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Cognitive exposure versus avoidance in patients with chronic pain: Adherence matters

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Abstract

Background: Behavioural exposure methods can reduce pain-avoidance behaviours, but outcomes vary. One possible explanation is that patients employ cognitive (experiential) avoidance during behavioural exposure. If so, reducing cognitive avoidance during behavioural exposure should help. One option is interoceptive exposure (IE), which involves sustained exposure (via attention) to pain sensations. In order to test if IE could improve outcomes from behavioural exposure, this study with mixed chronic pain patients compared outcomes from a cognitive behavioural therapy (CBT) pain management programme incorporating either IE or distraction from pain.

Methods: One hundred forty chronic pain patients were randomly assigned to CBT + IE or CBT + distraction. Outcome measures included pain, disability, depression and medication. Measures reflecting degree of threat of pain were also employed (catastrophizing, fear-avoidance, pain self-efficacy and pain acceptance). An intention-to-treat approach, using mixed-effects model repeated measures, as well as conventional inferential statistical tests, effect sizes and reliable change indices were employed to evaluate the outcomes up to 1-year post-treatment.

Results: Significant improvements were achieved by both treatment conditions on all outcome measures and on measures reflecting the threatening nature of pain, with no differences between treatment conditions.

Conclusions: The addition of IE to behavioural exposure did not improve outcomes. However, higher adherence to either attentional strategy was associated with larger effect sizes on all measures, suggesting factors shared by the two treatments could have contributed to the outcomes. Taken as a whole, the results suggest that increasing adherence to treatment strategies, possibly by motivational measures, would improve the overall outcomes of these interventions.

1. Introduction

Cognitive behavioural therapy (CBT) interventions can reduce disability in chronic pain patients, but outcomes vary and effect sizes are often small, prompting calls for improvements (Eccleston et al., 2009). The disappointing outcomes have been attributed to interventions being too generic, too brief and of variable quality (Morley, 2011), leading to suggestions that if we are to improve outcomes from these interventions, we need to return to their theoretical roots.

One theory underpinning CBT interventions for chronic pain is the fear-avoidance model (FAM; Vlaeyen and Linton, 2000). Recent versions have

What's already known about this topic?
- Behavioural exposure can reduce pain-avoidance behaviours in chronic pain patients, but outcomes vary.
- Cognitive avoidance of pain may influence these outcomes.

What does this study add?
- In the presence of behavioural exposure, cognitive exposure and cognitive avoidance (distraction) were equally effective in improving outcomes.
- Adherence to either cognitive strategy was associated with stronger effects when combined with behavioural exposure.

emphasized the roles of hypervigilance and catastrophic beliefs about pain (viewing pain as a threat) and experiential avoidance in promoting fear of pain, avoidance behaviour and disability (Leeuw et al., 2007; Vlaeyen and Linton, 2012). One clinical implication of the model is that reducing the threat value of a specific pain should diminish disability related to that pain. To some extent, treatment studies have generally supported this hypothesis (Smeets et al., 2006; Turner et al., 2007).

The primary strategy for reducing pain-avoidance behaviours is behavioural exposure, requiring the repeated performance of avoided activities under the assumption that fear will be reduced (de Jong et al., 2005). However, variable outcomes are reported (Boersma et al., 2004; Linton et al., 2008) and this may be related to patients engaging in cognitive (experiential) avoidance during behavioural exposure (Boersma et al., 2004; Van Damme et al., 2006).

If so, reducing cognitive avoidance (i.e., distraction) during behavioural exposure should help. One option here is interoceptive exposure (IE; Barlow et al., 2004; McNally, 2007). In IE, the patient is asked to sustain their exposure (via attention) to aversive internal sensations for extended periods. For pain, this means deliberately experiencing pain rather than trying to avoid it by distraction.

De Peuter *et al.*'s (2011) review of interoceptive conditioning as a means of sustaining fear of pain concluded that IE might reduce this fear. Flink et al. (2009) found that IE with chronic low back pain patients could work, but mixed results suggested it was not sufficient by itself. Wald et al. (2010) found that IE was associated with reduced pain in patients with chronic pain and post-traumatic stress disorder. In patients with irritable bowel syndrome (IBS), Craske et al. (2011) found that CBT + IE had some benefits over CBT + stress management (relaxation training). However, to date, no studies have compared the relative benefits of CBT + IE versus CBT + distraction in chronic pain patients.

The aim of the current study is to compare the efficacy of CBT + IE in comparison to CBT + distraction in a large group of chronic pain patients. If reducing cognitive avoidance could reduce fear of pain, this would potentially facilitate more effective functional exposure to other aspects of the programme (such as graded activity) and hence result in better outcomes overall. In contrast, if CBT + distraction were found to result in similar changes, then this would suggest that reducing experiential avoidance may not be necessary in order to facilitate the outcomes of CBT.

2. Methods

2.1 Participants

One hundred forty patients (aged between 18 and 65 years) referred by their doctor to the Pain Management and Research Centre, Royal North Shore Hospital, Sydney, were admitted to a 3-week (115 h) pain management programme (ADAPT) after being assessed as suitable by a multidisciplinary team.

Inclusion criteria: (1) pain lasting ≥6 months and causing significant interference in normal activities despite appropriate treatments; (2) seeking help for pain; (3) no further medical or surgical treatments deemed appropriate after multidisciplinary review; and at least one of the following: (1) reliance on medication that was minimally helpful in reducing pain severity and its impact; (2) evidence of pain-related distress or sleep disturbance; and (3) using aids to manage (sticks, hot/cold packs).

Exclusion criteria: (1) unwilling or unable to attend the treatment programme (e.g., due to travel or family constraints, or still seeking curative treatment); (2) unable to speak adequate English; (3) presence of active major mental disorder (e.g. major depression with active suicidal ideation); and (4) a primary drug addiction problem.

2.2 Sample size

Sample size was calculated from pain-related disability [measured by the modified Roland–Morris Disability Questionnaire (mRMDQ)] (Roland and Morris, 1983) as a primary outcome measure. We previously reported (Nicholas et al., 2012) in a pre-/post-treatment outcome study, with similar patients, a mean of 3.4 [standard deviation (SD) 4.8] point reduction on the 24-item mRMDQ, which was statistically and clinically significant (Deyo et al., 1998). That study used the IE intervention as well. As we had no data for the

distraction approach, we based our sample size calculations on that difference (i.e., a mean reduction of 3.4). We calculated that a sample size of 44 per condition would provide 80% power to detect a difference of 3.4 on the mRMDQ, assuming an α of 0.05 (Browner et al., 2007). Allowing for loss to follow-up of 50%, we needed to recruit 44 + 22 = 66 participants per condition, or 132 in total [i.e., roughly 20 more per group than in the similar Craske et al. (2011) study of CBT + IE vs. CBT+ stress management with IBS patients].

2.3 Study design

Once patients accepted the offer of the programme, a start date was arranged. The programmes were conducted consecutively. In total, 16 programmes were conducted between April 2008 and June 2009. Randomization was by group. The order was determined by a researcher (AA) not involved in the treatments using the methods described by Altman and Bland (1999) for allocation within blocks and blocks of varying size (recommended by Schulz and Grimes, 2002), using published random number tables. The treatment team was unaware of the treatment condition until the day the treatment started (i.e., after the patients had been assigned to a group).

Two to three weeks prior to a programme, a member of the treatment team met patients individually to prepare them for the programme. This included identifying the patient's personal goals for the programme. Pretreatment assessment measures were completed at home and brought to the centre on the first day of the programme. Post-treatment measures were completed on the final day of the programme, and the 1-month follow-up measures were completed at home and brought to the centre on the review day. The measures for 6- and 12-month follow-ups were sent by post. If there was no response within 10 days, the research assistant (A.S.) contacted them by telephone and mail.

The study was approved by the Northern Sydney Area Health Human Research Ethics Committee. All participants gave informed consent for their de-identified data to be used for research purposes. Of the 144 patients assessed as potentially suitable to participate, 4 refused to participate in the study, leaving the total sample at 140 (97% recruitment rate).

2.4 Measures

Data were gathered on three groups of variables: (1) primary outcomes; (2) cognitive process variables; and (3) adherence to pain self-management strategies.

2.4.1 Primary outcome measures

Modified Roland and Morris Disability Questionnaire (mRMDQ; Roland and Morris, 1983). As the participants were heterogeneous for pain sites, the modified form of the RMDQ was used to measure current pain-related disability. The psychometric properties of this modified version of the RMDQ have been published (Jensen et al., 1992; Asghari and Nicholas, 2001). Nicholas et al. (2008) reported the internal consistency (α) = 0.88. The mRMDQ scores range between 0 and 24, with higher scores indicating more severe physical disability.

Pain intensity scale of the *Multidimensional Pain Inventory* (MPI; Kerns et al., 1985). The 3-item pain intensity scale covers pain experience in the previous week. The MPI has been shown to have good reliability and validity (Jacob and Kerns, 2001). Nicholas et al. (2008) reported the internal consistency (α) = 0.78. The scores range between 0 and 6, with higher scores indicating more severe pain.

The depression scale of the *Depression Anxiety Stress Scales* (DASS; Lovibond and Lovibond, 1995) was used to measure depression severity. The DASS has been validated for use with chronic pain patients (Taylor et al., 2005). Nicholas et al. (2008) reported the internal consistency (α) = 0.96. The scores range between 0 and 42, with higher scores indicating more severe depressive symptoms.

Total medication. As dose reports may be unreliable, we used total medication classes as the measure of medication used (Turner et al., 1982). The total represented summation of nine medication classes (scores could range between 0 and 9).

2.4.2 Cognitive process (threat) measures

Four cognitive process variables reflecting the threat value of pain were employed.

The catastrophizing scale of the *Pain Response Self-Statements Scale* (PRSS; Flor et al., 1993). This 9-item scale asks patients to rate on a 0–5 scale (0 = *almost never* to 5 = *almost always*) the frequency of catastrophic thoughts when they experience severe pain. Higher mean scores indicate more frequent catastrophizing. Flor et al. (1993) established the psychometric properties of the PRSS. Nicholas et al. (2008) reported the internal consistency (α) = 0.86.

The *Tampa Scale for Kinesiophobia* (TSK; Kori et al., 1990) was used to assess fear and avoidance beliefs about movement and re-injury. The 17 statements, scored on 4-point scales from 'strongly disagree' to 'strongly agree', yield a total range from 17 to 68. Higher scores indicate more severe fear-avoidance beliefs. The TSK has been well-validated in pain populations (Vlaeyen et al., 2002). Nicholas et al. (2008) reported the internal consistency (α) = 0.83. While some have questioned the reliability and validity of the measure, it is in widespread use, and to increase comparability with other similar studies, we have included it here.

The *Pain Self-Efficacy Questionnaire* (PSEQ; Nicholas, 2007) has 10 items and measures the strength and generality of a patient's beliefs about his/her ability to accomplish various activities despite their pain. Scores range from 0 to 60. Higher scores indicate stronger self-efficacy beliefs. Nicholas (2007) established the psychometric properties of this measure. Nicholas et al. (2008) reported the internal consistency (α) = 0.93.

Chronic Pain Acceptance Questionnaire (CPAQ; McCracken et al., 2004). This 20-item scale reflects the degree to which a person engages in life activities regardless of pain and the degree to which the person feels little need to avoid or control painful experiences. In this study, a total score (range 0–120) was used, with higher scores reflecting higher pain acceptance. Nicholas and Asghari (2006) reported the internal consistency (α) = 0.85.

2.4.3 Adherence to specific pain self-management strategies

Five strategies were evaluated: activity pacing, goal setting, cognitive challenging, attentional techniques and stretch exercises. The method of assessing the use of the strategies is described in Nicholas et al. (2012). The degree of adherence to each strategy was converted into one of the three categories on a 0–2 scale by a researcher (AA) not involved in the treatment. These categories were: 0 = 'not using the strategy at all', 1 = 'using it inconsistently', and 2 = 'using it consistently'. Using 'inconsistently' meant the strategy was used irregularly or less than recommended. Using 'consistently' meant using the strategy regularly each day and as recommended.

2.5 Treatment

Patients attended in groups of 8–10 on weekdays for three consecutive weeks, from 9:00 a.m. to 5:00 p.m. The treatment team comprised a clinical psychologist, physiotherapist, nurse, rehabilitation advisor and medical pain specialist, with between 5 and 14 years of experience on the ADAPT programme. The programme employs an interdisciplinary style with cognitive behavioural principles informing all interactions between staff and patients (see Nicholas and George, 2011). Specific programme details can be found in Nicholas et al. (2004), and only the attention methods differed between conditions (see below). From a theoretical perspective, the behavioural exposure involved the graduated increments in activities previously avoided due to pain or fear of pain. Simultaneously, safety behaviours (e.g., medication consumption, extended rest, use of aids) were reduced. Pacing principles (Nicholas and George, 2011) were used to achieve increments in specific tasks/positions (e.g., sitting, standing, carrying), and reductions in pain medication and the use of aids.

2.5.1 Interoceptive Exposure (IE)

On day 2 of the programme, the psychologist introduced IE to the group. Consistent with other versions of IE (Wald and Taylor, 2005; Craske et al., 2011), this included: education (about chronic pain as an experience incorporating sensations, affect and meaning that often lead to avoidance/escape responses, like taking analgesics, ceasing activities); self-monitoring of sensations; identifying and responding to unhelpful cognitions about these sensations; repeated deliberate exposure to the pain; and engaging in activities expected to aggravate pain (e.g., exercises, sitting and walking, which were progressively increased through the programme). It was explained that the aim was to reduce how bothersome pain was so efforts could be applied to achieving functional goals despite pain (see Nicholas et al., 2004). During supervised practice, the patients were asked to calmly focus (and hold) their attention as much as possible on their pain sensations, whether sitting or performing activities associated with pain (e.g. exercises). They were to expect more pain initially, but to keep their attention calmly focused on the pain (which was just activity in their nervous system and not harmful), allowing themselves to feel it without reacting to it or trying to change or fight it. If worrying thoughts occurred, they should recognize them as just thoughts. Patients were asked to practice this for at least 20 min three times a day (two supervised and one at night), plus multiple brief sessions whenever they noticed their pain or found it bothersome (e.g., while exercising). The practice was to be recorded in daily record charts.

2.5.2 Distraction/Relaxation (DR)

The combined relaxation and distraction technique was introduced as a way of reducing pain. The relaxation/distraction technique (see Nicholas et al., 2004) employs the breathing method described by Benson et al. (1975), including releasing tension with each exhalation, making no effort and focusing attention on a pleasant thought or image not involving pain. As in the IE condition, the harmless nature of chronic pain was explained and differentiated from acute pain. The focus of their attention could be any non-pain image they chose. Examples were provided of relaxing scenes, whether real or imaginary. Creative and personally relevant images were encouraged. They were asked to try to keep their attention on these scenes or images, not just the visual image but trying to become as engaged as possible in it, noticing any pleasant sensations or sounds associated with it. As with IE, patients in the DR condition were asked to practice this technique at least 60 min a day (3×20 min sessions; two supervised and one at night), and whenever they found their pain starting to bother them. As in the IE condition, all patients recorded their performance of DR in a daily chart.

Overall treatment credibility/acceptability. At the end of day 1, before the attention methods were explained, patients completed a treatment credibility rating form (Borkovec and Nau, 1972) for the overall programme. This (the mean of three 0–10 scales) provides an indication of perceived credibility and expectations for improvement between conditions.

Attention strategy credibility/acceptability. After day 2, and an explanation and trial of the two attention strategies, all patients completed a strategy credibility rating form (similar to the one mentioned above) to evaluate the comparability of perceived credibility and expectation for improvement between attention conditions.

Treatment satisfaction was assessed with a scale completed on the last day of treatment. This was to ensure that any differences observed in the outcome measures could not be attributed to complaints or dissatisfaction with the treatment team or the interventions. The scale asked respondents to rate how useful they had found the treatment programme (from 'not at all useful' to 'extremely useful') on a 1–5 scale.

Treatment integrity. Treatment integrity was evaluated by audio-taping the explanatory session by the psychologists for both attention conditions (IE and DR). These tapes were reviewed by two independent psychology researchers experienced with chronic pain management but not part of the treatment team and were blinded to treatment identity. They identified which treatment (IE or DR) they thought was being administered.

2.6 Analyses

All data were collected, scored and entered into a secure database by a researcher (A.S.) not involved in the treatments. This researcher conducted all follow-up assessments. All analyses were conducted by two researchers (A.A., A.B.), also not involved in the treatments. As there were many analyses, data are not always shown in tables, but when this occurs, it is indicated in the text. The missing data are available from the first author.

2.6.1 Statistical significance

A likelihood-based, mixed-effects model repeated measures (MMRM) approach (Gueorguieva and Krystal, 2004) was used to analyse the longitudinal data obtained from the two conditions for the continuous outcome measures and was implemented using SAS PROC MIXED (SAS for Windows; SAS Institute, 2006). MMRM models for change from pre- to post-treatment for each outcome variable were fitted with the following predictor variables: the fixed effects of baseline score, treatment group, time (fitted as continuous), treatment group by time interaction, and pre-intervention score by time interaction. An unstructured covariance matrix was used to estimate within-patient errors, and the method of Kenward and Roger (1997) was used to estimate denominator degrees of freedom. Type III sums-of-squares were used for the significance testing of contrasts between the least squares (LS) means. To deal with the problem of missing data (e.g. from dropouts), we employed the intention-to-treat (ITT) method recommended by Siddiqui et al. (2009) who demonstrated the commonly used last observation carried forward (LOCF) approach risks bias. MMRM was chosen for these analyses so as to model all patient data along with its ability handle missing data as was observed in this study. Siddiqui et al. compared the results obtained from the analysis of covariance LOCF approach with the results obtained from MMRM and concluded that the MMRM is better for controlling type 1 error rates and minimizing biases in treatment differences. This approach was recently supported by Moore et al. (2012). Fig. 1 provides the numbers available at each occasion.

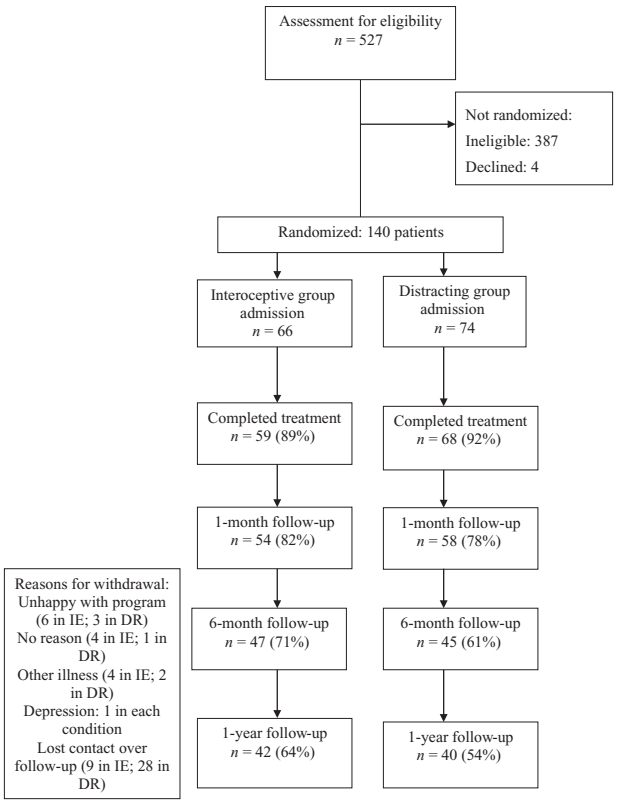

Figure 1 Study flow diagram.

A series of *t*-tests (for continuous data) and chi-square (for categorical data) analyses were conducted on baseline data to check for any differences between treatment conditions on baseline characteristics, as well as between those who completed all stages of the study and those who dropped out.

2.6.2 Effect sizes

Estimates from the MMRM analyses were also used to calculate treatment effect sizes covering the period from pre-treatment to 1 year follow-up. Effect sizes (d) have been classified as small (0.2–0.5), medium (0.5–0.8) and large (>0.8) (Cohen, 1988).

2.6.3 Reliable change estimates

Relative to estimates of statistical significance, this approach provides a more conservative method for evaluation of treatment outcomes and may be used to gain an indication of the proportion of cases who achieve a change greater than possible measurement error (Kendal et al., 1999; Morley and Williams, 2002). In this study, reliable change estimate cut-off points were calculated using Jacobson's method (Jacobson and Revensdorf, 1988; Jacobson et al., 1999). We used temporal stability data (test–retest reliability) for establishing reliable change estimates (RCI). Hence, a person's

Table 1 Baseline characteristics of patients who started treatment (n = 140), presented as means (standard deviation) or percentage.

Variable	Interoceptive exposure condition	Distraction condition
Number of participants	66	74
Age (years)	42.05 (12.33)	43.22 (11.08)
Pain duration (months)	67.16 (87.14)	77.71 (89.28)
Gender (% women)	51	55
Born in Australia (% yes)	74	80
Main pain site		
Shoulder/arms/neck (%)	15	17
Lower limbs (%)	10	10
Lower back and legs (%)	40	24
More than 2 major sites (%)	28	42
Other sites (%)	7	7
Working (full-time or part-time) (%)	32	30
Not working due to pain (%)	66	54
Compensation claim (%)	70	65
Education		
University (%)	18	22
TAFE (technical training) (%)	37	33
Completed 12 years at school (%)	10	14
Completed 10 years at school (%)	22	24
Less than 10 years at school (%)	13	7
Fear avoidance (TSK) (17–68)	40.37 (8.67)	40.55 (9.14)
Pain self-efficacy (PSEQ) (0–60)	25.81 (11.26)	23.49 (12.05)
Catastrophizing (PRSS) (0–5)	3.03 (0.95)	3.04 (0.99)
Acceptance (total) (CPAQ) (0–120)	44.67 (16.42)	43.11 (16.14)
Total medication categories (0–9)	2.45 (1.43)	2.73 (1.78)
Usual pain (MPI) (0–6)	4.15 (1.02)	4.01 (1.02)
Depression severity (DASS-D) (0–42)	19.70 (11.58)	18.66 (11.65)
Disability (mRMDQ) (0–24)	13.22 (5.65)	12.73 (4.96)

CPAQ, Chronic Pain Acceptance Questionnaire; DASS, Depression scale of the Depression Anxiety Stress Scales; MPI, Multidimensional Pain Inventor; mRMDQ, modified Roland–Morris Disability Questionnaire; PSEQ, Pain Self-Efficacy Questionnaire; PRSS, Pain Response Self-Statements Scale; TSK, Tampa Scale for Kinesiophobia.

individual score must change by a larger amount than would be anticipated simply due to the error variance associated with each measure. With one exception (*Medication use*, $r = 0.66$), the correlations and method used in Nicholas et al. (2012) were also used here.

2.6.4 Changes in primary outcome and threat measures according to adherence to attention strategy during treatment, from pretreatment to 1-year follow-up

Using the adherence categories described earlier, we examined within- and between-group differences over time (from pretreatment to 1-year follow-up) on both threat and outcome measures. As with the primary, longitudinal analysis, the MMRM approach was also used here. A test for significance of differences in proportions (Ferguson and Takane, 1989) was conducted to examine whether there were any differences in proportions between low and high adherers to the attention strategies who achieved mean RCI threshold levels of change for both outcome and threat measures.

3. Results

One hundred forty patients started the programme (IE: 66 and DR: 74). Fig. 1 describes the attrition rate, but only 9% dropped out during treatment and there were no differences between conditions on 1-year follow-up rate. Comparison of baseline characteristics between the dropouts and those retained over the treatment and 1-year follow-up revealed relatively few differences: usual pain severity [4.30 (SD = 0.99) for dropouts vs. 3.93 (SD = 1.01) for participants; $p < 0.05$], pain self-efficacy [21.90 (SD = 11.56) for dropouts vs. 26.25 (SD = 11.53) for participants; $p < 0.05$], gender (more women were retained; $\chi^2 = 4.01$; $p < 0.05$) and education level (higher levels of education favoured retention; $\chi^2 = 12.04$; $p < 0.05$).

Comparison of baseline characteristics between conditions (Table 1), using t-tests for continuous variables and chi-square analyses for categorical data, revealed no significant differences between them ($p = 0.05$).

The psychological and pain site characteristics were similar to those reported by Williams et al. (1996). However, more had a compensation claim (70%) in our sample, versus 21% in Williams et al. Compared with our normative pain clinic data (Nicholas et al., 2008), the present sample was slightly more depressed, and reported slightly higher catastrophizing, but were similar for usual pain, disability, fear-avoidance and pain self-efficacy beliefs.

3.1 Retention rates and reasons for withdrawal

The main reasons for patients withdrawing were (1) uncontactable (changed address, changed details or unresponsive to contact attempts); (2) dissatisfaction with the programme (4 in the IE group and 3 in the DR group); (3) no reason, IE group: 4, DR: 1, while 2 (in IE) felt the programme was not suitable; (5) other illness: 4 in the IE group, and 2 in the DR group, as well as depression for 2 withdrawals (1 per group).

3.2 Credibility and satisfaction

t-Tests revealed no significant differences on treatment credibility and satisfaction between conditions. Overall treatment credibility means (SD) were 6.9/10 (1.6) and 6.5/10 (1.8) ($p = 0.49$) for IE and DR conditions, respectively. Means (SD) for credibility of the attention strategies were IE: 6.6/10 (2.7) and DR: 6.3/10 (2.5) ($p = 0.74$). Means (SD) for treatment satisfaction (usefulness) were IE: 4.2/5 (1.1) and DR: 3.9/5 (1.0) ($p = 0.29$). Thus, any differences in outcomes should not be related to these dimensions.

3.3 Treatment integrity

The two independent psychologists (LS, MC) correctly (100% for all 16 groups) differentiated between the two conditions from audiotapes. This indicates that the attention strategies were consistent with the treatment protocols.

3.4 Changes in outcome measures from pretreatment to 1-year follow-up

Significant improvements in all mean outcome measures were found for both conditions (see Table 2), but there were no differences between conditions from baseline to 1-year follow-up. The treatment effect sizes (Cohen's *d*) ranged from small to large. Specifically, for pain it was small in the IE condition and medium in DR condition; for depression, it was small in both conditions; for disability, it was medium in both conditions; and for medication, it was large in both conditions. The mean effect size for the four outcome measures was 0.64 (range: 0.42–1.00) (medium range).

3.5 Reliable change estimates

The mean proportion of cases reliably improved over 1 year (on all outcome measures) was just over one-third in both conditions. In the IE condition, a mean of 35% of cases improved reliably (range across measures: 30–39%), versus 35% (range: 25–50%) for the DR condition. Conversely, the mean proportion of cases that reliably deteriorated was 3% (range: 0–7%) in the IE condition, versus 4% (range: 2–10%) in the DR condition.

3.6 Changes in threat value of pain

Significant changes (improvements) in mean scores were found on all threat measures, from pretreatment to 1-year follow-up, for both conditions (see Table 3), but there were no differences between conditions. Effect sizes for both conditions were medium for fear-avoidance and large for catastrophizing, pain self-efficacy and pain acceptance. Overall, the mean effect size for the four measures was 0.92 (range: 0.67–1.10).

3.7 Effects associated with consistent adherence to attentional strategies

Consistent adherence to the attention strategies was 42 (61%) in the IE condition versus 38 (51%) in the DR condition. To evaluate the relative outcomes of the adherers to the attentional strategies, for both conditions, *post hoc* per protocol (PP) analyses that repeated the MMRM approach used in the ITT analyses were conducted. The results (see Table 4) mirror those found in the ITT analyses (Table 2); significant effects for time were found on all outcome variables for both conditions, with no differences between conditions. However, effect sizes for the consistent adherers from both conditions were higher than for the full sample in each condition (Table 2) on all outcome variables; mean of 0.85 (high range) versus 0.64 for the full sample. In contrast, the mean effect size on the outcome measures for the low adherers was 0.62 (medium range).

These results suggest clear advantages for adherence to the attention strategies during treatment and they were still present for outcomes at 1-year post-treatment. However, a slightly different picture emerges when the adherence groups are compared on

Table 2 Mean and standard deviations of outcome variables (from pretreatment to 1-year follow-up) and level of significance (mixed-effects model repeated measure intention-to-treat analyses).

Variable	Interoceptive Exposure Mean (SD)	Distraction Mean (SD)	Overall least mean difference between the two groups (95% CI)	Level of significance
Pain intensity (MPI) (0–6)			0.03(–0.27 to 0.35)	$p = 0.82$
Pretreatment	4.15 (1.02)	4.01 (1.02)		
Post-treatment	3.69 (1.18)	3.62 (1.20)		
1-month follow-up	3.50 (1.31)	3.37 (1.41)		
6-month follow-up	3.46 (1.47)	2.93 (1.63)		
12-month follow-up	3.02 (1.42)	2.96 (1.55)		
Overall LS mean change (95% CI)	–0.51(–0.73 to –0.28)	–0.55 (–0.76 to –0.33)		
t value and *p*	–4.41; $p = 0.001$	–5.05; $p = 0.001$		
Effect size (95% CI)	–0.50 (–0.8 to –0.20)	–0.54 (–0.82 to –0.25)		
Depression (DASS) (0–42)			–1.40 (–3.68 to 1.59)	$p = 0.43$
Pretreatment	19.70 (11.58)	18.66 (11.65)		
Post-treatment	11.39 (9.89)	12.36 (10.65)		
1-month follow-up	13.11 (10.73)	14.97 (13.01)		
6-month follow-up	14.60 (12.30)	12.20 (12.53)		
12-month follow-up	12.50 (10.97)	12.56 (12.17)		
Overall LS mean change (95% CI)	–5.92 (–7.83 to –4.01)	–4.87 (–6.69 to –3.05)		
t value and *p*	–6.53; $p = 0.001$	–5.30; $p = 0.001$		
Effect size (95% CI)	–0.50 (–0.80 to –0.21)	–0.42 (–0.70 to –0.13)		
Disability (mRMDQ) (0–24)			–0.31 (–1.72 to 1.08)	P = 0.65
Pretreatment	13.22 (5.65)	12.73 (4.96)		
Post-treatment	9.87 (6.22)	9.46 (6.14)		
1-month follow-up	8.64 (5.78)	9.13 (6.69)		
6-month follow-up	8.97 (6.11)	8.06 (5.94)		
12-month follow-up	8.33 (5.93)	9.47 (6.71)		
Overall LS mean change (95% CI)	–3.40 (–4.42 to –2.37)	–3.07 (–4.04 to –2.11)		
t value and *p*	–6.57; $p = 0.001$	–6.34; $p = 0.001$		
Effect size (95% CI)	–0.64 (–0.94 to –0.34)	–0.58 (–0.86 to –0.30)		
Total medication (0–9)			0.09 (–0.17 to 36)	$p = 0.48$
Pretreatment	2.48 (1.47)	2.72 (1.80)		
Post-treatment	0.90 (0.98)	1.12 (1.35)		
1-month follow-up	1.09 (1.06)	1.16 (1.23)		
6-month follow-up	0.85 (1.46)	0.71 (1.77)		
12-month follow-up	0.91 (1.24)	0.80 (1.25)		
Overall LS mean change (95% CI)	–1.58 (–1.78 to –1.39)	–1.68 (–1.86 to –1.49)		
t value and *p*	16.08; $p = 0.001$	17.92; $p = 0.001$		
Effect size (95% CI)	1.01 (0.76–1.42)	1.00 (0.74–1.38)		

CI, confidence interval; DASS, DASS, Depression scale of the Depression Anxiety Stress Scales; MPI, Multidimensional Pain; mRMDQ, modified Roland–Morris Disability Questionnaire.

RCI thresholds at post-treatment and 1-year follow-up. *Post hoc* tests of significance for proportions (Ferguson and Takane, 1989) revealed that, relative to low adherers, a larger proportion of high adherers achieved the mean RCI for the different outcome measures at post-treatment (49% vs. 30%, respectively, $z = 2.02$; $p < 0.05$). However, for pretreatment to 1-year follow-up, the difference was less (42% vs. 33%, respectively, $z = 0.23$, non-significant), suggesting a loss of effect over time.

Adherence to the attentional strategies was also associated with higher effect sizes on threat measures from pretreatment to 1-year follow-up. The mean effect size for high adherers on threat measures was 1.10 (range: 0.7–1.39) versus 0.65 (range: 0.39–1.09) for low adherers. However, (*post hoc*) analyses of differences in the proportion of patients from the two adherence groups achieving threshold levels for mean RCIs on the threat measures revealed a pattern similar to that found with the outcome measures. Specifically, a significantly greater proportion of high adherers achieved the RCI threshold compared to the low adherers at post-treatment (61% vs. 42%, respectively, $z = 2.22$; $p < 0.05$), but not at 1-year

Table 3 Mean (standard deviation) of threat-value measures across time (pretreatment to 1-year follow-up) and levels of significance (mixed-effects model repeated measure intention-to-treat analyses).

Variable	Interoceptive exposure Mean (SD)	Distraction Mean (SD)	Overall least mean difference between the two group (95% CI)	Level of significance
Fear avoidance (TSK)			–0.25 (–2.27 to 2.32)	$p = 0.98$
Pretreatment	40.37 (8.67)	40.55 (9.14)		
Post-treatment	33.19 (9.72)	33.25 (9.57)		
1-month follow-up	32.38 (8.22)	33.53 (10.75)		
6-month follow-up	34.93 (8.74)	34.29 (11.26)		
12-month follow-up	34.47 (9.13)	33.13 (9.63)		
Overall LS mean change (95% CI)	–6.01 (–7.67 to –4.34)	–6.30 (–7.61 to –4.46)		
t value and *p*	–7.14; $p = 0.001$	–7.57; $p = 0.001$		
Effect size (95% CI)	–0.67 (–0.96 to –0.37)	–0.67 (–0.95 to 0.38)		
Pain self-efficacy (PSEQ)			1.09 (–2.75 to 4.94)	$p = 0.57$
Pretreatment	25.81 (11.26)	23.49 (12.05)		
Post-treatment	39.55 (12.09)	36.38 (16.23)		
1-month follow-up	37.81 (13.52)	34.53 (14.98)		
6-month follow-up	36.78 (15.36)	39.53 (13.63)		
12-month follow-up	37.85 (13.82)	38.05 (15.67)		
Overall LS mean change (95% CI)	11.67 (8.88–14.25)	10.57 (7.93–13.22)		
t value and *p*	8.29; $p = 0.001$	7.90; $p = 0.001$		
Effect size (95% CI)	1.00 (0.67–1.32)	0.90 (0.60–1.21)		
Catastrophizing (PRSS)			0.02 (–0.34 to 0.31)	$p = 0.92$
Pretreatment	3.03 (0.95)	3.04 (0.99)		
Post-treatment	2.24 (1.21)	2.15 (1.32)		
1-month follow-up	1.79 (1.11)	2.04 (1.28)		
6-month follow-up	1.91 (1.18)	1.88 (1.36)		
12-month follow-up	1.81 (1.19)	1.67 (1.24)		
Overall LS mean change (95% CI)	–0.94 (–1.18 to –0.70)	–0.93 (–1.15 to –0.69)		
t value and *p*	–7.80; $p = 0.001$	–8.04; $p = 0.001$		
Effect size (95% CI)	–0.98 (–1.27 to –0.69)	–0.96 (–1.24 to –0.68)		
Acceptance (CPAQ)			0.48 (–5.10 to 6.06)	$p = 0.86$
Pretreatment	44.67 (16.42)	43.11 (16.14)		
Post-treatment	61.52 (16.16)	59.32 (17.65)		
1-month follow-up	66.38 (17.10)	59.50 (23.60)		
6-month follow-up	65.48 (19.69)	67.62 (22.70)		
12-month follow-up	68.50 (22.10)	65.85 (21.74)		
Overall LS mean change (95% CI)	17.02 (13.10 to –21.40)	16.54 (12.69–20.40)		
t value and *p*	8.41; $p = 0.001$	8.50; $p = 0.001$		
Effect size (95% CI)	1.10 (0.76–1.43)	1.10 (0.75–1.38)		

CI, confidence interval; CPAQ, Chronic Pain Acceptance Questionnaire; PSEQ, Pain Self-Efficacy Questionnaire; PRSS, Pain Response Self-Statements Scale; TSK, Tampa Scale for Kinesiophobia.

follow-up (57% vs. 39%, respectively, $z = 1.63$, non-significant).

To check if there was a relationship between adherence to the attention strategies and the other self-management strategies, chi-square analyses indicated that consistent use of the attention strategies was also significantly ($p < 0.01$) associated with consistent use of the other strategies measured (data not shown). This suggests that there is a relationship between adherence to the attention strategies and the other strategies; high adherers to the attention strategies also adhered to the other strategies.

3.8 Motivational contributors to adherence to attention strategies

Willingness to adhere to a particular attention strategy may depend on motivation (Van Damme et al., 2010).

Table 4 Mean and standard deviations of outcome measures across time (pretreatment to 1-year follow-up) and levels of significance for high adherers to the attentional strategies in both conditions (mixed-effects model repeated measure per protocol analyses).

Variable	Interoceptive exposure Mean (SD)	Distraction Mean (SD)	Overall least mean difference between the two group (95% CI)	Level of significance
Pain intensity (MPI) (0–6)			0.22 (–0.26 to 0.71)	$p = 0.36$
Pretreatment	4.13 (0.95)	3.69 (1.07)		
Post-treatment	3.52 (1.21)	3.29 (1.08)		
1-month follow-up	3.30 (1.24)	2.91 (1.29)		
6-month follow-up	3.38 (1.51)	2.37 (1.48)		
12-month follow-up	3.18 (1.30)	2.61 (1.56)		
Overall LS mean change (95% CI)	–0.56 (–0.93 to –0.19)	–0.78 (–1.09 to –0.48)		
t value and *p*	–3.05; $p = 0.003$	–5.11; $p = 0.001$		
Effect size (95% CI)	–0.55 (–0.99 to –0.11)	–0.77 (–1.15 to –0.39)		
Depression (DASS) (0–42)			1.34 (–1.38 to 4.07)	$p = 0.32$
Pretreatment	17.78 (11.6)	16.71 (12.21)		
Post-treatment	10.00 (9.26)	9.05 (8.86)		
1-month follow-up	10.81 (9.10)	10.48 (10.27)		
6-month follow-up	13.04 (10.65)	8.03 (9.14)		
12-month follow-up	9.60 (7.57)	8.30 (9.02)		
Overall LS mean change (95% CI)	–5.54 (–7.60 to–3.47)	–6.88 (–8.66 to –5.10)		
t value and *p*	–5.39; $p = 0.001$	–7.75; $p = 0.001$		
Effect size (95% CI)	–0.76 (–1.19 to –0.33)	–0.94 (–1.32 to –0.56)		
Disability (mRMDQ) (0–24)			0.74 (–1.21 to 2.70)	$p = 0.45$
Pretreatment	12.41 (5.42)	11.56 (4.36)		
Post-treatment	8.33 (5.58)	7.28 (5.53)		
1-month follow-up	8.00 (5.72)	6.57 (5.02)		
6-month follow-up	9.00 (6.82)	5.96 (4.41)		
12-month follow-up	8.45 (6.66)	8.34 (6.23)		
Overall LS mean change (95% CI)	–3.47 (–5.23 to –2.25)	–4.48 (–5.76 to –3.20)		
t value and *p*	–5.05; $p = 0.001$	–7.04; $p = 0.001$		
Effect size (95% CI)	–0.78 (–1.21 to –0.33)	–0.93 (–1.31 to –0.55)		
Total medication (0–9)			0.04 (–0.42 to 0.50)	$p = 0.86$
Pretreatment	2.33 (1.33)	3.01 (1.90)		
Post-treatment	0.74 (0.85)	1.13 (1.37)		
1-month follow-up	0.75 (0.79)	1.22 (1.38)		
6-month follow-up	1.22 (1.21)	0.97 (1.35)		
12-month follow-up	1.11 (1.28)	0.92 (1.28)		
Overall LS mean change (95% CI)	–1.77 (–2.11 to –1.42)	–1.81 (–2.10 to –1.51)		
t value and *p*	–10.2; $p = 0.001$	–12.3; $p = 0.001$		
Effect size (95% CI)	–1.03 (–1.45 to –0.61)	–1.05 (–1.43 to –0.68)		

CI, confidence interval; DASS, Depression scale of the Depression Anxiety Stress Scales; MPI, Multidimensional Pain Inventor; mRMDQ, modified Roland–Morris Disability Questionnaire.

For example, high catastrophizers might engage less in distraction (Van Damme et al., 2006, 2008, 2010). To examine this, patients in both conditions were divided into high versus low catastrophizing using the median score (3/5) for the total sample at pretreatment as the cut-point (i.e., the 65th percentile on this scale from our normative dataset; Nicholas et al., 2008). No significant differences were found between attention conditions on baseline catastrophizing ($t = 0.015$; $p = 0.98$), and no significant differences were found between the two conditions in the distribution (frequency) of high versus low catastrophizing scores ($\chi^2 = 0.086$; df = 1; $p = 0.45$). Similarly, there were no significant differences between both conditions in proportion of high versus low adherers to the attention strategies ($\chi^2 = 0.61$; df = 1; $p = 0.36$). Pre- to post-treatment changes on the outcome and threat measures were compared with paired sample *t*-tests for the

high catastrophizers in both conditions and low catastrophizers in both conditions (data not shown). No significant differences were found between treatment conditions on any change score for both high and low catastrophizing groups, suggesting that the level of catastrophizing made no difference to the effect of either IE or distraction. Similar analyses were conducted for fear-avoidance (TSK) (high vs. low), but the results were the same. These findings suggest that motivational value of pain, as reflected in the levels of catastrophizing and fear-avoidance, made no contribution to either adherence to the attention strategies or treatment responses in this study.

4. Discussion

This study tested whether combined behavioural and cognitive exposure to pain could achieve better outcomes than behavioural exposure and distraction (from pain) in chronic pain patients. The results, to 1-year post-treatment, revealed significant improvements for both treatments on measures reflecting the threatening nature of pain. Similarly, sustained improvements were also found in pain, disability, depression and medication use. However, there were no significant differences between treatments. Mostly, medium to large treatment effect sizes across key outcomes were found, as well as reliable gains by 35% of all patients in both conditions, versus deterioration in 3–4%. Treatment effect sizes were greater for those who adhered to their attentional strategy (regardless of direction). Overall, the study confirms the effectiveness of the programme, with outcomes better than the median reported in the Cochrane review reported by Eccleston et al. (2009).

Before discussing the theoretical and clinical implications of these findings, the strengths and limitations of this study should be acknowledged. The strengths include most of the recommended features for trials of psychological interventions in pain research (Yates et al., 2005), including the use of a treatment manual and highly skilled staff, evaluation of treatment validity and assessment of active engagement by patients. Also, we evaluated outcomes with an intention to treat analysis using an MMRM rather than a LOCF approach, as well as using conventional inferential statistical tests, effect sizes and proportions of patients who made reliable changes on outcome measures (Lambert et al., 2008; Morley et al., 2008).

The main limitation was not controlling for the possible effects of time or therapists' attention. While these cannot be excluded, all patients had long histories of previous treatment failures. Also, as ADAPT was based closely on a programme already demonstrated as more efficacious than treatment as usual (Williams et al., 1996), the value of a similar control is doubtful. Furthermore, on a pragmatic level, about 70% of the patients recruited were funded by insurance companies who would not support participation in a control condition.

The lack of objective outcome measures may have biased our results, but self-report is the only option for measures of pain and depression. Also, the disability measure has strong reliability and validity properties (Jensen et al., 1992; Asghari and Nicholas, 2001). Observation of performance during treatment did contribute to the adherence assessment and this had a consistent relationship to the self-reported changes in pain, depression, disability and medication use. These findings are consistent with those we previously published using a different sample, suggesting the method is replicable (Nicholas et al., 2012). No doubt, the adherence measure could be improved, but the available options are limited (Curran et al., 2009).

We may also have underestimated the sample size required to test the hypothesis. However, our power calculations indicated that 88 participants would have sufficed, and we added another 52. Interestingly, the sample was large relative to other studies in this area (see Eccleston et al., 2009) and a higher number would suggest that the effects of cognitive exposure versus distraction are so small that they are of limited clinical significance. We would also note that the similar study on CBT + IE versus CBT + stress management with IBS patients (Craske et al., 2011) used a smaller sample ($n = 88$). Overall, there are grounds for having reasonable confidence in our findings.

The study has a number of theoretical and clinical implications. Broadly, the results are consistent with the FAM (Vlaeyen and Linton, 2012). Specifically, consistent with the findings of Smeets et al. (2006) and Turner et al. (2007), reductions in the threat value of pain were associated with improved mood, less pain and reduced disability. However, our findings do not support the hypothesis that the effectiveness of behavioural exposure methods may be undermined by the simultaneous use of cognitive avoidance (Boersma et al., 2004; Van Damme et al., 2006). Adherent patients in both conditions improved equally, and they performed previously avoided activities, a central feature of behavioural exposure methods (de Jong et al., 2005).

It is possible that the behavioural exposure tasks (which included multiple activities targeted simultaneously) in the present study were not equivalent to

the specific behaviours targeted in the studies by Boersma et al. and de Jong et al., but the underlying principles are the same. It is also possible that the lower mean TSK scores in the present study, relative to those in the Boersma et al. study in particular, may have contributed to the null finding (i.e., pain may have represented less of a threat to be avoided in our study). Against that, 92% of our sample was taking drugs to avoid pain, and mean catastrophizing and TSK scores were moderately high. If TSK scores of >33 reflect at least moderate fear of movement/(re)injury (Leeuw et al., 2007), that would represent 82% of our sample.

As both treatments had equal effects on the threat value of pain, it could be argued that either attentional strategies add nothing, but without a programme that excludes both, this remains speculative. Alternatively, they share some common feature that accounts more for their effects than their ostensible natures. Given that the adherence results were obtained only from those adhering to attentional strategies, it seems more likely that both share some common features. One possibility is that the adherent patients in both groups could have effectively activated positive rather than negative representations of their pain. Brewin (2006) proposed this as a core element that could account for the effects of different versions of CBT in many clinical conditions. Another possibility is that adherence to either method enhanced a belief in ability to control pain. Vancleef and Peters (2011) found this belief promoted greater pain relief in experimental settings, while Tan et al. (2002) reported similar findings for reduced disability in chronic pain patients. It is also possible that both strategies allowed patients to disengage from their pain, as proposed by McCracken et al. (2007) as a key element in acceptance-based methods. Also, as both conditions emphasized remaining active despite pain, it could be argued they had a similar degree of exposure to the feared stimulus anyway (De Peuter *et al*., 2011).

The lack of difference between treatment outcomes may also cast doubt on the clinical applicability of results from some laboratory studies (with experimental pain) (Villemure and Bushnell, 2002; Van Bockstaele et al., 2010). Questions may also be raised about acceptance-based approaches, which target experiential avoidance (Hayes et al., 1999; McCracken et al., 2007) by not trying to control or avoid pain while engaging in desired activities. This approach could be considered analogous to the IE condition. From both the acceptance and the FAM perspectives, IE should have been more effective than distraction. That this was not found suggests that the use of acceptance methods within pain rehabilitation programmes may not be as important as the combination of an effective 'anti-catastrophizing' cognitive strategy and behavioural exposure aimed at achieving desired goals, as in the present study and others (Wideman et al., 2009).

Consistent adherence to the attentional strategies was strongly associated with consistent adherence to the other self-management strategies taught. Like relaxation training in pain management (Kerr, 2000), attentional strategies alone are unlikely to be sufficient to achieve meaningful changes (Linton et al., 2008). However, there may be synergistic effects between the components of CBT programmes and such contextual aspects need to be considered when determining the necessary components in these programmes (e.g., Eccleston et al., 2003; Morley, 2011).

Our findings suggest that chronic pain patients may be offered both attention strategies to trial within a treatment package. They could select whichever worked best for them and when (see Elliott and Eccleston, 2003; Elomaa et al., 2009). In reality, many chronic pain patients will probably do this anyway (Buck and Morley, 2006). While our findings indicate that at the group level it may not matter which method is used (providing it is used consistently), some studies have suggested it might matter at the individual level. For example, Van Damme et al. (2008) found that high catastrophizing reduced adherence to distraction. That we did not find this might be explained by evidence that higher motivation to achieve a goal can inhibit the effect of catastrophizing (Verhoeven et al., 2010). Van Damme et al. (2010) also concluded that differences in motivation for goal pursuit may explain differences in attentional processes. That point may also partly explain the differential adherence we found. Although we did not assess goal motivation directly, all patients were expected to have personally meaningful goals, but their value probably varied.

Overall, our findings echo the recommendations of Turk and Rudy (1991) and suggest that future pain treatment research should investigate methods for increasing adherence to the more consistent use of pain self-management strategies. Vong et al. (2011), e.g., recently found that that motivational enhancement can improve outcomes in pain rehabilitation. This would be consistent with the case argued by Van Damme et al. (2010) and Verhoeven et al. (2010). Other options might include improving preparation for these interventions and reinforcement for participation by key stakeholders (Newton-John and Geddes, 2008).

Author contributions

All authors made substantial contributions to the development of the study, its design, data acquisition and interpretation of data. All authors discussed the results, and commented on the manuscript. All authors were therefore significantly involved in drafting and revising the manuscript and approved the final version of the manuscript.

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