participant retention and exercise completion rates showed that the intervention was acceptable to participants. Repeated measures analysis of variance showed that by comparison with RM, the CMT group had reduced prescription analgesic use (F=6.123, p=0.015), analgesic dependence (F=14.322, p<.001), self-hate (F=12.218, p<0.001), negative urgency (F=7.323, p=0.006) and lack of perseverance (F=7.453, p=0.001) from baseline to post-intervention, and those improvements were maintained at follow-up. The results show that exercises based on CMT principles and techniques and delivered online can reduce analgesic use, risk of analgesic dependence, and some aspects of self-criticism and impulsivity.

Keywords: Analgesic misuse; dependence; chronic pain; compassionate mind training; RCT

Introduction

Chronic pain affects up to 1.5 billion people worldwide, including up to 100 million in the USA and 7.8 million in the UK (Institute of Medicine of the National Academies, 2011). Rates of misuse and dependence are high and increasing in Europe and North America, including prescribed opioids but also non-prescribed and non-opioid analgesics (Berterame et al., 2016; Casati et al., 2012; Fingleton et al., 2016).

Chronic pain causes significant negative emotions and negative self-evaluations (Lumley et al., 2011) which can increase impulsivity (Schreiber et al., 2012), and both negative emotions and impulsivity are associated with analgesic misuse (Martel et al., 2014; Vest et al., 2016). Recent interventions for chronic pain and problem analgesic use include cognitive behavioral therapy (CBT), acceptance and commitment therapy, mindfulness-based cognitive therapy, and mindfulness-based stress reduction (Hruschak et al., 2018).

Compassionate mind training (CMT) involves cultivating self-compassion, with exercises to make psychological and physiological changes by focusing on postural and breathing patterns, compassion-focused motives and imagery, behavioral practices, emotion regulation strategies, and prosocial behavior to self and others (Gilbert & Procter, 2006; Matos et al., 2017). Compassion-based interventions can be especially effective for people who are high in self-criticism or have low motivation to change (Kelly et al., 2010; Leaviss & Uttley, 2015; Matos et al., 2017), whereas high self-criticism predicted poorer responses to CBT or psychotherapy for depression (Rector et al., 2000; Marshall et al., 2008).

Self-compassion and analgesic use both involve relief of suffering, and self-compassion was associated with a reduced impact of chronic pain (Carvalho et al., 2018). Brief compassion-focussed therapy was shown to be feasible for opioid use disorder (Carlyle et al., 2019), but CMT has not yet been applied specifically to problematic painkiller use in chronic pain.

Online mental health interventions are effective and cost-effective (Hedman et al., 2014) and enable people to access help anonymously, which can be important for substance-related problems (Luoma et al., 2007). Recent evaluations include online CBT for chronic pain and problematic drug use (Guarino et al., 2018), and online CMT (Kelman et al., 2018), but to our knowledge there have been no trials of online CMT for people using analgesics for pain.

The present study therefore aimed to conduct a pilot trial of an online CMT intervention for people with concerns about analgesic dependence. The objectives were to assess the acceptability of the intervention and obtain initial evidence about its effectiveness. Compared with a control condition, we predicted the CMT intervention would 1) reduce analgesic use and dependence, 2) reduce self-criticism and increase self-reassurance, and 3) reduce impulsivity.

Methods

This was a prospective, randomized-controlled trial of online compassionate mind training (CMT) versus relaxation music (RM), with primary outcomes (analgesic use) and secondary outcomes (self-criticism, self-reassurance and impulsivity) measured online at baseline, post-intervention (three weeks post-entry), and 1-week post-intervention (four weeks post-entry).

Participants

The inclusion criteria were age > 18 years, pain ≥ 15 days per month in the last three months, and using analgesics in the last month. The exclusion criteria were taking illegal drugs in the last month, diagnosed attentional/hyperactive disorder or terminal illness, taking non-analgesic psychoactive medication, receiving psychotherapy or cognitive behavioral therapy, or having a family member participating in the trial.

Measures

Participant retention and rates of CMT exercise completion were recorded to measure acceptability. There were no changes to outcome measures after the trial commenced.

Primary outcomes. After being shown definitions and examples of over-the-counter (OTC) and prescription painkillers, participants were asked how many of each type they used daily during the last month, and how often they used analgesics for longer and at higher doses than recommended. Participants also completed the Leeds Dependence Questionnaire, a 10-item measure of substance dependence (Raistrick et al., 1994), with the words 'drink or drugs' in each item replaced by 'painkillers.'

Secondary outcomes. Participants completed the 22-item Forms of Self-Criticising and Self-Reassuring scale with three subscales: Inadequate Self (nine items), Hated Self (five items), and Reassured Self (seven items) (Gilbert et al., 2004). Participants also completed the UPPS-P (Urgency, Perseverance, Premeditation, Sensation seeking and Positive urgency), a 59-item scale measuring five traits related to impulsivity: Negative Urgency (12 items), Lack of Perseverance (10 items), Lack of Premeditation (11 items), Sensation-seeking (12 items) and Positive Urgency (14 items) (Whiteside & Lynam, 2009).

Participants also completed a behavioral impulsivity measure developed for the study and based closely on the delay discounting paradigm (Lane et al., 2003). This involved behavioral choices between two cards associated with immediate and delayed hypothetical rewards (Cherek et al., 1997). Choosing card A led to a hypothetical £5 reward followed by a fixed, five-second inter-trial interval. Choosing card B led to a £15 hypothetical reward followed by a variable inter-trial interval that began at 15 seconds, increased by two seconds each time card B was chosen, and decreased by two seconds each time card A was chosen, but never reduced below seven seconds. Participants were not told the number of trials or the rewards and time delays associated with each card. There were 20 practice and 30 experimental trials. The score recorded was the total hypothetical reward after 30 trials, ranging from £150 (30 x £5) to £450 (30 x £15). Higher scores indicated more rational, less impulsive choices.

Participants also self-rated their pain frequency using an 11-point scale ranging from 'not frequent at all' (0) to 'very frequent' (10), and their pain intensity using an 11-point scale ranging from 'no pain' (0) to 'extreme pain' (10) (Cleeland & Ryan, 1994).

Procedure

The study protocol was approved by the University Psychology Research Ethics Committee. Recruitment was via a brief invitation on internet forums and social media platforms related to pain. The invitation directed potential participants to the study website, where there was further information about the study. Participants confirmed they met the eligibility criteria, then gave consent. The instructions for each condition requested participants

to contact the researchers if they found tasks uncomfortable, and emails from participants were checked daily to monitor safety concerns, adverse events or questions about the exercises.

After completing baseline measures, eligible, consenting participants were randomized in a 1:1 ratio to compassionate mind training (CMT) or relaxation music (RM) using an adapted online algorithm (Kim & Shin, 2014). Participants were not informed about the other condition and all the measures were administered online without researcher involvement.

Both groups first watched a short introductory video and received a dynamic timetable showing the daily activities. Both CMT and RM programs lasted 20 days. The study took place between July 2016 and November 2016, and the trial ended at the end of the follow-up period. The trial was not registered. The trial protocol is available from the authors. No changes were made to the methods, materials or eligibility criteria after the trial commenced.

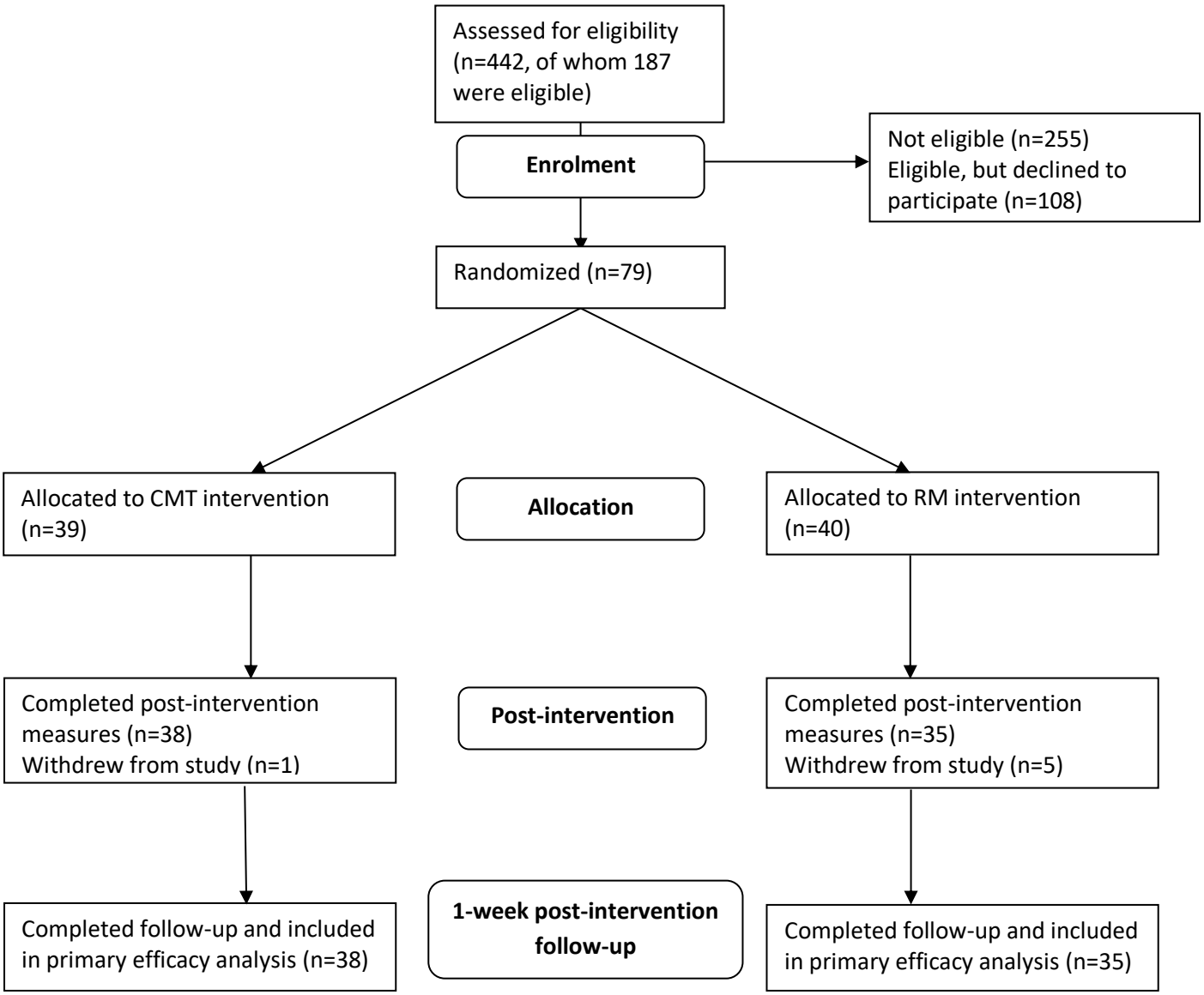
The intervention

The CMT intervention comprised psycho-educational videos with audio and computerized tasks designed to replace self-critical thoughts with self-reassuring thoughts. It maintained conformity with the key principles of manualized, in-person CMT while contextualising the materials and exercises, for example by focusing on self-critical thoughts during pain or about using analgesics. All the videos ended with practical exercises and the final video was a practical CMT exercise that brought together all the skills involved. Prior to finalization, a pilot study was conducted with five participants to assess feasibility and obtain participant feedback, in response to which changes were made to the website aesthetics and font sizes, and the dynamic timetable was added. The relaxation music comprised selected tracks from a relaxation music library. Full descriptions of the CMT and RM conditions are given in Appendix 1.

Analytic strategy

An a priori power calculation using G*Power (Faul et al., 2007) suggested n=106 would give 95% power to detect a moderately small effect (f = 0.2). The data were analysed in three repeated measures MANOVAs, each with between-participants ('group'; CMT vs. RM) and within-participants ('time'; baseline vs. post-intervention vs. follow-up) factors. The group x time interactions, which test differential change between groups, tested the predictions in each analysis. Univariate effects were examined only where multivariate effects were significant. Significant univariate interactions were evaluated with simple planned contrasts (baseline vs. post-intervention and baseline vs. follow-up). Because there were three separate analyses, the alpha level was set to 0.01667 (0.05/3) to account for inflation of type 1 error. Significant group x time effects were explored further using independent samples t-tests to compare groups at each time point. Because these illustrated effects already shown to be significant, an unadjusted alpha level of 0.05 was used. Effect sizes were computed as partial Eta Squared (η^2_p) and Cohen's f. Values of Cohen's f up to 0.24 are considered small, 0.25 to 0.39 medium, and 0.40 and over large (Cohen, 1988). All p values given are two-tailed.

Figure 1
CONSORT Flowchart of Participants



Note. CMT=compassionate mind training; RM=relaxation music.

Results

Of 442 individuals who responded to invitations, 255 (58%) did not meet the study criteria. Of the 187 who were eligible, 108 (58%) chose not to take part, and 79 were randomized. Six participants subsequently withdrew (four shortly after randomization and two others before post-intervention measures), giving a final sample of 73 (38 CMT, 35 RM) who were included in all the analyses. Recruitment and participation are shown in Fig. 1.

The sample size was below the target because slower than expected recruitment coupled with practical considerations meant that the study closed before reaching the target sample size. However, post hoc calculation based on the final sample size indicated that power was 84.3% based on the same assumptions used for the a priori calculation.

Table 1 gives participant information. There were 25 (34.2%) males and 48 (65.8%) females, aged 23 to 66 years (mean age 45.53 years; SD 10.32). The most common causes of pain were rheumatoid arthritis, fibromyalgia and back pain, with no differences between groups. The most common prescription analgesics were opioids including hydrocodone (n=25; 34.2%), oxycodone (n=11; 15.1%), oxycodone combined with acetaminophen (n=3; 4.1%), tramadol (n=8; 11%) and fentanyl (n=5; 6.8%), as well as the anticonvulsant medication gabapentin (n=23; 31.5%). The most common OTC analgesics were ibuprofen (n=34; 46.6%), aspirin (n=13; 17.8%), acetaminophen/paracetamol (n=11; 15.1%), acetaminophen and codeine combined (n=8; 11%) and aspirin and acetaminophen combined (n=7; 9.6%). The mean completion rate for CMT exercises was 86.25% per day (range 79% to 92%).

Table 1
Participant information

Characteristic	CMT group	RM group	Total	X^2 or t
N	38	35	73	
Female: N (%)	25 (65.8%)	23 (65.7%)	48 (65.8)	X^2=0.00, p=0.99
Age: mean (SD)	45.63 (9.81)	45.43 (10.98)	45.53 (10.98)	t=0.08, p=0.93
Rheumatoid arthritis	16 (42.1%)	18 (51.4%)	34 (46.6%)	X^2=0.64, p=0.43
Fibromyalgia	9 (23.7%)	8 (22.9%)	17 (23.3%)	X^2=0.01, p=0.93
Back pain	5 (13.2%)	4 (11.4%)	9 (12.3%)	X^2=0.05, p=0.82
Other cause of pain	8 (21.1%)	5 (14.3%)	13 (17.8%)	X^2=0.57, p=0.45

Note. Differences between groups were tested with Chi Square (X^2) tests (for gender and causes of pain) and independent groups t-tests.

Table 2 shows mean values for each group at each time point. There were no baseline differences between groups. None of the Mahalanobis Distance values exceeded 39.25 and no correlations among baseline measures exceeded 0.70, indicating no significant multivariate outliers or multicollinearity (Tabachnic & Fidell, 2006).

In the MANOVA of analgesic use, there was a significant multivariate effect of time [Wilks λ=0.685; $F(10,62)$=2.851; p=0.006; η^2_p=0.315; f=0.678] and group x time [Wilks λ=0.664; $F(10,62)$=3.141; p=0.003; η^2_p=0.336; f=0.711], but not group. Results of univariate group x time tests are shown in Table 2. These were significant for daily prescription analgesic use and analgesic dependence.

Table 2

Mean (SD) scores for the two groups at each time point

Measure	Compassionate mind training (n=38)			Relaxation music (n=35)			Baseline group difference	Univariate group x time p (η^2_p; Cohen's f)
	Baseline	Post-intervention	Follow-up	Baseline	Post-intervention	Follow-up		
OTC painkiller use[a]	2.50 (1.06)	1.74 (0.89)	1.79 (1.12)	2.60 (1.83)	2.54 (1.80)	2.51 (1.74)	t=0.28, p=0.77	0.118 (0.033; 0.185)
Prescription painkiller use[a]	2.79 (1.70)	2.00 (1.19)	2.11 (1.23)	2.66 (1.64)	2.71 (1.60)	2.71 (1.60)	t=0.34, p=0.74	0.015 (0.079; 0.293)
Over the recommended dose[b]	2.24 (1.15)	1.66 (0.75)	1.92 (0.85)	2.23 (1.09)	2.14 (0.97)	2.06 (1.00)	t=0.03, p=0.98	0.042 (0.047; 0.222)
Longer than recommended[b]	1.53 (0.65)	1.26 (0.60)	1.30 (0.50)	1.29 (0.52)	1.26 (0.51)	1.29 (0.46)	t=1.76, p=0.08	0.168 (0.025; 0.160)
Analgesic dependence[c]	8.50 (5.15)	6.34 (3.55)	6.53 (4.34)	8.89 (6.11)	8.97 (6.23)	9.14 (6.33)	t=0.29, p=0.77	<0.001 (0.168; 0.449)
Inadequate self (0-36 scale)	13.55 (6.61)	12.24 (6.44)	14.82 (5.63)	13.86 (6.66)	15.09 (5.77)	12.83 (5.41)	t=0.20, p=0.85	0.045 (0.043; 0.212)
Hated self (0-20 scale)	3.79 (3.08)	2.05 (1.83)	1.76 (1.88)	2.71 (3.53)	3.86 (3.99)	3.54 (3.81)	t=1.39, p=0.17	<0.001 (0.147; 0.415)
Reassured self (0-28 scale)	17.42 (5.66)	21.79 (6.48)	20.24 (7.48)	18.89 (7.02)	17.97 (5.36)	19.34 (6.40)	t=0.98, p=0.33	0.043 (0.044; 0.215)
Negative urgency	27.21 (6.45)	23.79 (6.15)	23.58 (5.82)	25.60 (5.76)	26.54 (5.66)	27.34 (5.41)	t=1.12, p=0.27	0.006 (0.093; 0.320)
Lack of premeditation	20.89 (2.65)	20.45 (4.47)	21.29 (4.62)	20.03 (3.35)	19.86 (4.07)	20.49 (4.04)	t=1.23, p=0.22	0.974 (0.000; 0.000)
Sensation seeking	24.32 (5.47)	28.34 (7.14)	30.55 (12.55)	24.66 (6.07)	29.57 (8.01)	19.86 (4.07)	t=0.25, p=0.80	<0.001 (0.173; 0.457)
Lack of perseverance	19.13 (4.14)	18.13 (4.56)	18.71 (4.56)	19.60 (3.61)	24.11 (6.64)	24.60 (7.20)	t=0.51, p=0.61	0.001 (0.095; 0.324)
Positive urgency	22.68 (5.87)	18.68 (4.15)	19.71 (5.47)	21.54 (5.47)	20.40 (6.15)	20.03 (5.54)	t=0.86, p=0.39	0.214 (0.022; 0.150)
Delay discounting	349.3 (87.3)	404.2 (62.3)	413.9 (97.0)	374.1 (76.0)	373.3 (57.2)	388.9 (53.9)	t=1.29, p=0.20	0.047 (0.047; 0.222)
Pain intensity	6.63 (2.26)	6.13 (2.50)	6.42 (2.27)	6.83 (2.36)	7.26 (1.98)	7.29 (1.81)	t=0.37, p=0.72	0.09 (0.40; 0.816)
Pain frequency	5.82 (2.10)	5.76 (2.15)	5.92 (2.34)	5.46 (2.61)	6.00 (2.80)	5.74 (2.31)	t=0.65, p=0.52	0.37 (0.11; 0.352)

Notes. η^2_p = partial Eta squared; OTC=over the counter; Cohen's f computed from η^2_p using the formula f = sqr (eta^2 / (1 - eta^2)) given by Cohen (1988).
[a] Tablets per day. [b] 0-3 scale. [c] 0-30 scale.

Table 3

Results of planned contrast tests partitioning group x time interaction effects

Contrast	F	p
Prescription analgesic use		
Baseline vs post-intervention	6.807	0.011
Baseline vs follow-up	5.465	0.022
Analgesic dependence		
Baseline vs post-intervention	16.046	<0.001
Baseline vs follow-up	21.200	<0.001
Hated self		
Baseline vs post-intervention	22.088	<0.001
Baseline vs follow-up	19.970	<0.001
Negative Urgency		
Baseline vs post-intervention	6.060	0.016
Baseline vs follow-up	9.204	0.003
Lack of Perseverance		
Baseline vs post-intervention	11.147	0.001
Baseline vs follow-up	12.524	0.001
Sensation Seeking		
Baseline vs post-intervention	0.208	0.650
Baseline vs follow-up	19.819	<0.001

Note. F=F ratio; p=probability

Table 4

Results of post-hoc t-tests to compare groups at each time point

Measure and time point	t	p
Prescription analgesic use		
Baseline	0.338	0.736
Post-intervention	2.152	0.035
Follow-up	1.814	0.074
Analgesic dependence		
Baseline	0.293	0.771
Post-intervention	2.190	0.033
Follow-up	2.043	0.046
Hated self		
Baseline	1.390	0.169
Post-intervention	2.447	0.018
Follow-up	2.499	0.016
Negative Urgency		
Baseline	1.122	0.266
Post-intervention	1.984	0.051
Follow-up	2.857	0.006
Lack of Perseverance		
Baseline	0.513	0.609
Post-intervention	4.449	<0.001
Follow-up	4.137	<0.001
Sensation Seeking		
Baseline	0.253	0.801
Post-intervention	0.693	0.490
Follow-up	4.978	<0.001

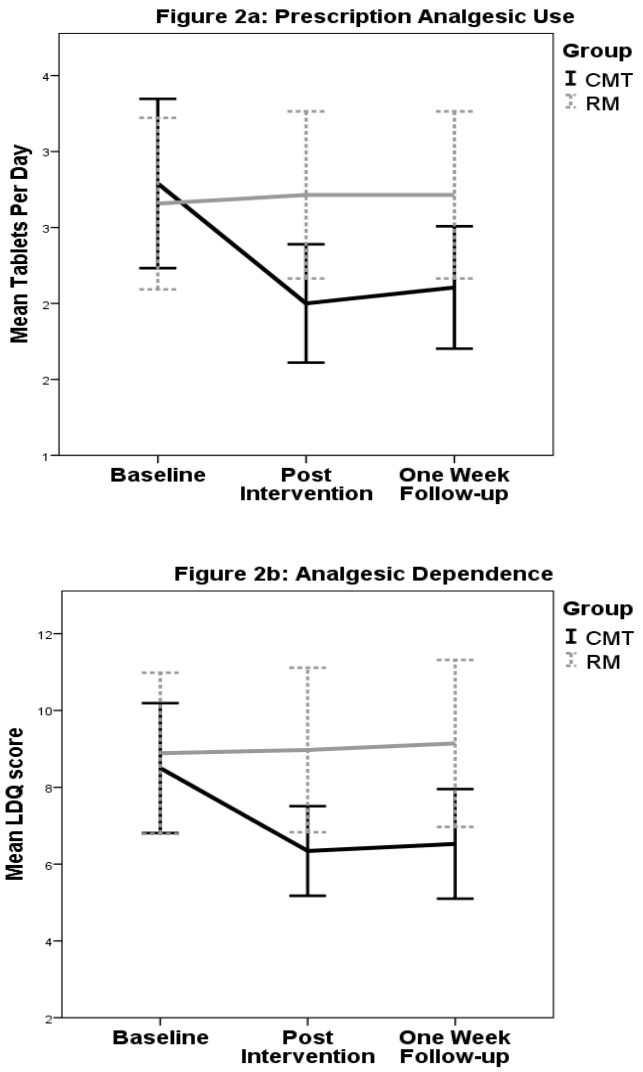
Note. p=probability

The results of planned contrasts to test the univariate interaction effects between baseline and post-intervention and between baseline and follow-up, and the results of the post-hoc t-tests between CMT and RM groups at each time point, are given in Tables 3 and 4.

Prescription analgesic use decreased among the CMT group compared with the RM group (Fig 2a). The interaction was significant between baseline and post-intervention but not between baseline and follow-up (Table 3), and the groups differed significantly at post-intervention but not baseline or follow-up (Table 4). Analgesic dependence also decreased among the CMT group compared with the RM group (Fig 2b). The interaction was significant between baseline and post-intervention and between baseline and follow-up (Table 3), and the groups differed significantly at post-intervention and follow-up but not baseline (Table 4).

Figure 2

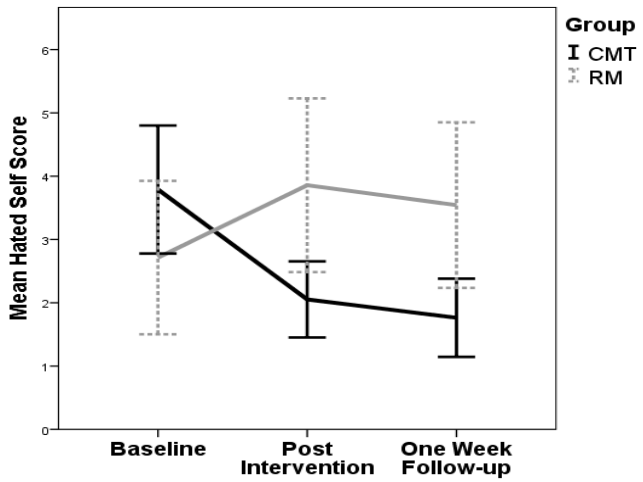
Changes in analgesic use and dependence



Notes. CMT=compassionate mind training; RM=relaxation music. For CMT n=38, for RM n=35 at each time point. LDQ=Leeds Dependence Questionnaire. Figs. 2a and 2b illustrate significant univariate group x time effects (prescription analgesic use F=6.12, p=0.015; analgesic dependence F=14.32, p<0.001). Error bars show 95% confidence intervals.

For self-criticism and self-reassurance, there was no significant multivariate effect of group or time, but there was a significant multivariate effect of group x time [Wilks λ=0.585; $F(6,66)=7.813$; $p<0.001$; $\eta^2_p=0.415$; f=0.842]. The univariate group x time tests were significant for Hated Self (Table 2). Fig. 3 shows the group x time effect on Hated Self, which decreased among the CMT group compared with the RM group. The interaction was significant between baseline and post-intervention and between baseline and follow-up (Table 3), and the groups differed significantly at post-intervention and follow-up but not baseline (Table 4).

Figure 3
Changes in self-criticism (Hated Self)

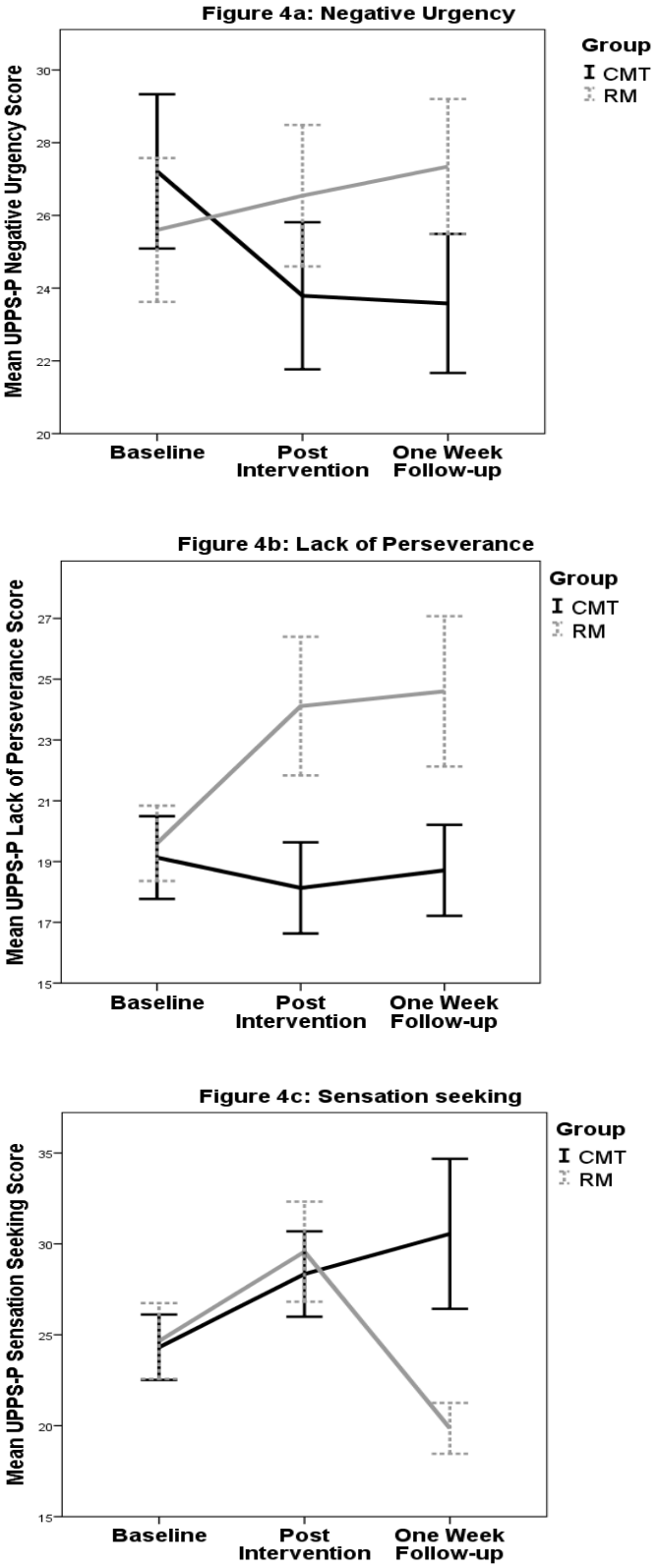


Note. CMT=compassionate mind training; RM=relaxation music. For CMT n=38, for RM n=35 at each time point. Fig. 3 illustrates a significant univariate group x time effect on Hated Self scores (F=12.22, $p<0.001$). Error bars show 95% confidence intervals.

For impulsivity, there were significant multivariate effects of group [Wilks λ=0.596; $F(6,66)=7.467$; $p<0.001$; $\eta^2_p=0.404$; f=0.823], time [Wilks λ=0.499; $F(12,60)=5.024$; $p<0.001$; $\eta^2_p=0.501$; f=1.002], and group x time [Wilks λ=0.531; $F(12,60)=4.41$; $p<0.001$; $\eta^2_p=0.469$; f=0.940]. The univariate group x time tests were significant for Negative Urgency, Lack of Perseverance and Sensation Seeking (Table 2). Fig. 4 shows the significant group x time effects.

Negative Urgency decreased among the CMT group compared with the RM group (Fig. 4a). The interaction was significant between baseline and post-intervention and between baseline and follow-up (Table 3), and the groups differed significantly at follow-up but not baseline or post-intervention (Table 4). Lack of Perseverance also decreased slightly among the CMT group whereas it increased among the RM group (Fig. 4b). The interaction was significant between baseline and post-intervention, and between baseline and follow-up (Table 3), and the groups differed significantly at post-intervention and follow-up but not baseline (Table 4). Sensation Seeking increased among both groups from baseline to post-intervention, then increased further at follow-up among the CMT group whereas it fell among the RM group (Fig. 4c). The interaction was significant between baseline and follow-up, but not between baseline and post-intervention (Table 3). The groups differed significantly at follow-up but not baseline or post-intervention (Table 4).

Figure 4
Changes in cognitive impulsivity



Note. CMT=compassionate mind training; RM=relaxation music. For CMT n=38, for RM n=35 at each time point. Figs. 4a, 4b and 4c illustrate significant univariate group x time effects (Negative Urgency F=7.32, *p*=0.006; Lack of Perseveration F=7.45, *p* = 0.001; Sensation Seeking F=14.81, p=0.001). Error bars show 95% confidence intervals.

All the analyses were repeated on an intention to treat basis, which replicated each of the significant group x time interactions described (see Appendix 2). Although not specifically predicted, we also tested for changes in pain frequency and intensity, but there were no significant effects of group, time, or group x time. No adverse events were reported, and no indications or communications about safety were received; the only problems raised by participants concerned forgotten passwords.

Discussion

The study showed that compassion-based interventions can help people reduce their risk of analgesic misuse. The intervention reduced aspects of self-criticism, impulsivity and analgesic use as predicted, and the reductions in analgesic dependence, Hated Self, Negative Urgency and Lack of Perseverance were maintained from post-intervention to follow-up. No adverse events were reported, so the reductions were achieved safely, and the low drop-out and high exercise completion rates showed that the intervention was acceptable to participants. One unexpected finding was that the CMT intervention increased sensation seeking. More research is needed, but this might reflect increased confidence or reduced concerns about pain, as CMT encourages active engagement and the sensation-seeking scale includes items about engaging in adventurous activities.

The study had limitations, however. First, we excluded participants taking psychotropic medication or receiving psychotherapy, when in fact many people with chronic pain may be treated for co-occurring anxiety or depression, so future research with other samples, including clinical samples, would be worthwhile. Second, a number of eligible people declined to participate, which meant the study did not have statistical power for sub-group analyses. Non-take-up is an important barrier to getting help, so future research might focus more on factors affecting engagement.

Third, relaxation music requires less engagement and interaction than CMT, and we do not know whether participants listened quietly to the music all the time it was playing, nor whether they found it relaxing, boring, pleasant, or even unpleasant or anxiety-provoking. A more stringent control condition might have been guided instructions on relaxation. Future studies could also attempt to assess the extent to which participants engaged as intended with both interventions and their experiences of doing so.

Fourth, the follow-up period was only one week, so future studies might involve longer follow-up periods. Only six participants dropped out, and we decided against presenting an intent-to-treat analysis so that all the findings were based on actual data, but an intent-to-treat analysis replicated the group x time interactions reported above (see Supplementary Information 2).

Fifth, we relied heavily on self-report, including for participant eligibility. Sixth, we did not differentiate between types of pain medication, mainly because there was insufficient statistical power for sub-group analyses, but also because the sample did not divide neatly into participants taking opioid versus non-opioid medications. Clinically it may make sense to consider opioids separately from less addictive analgesics, however, and in future trials, especially those with clinical samples, sub-group analyses for participants taking opioid medications may be useful.

These limitations mean we must interpret the findings of this pilot cautiously, and more research is needed to understand more fully the effects of CMT on analgesic users. However, these initial results showed that exercises based on CMT principles and techniques can reduce analgesic use and risk of analgesic dependence, and aspects of self-criticism and impulsivity. CMT delivered online was acceptable to pain sufferers, with high rates of retention and exercise completion. Future studies could explore how to improve the intervention and tailor it more specifically to this population.

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Appendix 1: Intervention Description

Compassionate mind training (CMT) intervention

The CMT intervention comprised a series of psycho-educational videos and computerized tasks designed to replace self-critical thoughts with self-reassuring thoughts. It was adapted by the first author in consultation with Professor Gilbert from the standardized CMT training manual (Gilbert, n.d.), which targeted people in the general population with emotion-related difficulties.

The intervention maintained conformity with the key principles of existing, manualized in-person CMT while contextualising the materials and exercises, for example by focusing on self-critical thoughts that occurred during pain and/or in relation to using analgesics. It involved a series of videos on topics that built on one another, starting with an introduction to the 'tricky mind', a concept linked to the fact that we all have brains built by our genes that can be difficult to regulate at times (Gilbert, 2009). It also included 'Soothing rhythm breathing', which utilises evidence-based postural and breathing practices associated with improving heart rate variability (Lin, Tai, & Fan, 2014), and teaching participants how to generate 'friendly faces and voice tones' because these two are linked to stimulating the vagus nerve (Porges, 2017). In addition, a range of compassion-focused imagery exercises were used, for example imagining oneself at one's compassionate best, the qualities that one would endorse and how to enact those on a regular basis.

All the videos ended with practical exercises and the final video was an 'all-in-one' practical CMT exercise that brought together all the skills involved.

Participation in the intervention involved daily, individual engagement in exercises that were designed to take around 10-15 minutes per day, although duration of engagement was not fixed and participants could take as long as they wanted on each exercise. The exercises had to be completed in order of presentation, and participants received reminders in a 'personal timetable' feature when an exercise was not completed that needed to be, and when an exercise was completed.

Relaxation music (RM) condition

Relaxation music was chosen as a control condition because it is a more stringent control than no treatment or waiting list (there is evidence that music can be an effective therapy in its own right; Kemper & Danhauer, 2005), and because an occasional criticism of CMT is that it consists mainly of teaching people to relax, as both CMT and relaxation affect the parasympathetic nervous system. The relaxation music condition comprised selected tracks compiled by the first author from public, copyright-free sources, comprising mainly classical piano music, including Rachmaninoff, Mozart, and Glenn Gould, and hosted on the study website. Tracks varied between six and nine minutes in length.

Induction procedure for both groups (day 1)

When participants landed on the study website homepage they saw a welcome message and information about the research team. A button at the bottom of the page directed participants to be assessed for eligibility. Upon clicking the button a new page would appear containing participant information, including information about confidentiality and ways to contact the research team. If participants wished to continue further they clicked on "I wish to continue" and progressed with the screening to assess eligibility. Participants not eligible for the study were thanked and released from the study. Those who were eligible were randomised using simple random sampling into one of two groups, compassionate mind training (CMT) or relaxation music (RM) by giving them a unique URL, which they were asked to bookmark.

Once participants were assigned to a group they viewed a short introductory video explaining the procedure for that group. A text-based version of the video was available for both groups. To reduce placebo effects, participants were not informed at the time of testing that the study concerned the effect of CMT on painkiller addiction, but were told the aim was to investigate the effects of a web-

based intervention on psychological processes. All participants were shown how to register by creating a username and password to use each time they access the website.

Participants in both groups were then given a unique dynamic timetable that highlighted exactly which tasks they needed to do each day (see Figs. A1 and A2 below). The timetable feature simplified site navigation and prevented participants from accessing or completing tasks specified for past or future days. Participants could also use the timetable to check their progress (Fig. A2). The progress feature of the timetable was colour coded to show which tasks were completed and which needed completing that day: green = completed; red = did not complete; yellow = must complete today; grey = no scheduled activities that day; clear = future event.

In Fig. A2, the participant is in week 1, day 1 and should complete two tasks within 24 hours as shown by the two yellow boxes, which will turn green when the two tasks are completed. On days when task completion was required, automated reminder e-mails were sent to participants 24 hours before, at 0200 GMT. The progress feature also calculated *how many* tasks were completed per week and this information was used to assess eligibility for the weekly prize draw. The progress feature also let the investigator to know the days when participants completed tasks and how many days that participants were absent.

The "computer task" in Fig. A2 comprised the delay discounting task. The "online questionnaire" comprised the self-report study measures. Participants in both groups completed the same computer task and online questionnaire on day 1 (baseline), day 20 (post intervention) and day 28 (follow-up). When participants clicked on "intervention and pain diary" they were directed to group-specific tasks; those in the CMT group completed the compassionate mind training exercises and those in the RM group listened to relaxation music. Group-specific tasks are described in detail below.

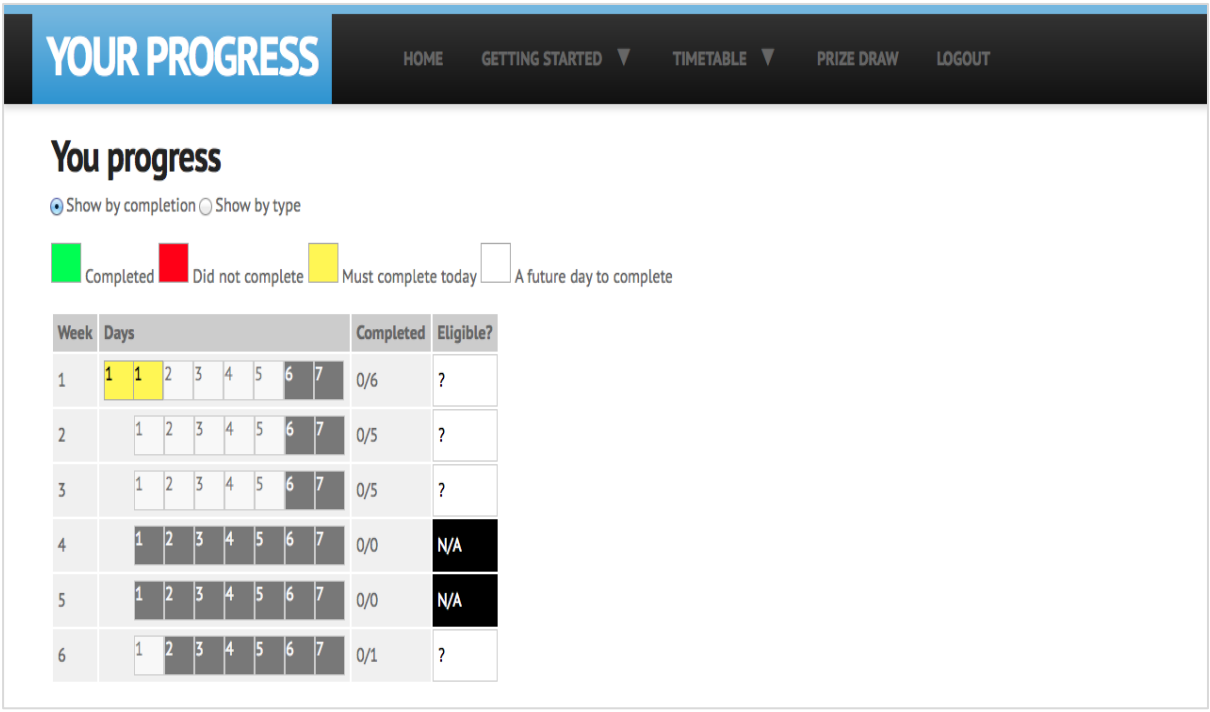

Figure A1. Progress of a participant as seen in the dynamic timetable

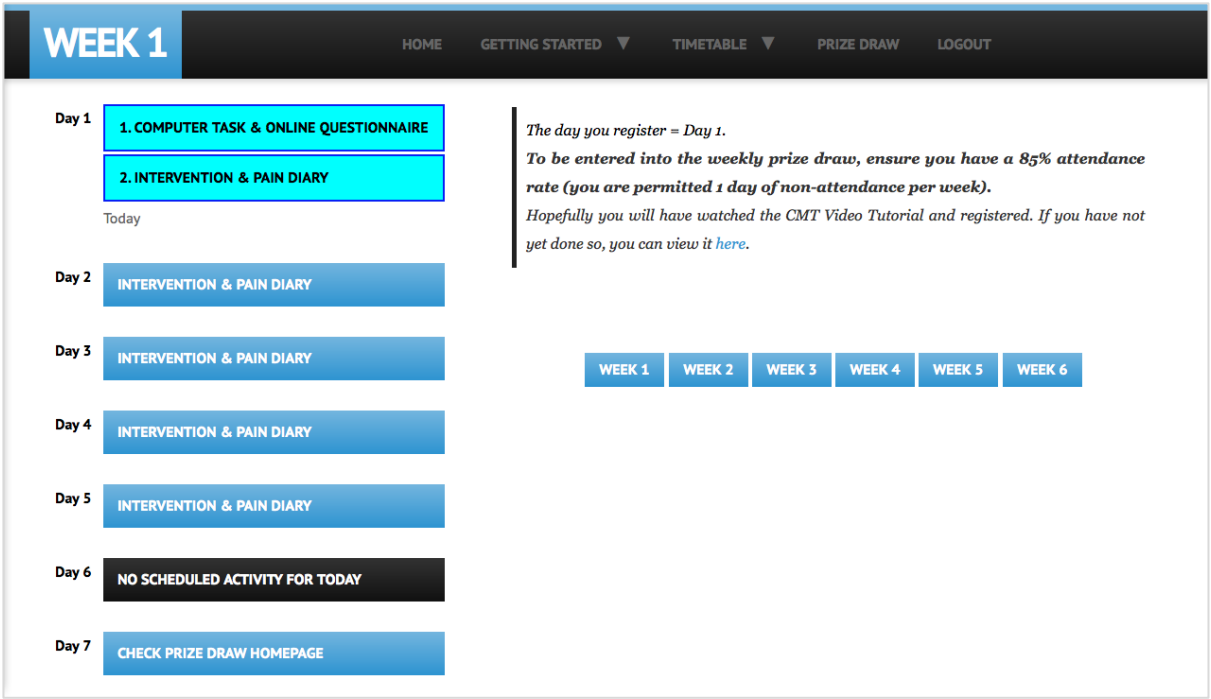

Figure A2. Daily schedule of activities as seen in the dynamic timetable

Compassionate mind training (CMT) group procedure (days 1-20)

Participants in the CMT group followed the sequence of steps shown in Fig. A3 below; first registering with a username and password, then watching five psycho-educational CMT videos designed to develop knowledge and skills in self-compassion: “Chapter 1: Introduction to Self-Compassion”; “Chapter 2: Soothing Rhythm Breathing”; “Chapter 3: Voice Tones and Facial Expressions”; “Chapter 4: Compassionate Self”; and “Chapter 5: Compassionate Coping”. All these videos included practise exercises, and all remained accessible to CMT group participants throughout the study, but were not required viewing prior to engaging with the CMT software.

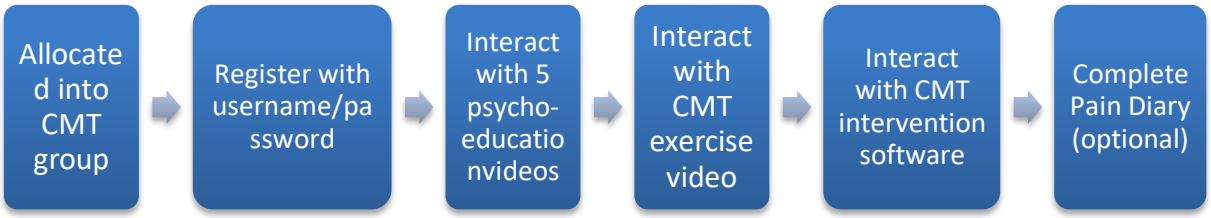

Figure A3. Flow of activities for CMT group participants

Participants then engaged with a video titled “CMT Exercises” (Fig. A4), which was required before engaging with the CMT software. This video incorporated the full range of CMT exercises from the five psycho-educational videos, including Soothing Rhythm Breathing, Compassionate Imagery, Friendly Faces and Voice Tones, Developing the Compassionate Self and Mindfulness. The content and scripts for all the CMT videos were based on the work of Professor Paul Gilbert and delivered by Mayoor Dhokia.

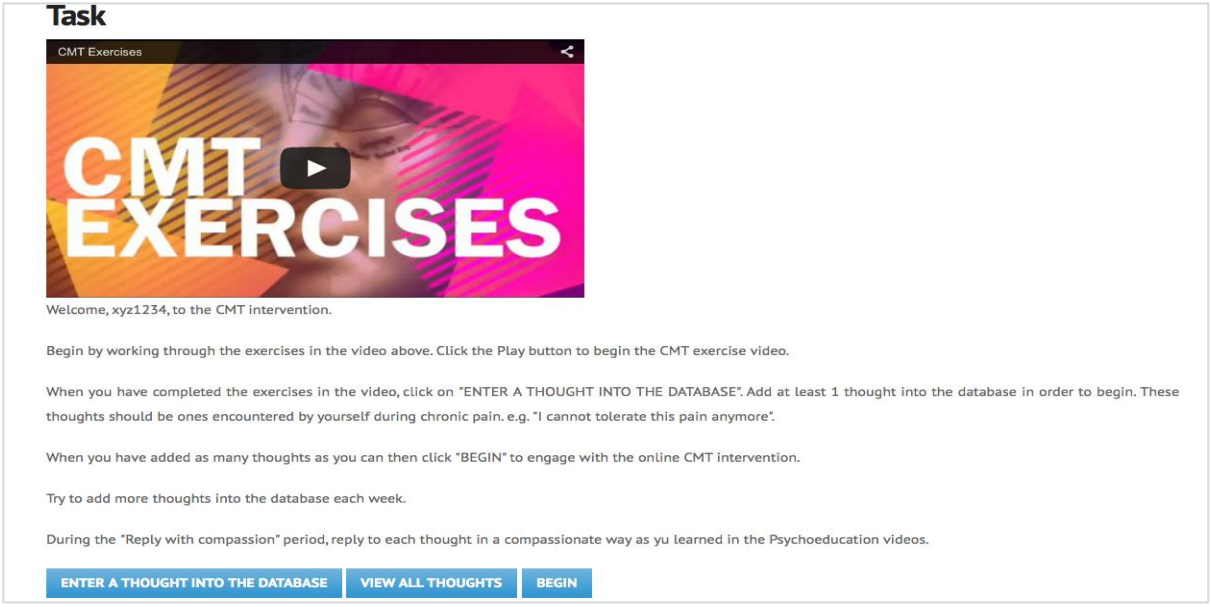

Figure A4. Preview of the CMT exercise video homepage

Immediately after watching the CMT exercise video, participants were redirected to a web page to engage with the CMT intervention software. This was designed to (a) increase awareness of self-critical thoughts and (b) develop effective responses to those thoughts using self-compassion skills learned from the videos. Participants began by adding at least one self-critical thought that occurred often and/or during pain, to a personal database, which participants could then view and edit, and which was not accessible or visible to anyone else.

When at least one thought was entered into the database, participants began interacting by clicking the *Begin* button. The screen faded to a black background and the instruction "*Press a key to begin*" appeared, which initiated the first trial. Fig. A5 below shows the sequence of a single trial. A * symbol appeared on the screen for three seconds, then the screen cleared and a thought from that participant's database appeared on screen for eight seconds. Then the screen cleared and the * symbol appeared for 5 seconds. The screen then cleared and the words "*Reply with Self-Compassion*" appeared for 120 seconds. During this period, participants used techniques from the psycho-education videos to reply to the thought just presented. After 120 seconds, a bell signalled the end of the trial (a sound was used to allow participants to close their eyes during the self-talk process).

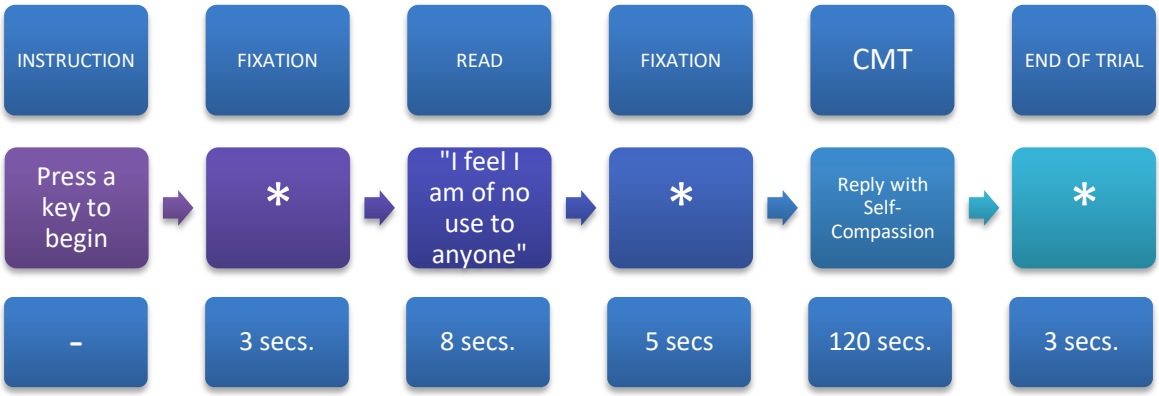

Figure A5. Schematic of a single CMT intervention trial

If more than one thought had been entered in the database then each was displayed in successive trials until all the thoughts had been displayed. If only one thought was entered, that was

displayed for seven trials. When all the thoughts in the database had been displayed, participants were asked whether they would like to enter any further thoughts into the database.

After the CMT intervention, participants were redirected to their personal online pain diary, an optional "e-Journal" in which participants could enter private thoughts. Any self-critical thoughts recorded in the pain diary could later be added to the participant's personal database.

Relaxation music (RM) group procedure (days 1-20)

Participants in the RM group followed the sequence of steps shown in Fig. A6 below; first registering with a username and password, then watching a brief introductory video on what was expected of them during the study. They then listened to a randomly selected track from a relaxation music library (copyright free) on the same days of the week as the CMT group undertook the CMT exercises. Music track lengths varied from six to nine minutes. After the relaxation music, participants were redirected to their personal online pain diary.

Figure A6. Flow of activities for RM group participants

Post-intervention procedure for both groups

On day 21, participants from both study groups completed the same computer task and the same self-report measures post-intervention as at baseline on day 1, in addition to their group-specific task i.e. engaging with the CMT Software or listening to relaxation music. Participants in both groups then took a break for six days during which they could not engage with the website, but were all invited to a follow-up session. An automated email reminder was sent to them three days and one day prior to the follow-up. At follow-up, participants did not engage with any group-specific tasks, and completed only the computer task and self-report measures as on Days 1 and 21. Participants were then thanked, debriefed and released from the study.

Acknowledgement

The software code for the website, behavioural measure and the CMT intervention software was written by Mayoor Dhokia using JavaScript, MySQL, PHP and HTML.

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Appendix 2: Intention to Treat Analysis

In order to examine the potential impact of participant drop out, all the analyses were repeated on an intention to treat basis, using the last-observation-carried-forward approach (Shao & Zhong, 2003; Streiner, 2014). This meant that for the six participants who provided baseline data and were randomised but dropped out of the trial between randomization and post-intervention, baseline values were used to replace missing values at post-intervention and follow-up. Note that the last-observation-carried-forward method is potentially flawed and can introduce bias when values are not missing at random (Lachin, 2016). The best strategy for missing data is to do everything possible to reduce the amount of missing data, which was the reason for the short (1-week) follow-up period.

The intention to treat analyses were conducted in the same way as the main analyses, with three repeated measures MANOVAs, one for each set of dependent variables, each with between-participants ('group'; CMT vs. RM) and within-participants ('time'; baseline vs. post-intervention vs. follow-up) factors (Dhokia, 2020).

The group x time interactions, which test differential change between groups, tested the predictions in each analysis. Univariate effects were examined only where multivariate effects were significant. Significant univariate interactions were further evaluated with simple planned contrasts (baseline vs. post-intervention, and baseline vs. 1-week post-intervention follow-up).

Because there were three separate analyses, the alpha level was set to 0.01667 (0.05/3) to account for inflation of type 1 error. Significant group x time intervention effects were explored further using independent samples t-tests to compare groups at each time point. Because these tests were used to illustrate effects already shown to be significant, an unadjusted alpha level of 0.05 was used.

Effect sizes were computed as partial Eta Squared (η^2_p) and Cohen's f. Values of Cohen's f up to 0.24 are considered small, 0.25 to 0.39 medium and 0.40 and over large (Cohen, 1988). All p values given are for two-tailed tests.

Analgesic use

In the MANOVA of analgesic use, there was a significant multivariate effect of time [Wilks λ=0.69, F(10,68)=3.13, p=0.002, η^2_p=0.3, f=0.66] and group x time [Wilks λ=0.67, F(10,68)=3.41, p=0.001, η^2_p=0.3, f=0.66], but not group. The univariate group x time tests were significant for prescription analgesic consumption [F(1.04,80.1)=6.70, p=0.01, η^2_p=0.08, f=0.30], exceeding the recommended daily allowance [F(1.6,124.3)=4.0, p=0.03, η^2_p=0.05, f=0.23] and analgesic dependence [F(2,154)=15.58, p<0.01, η^2_p=0.17, f=0.45], but not OTC analgesic consumption or taking analgesics for longer than prescribed.

For prescription analgesic consumption, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=7.46, p<0.01] and between baseline and follow-up [F(1,77)=5.98, p=0.02]. The CMT and RM groups did not differ at baseline, but differed significantly at post-intervention [t(77)=2.57, p=0.01] and follow-up [t(77)=2.22, p=0.03].

For exceeding the recommended daily allowance, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=6.23, p=.002], but not between baseline and follow-up. The groups did not differ at baseline or follow-up, but differed significantly at post-intervention [t(77)=3.02, p=0.03].

For analgesic dependence, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=17.57, p<0.001], but not between baseline and follow-up. The groups did not differ at baseline, but differed significantly at post-intervention [t(77)=2.2, p=0.03] and follow-up [t(77)=2.0, p=0.05].

Self-compassion and self-reassurance

In the MANOVA of self-criticism and self-reassurance, there was a significant multivariate effect of group x time [Wilks λ=0.6); F(6,72)=7.92, p<0.01; η^2_p=0.4; f=0.816] but not group or time. The

univariate group x time effects were significant for Hated Self [F(2,154)=12.58, p<0.001, η^2_p= 0.1, f=0.33], Inadequate Self [F(2,154)=3.24, p=0.04, η^2_p=0.04, f=0.82] and Reassured Self [F(2,154)=3.49, p=0.03; η^2_p=0.04; f=0.82].

For Hated Self, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=22.3, p<0.01] and between baseline and follow-up [F(1,77)=20.71, p<0.01]. The groups did not differ at baseline, but differed significantly at post-intervention [t(77)=6.7, p=0.04] and follow-up [t(77)=3.25, p=0.04].

For inadequate self, planned contrasts showed that the group x time interaction was not significant between baseline and post-intervention or between baseline and follow-up.

For reassured self, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=7.0, p=0.01] but not between baseline and follow-up. The groups did not differ at baseline or follow-up, but differed significantly at post-intervention [t(77)=0.27, p=0.02].

Impulsivity

In the MANOVA of impulsivity measures, there was a significant multivariate effect of group [Wilks λ=0.7, F(6,72)=6.32, p<0.001, η^2_p=0.3, f=0.66], time [Wilks λ=0.5, F(12,66)=4.73, p<0.001, η^2_p=0.46, f=0.92], and group x time [Wilks λ=0.6, F(12,66)=4.19, p<0.001, η^2_p=0.43, f=0.87]. The univariate effects were significant for Negative Urgency [F(1.2, 92.19)=7.65, p=0.001, η^2_p=0.01, f=0.33], Lack of Perseveration [F(2,154)= 6.78, p=0.002, η^2_p=0.08, f=0.29], Sensation Seeking [F(1.7,152)=14.0, p<0.001, η^2_p=0.15, f=0.42] and Delay Discounting [F(1.5,116.55)=3.94, p=0.03, η^2_p=0.05, f=0.2], but not Positive Urgency or Lack of Premeditation.

For Negative Urgency, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=6.44, p=0.01] and between baseline and follow-up [F(1,77)=9.50, p=0.03]. The groups did not differ at baseline, but differed significantly at post-intervention [t(77)=2.3, p=0.03] and follow-up [t(77)=3.15, p=0.002].

For Lack of Perseveration, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=10.19, p=0.002] and between baseline and follow-up [F(1,77)=11.07, p=0.002]. The groups did not differ at baseline, but differed significantly at post-intervention [t(77)=4.29, p<0.001] and follow-up [t(77)=3.95, p<0.001].

For Sensation Seeking, planned contrasts showed that the group x time interaction was not significant between baseline and post-intervention, but was significant between baseline and follow-up [F(1,77)=19.85, p<0.01]. The groups did not differ at baseline or post-intervention, but differed significantly at follow-up [t(77)=4.66, p<0.001].

For Delay Discounting, planned contrasts showed that the group x time interaction was significant between baseline and post-intervention [F(1,77)=7.3, p=0.008] but not between baseline and follow-up. The groups did not differ at baseline or follow-up, but differed significantly at post-intervention [t(77)=2.37, p=0.02].

Pain frequency and intensity

In the MANOVA of pain frequency and intensity, there was no significant multivariate effect of group, time, or group x time.

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