

Effect of Visual Feedback During Ultrasound-Guided Interfascial Injection for Myofascial Pain Syndrome: A Prospective, Multicenter, Observational Clinical Trial

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Abstract

Background: Expectations for treatment have a favorable effect on the subsequent course of pain and behavior in patients. It is not known whether receiving interfascial injection while patients view their ultrasound image with doctors (visual feedback) is associated with positive treatment expectations.

Methods: This was a prospective, multicenter, observational clinical trial. We evaluated whether visual feedback during ultrasound-guided interfascial injection affects treatment expectations and the subsequent course of pain in patients with myofascial pain syndrome. Treatment expectations were set as mediators of pain using path analysis. The primary endpoint was the proportion of patients who showed improvement in pain numerical rating scale score by 50% or more 14 days after initiation of treatment.

Results: During 2019 and 2020, 136 outpatients received ultrasound-guided interfascial injection for myofascial pain syndrome. Of these, 65 (47.8%) patients received visual feedback during ultrasound-guided interfascial injection. Compared with the non-visual feedback group, the visual feedback group had higher expectations for treatment, immediately after interfascial injection, and their expectations were maintained at day 14 of treatment ($p < .001$). In the visual feedback group, 67.7% of patients showed improvement in pain numerical rating scale score by 50% or more at day 14 (95% confidence interval: 56.5–78.9), whereas such improvement was observed in only 36.6% of the non-visual feedback group (95% confidence interval: 25.3–47.9; $p < .001$). Path analysis revealed that visual feedback had the largest influence on pain numerical rating scale reduction at 14 days, which was indirectly via higher expectations for treatment ($\beta = 0.434$).

Conclusions: Visual feedback during ultrasound-guided interfascial injection had a positive effect on the subsequent course of pain in patients with myofascial pain syndrome by increasing patients' treatment expectations.

Trial registration: UMIN000043160. Registered 28 January 2021 (registered retrospectively).

Background

According to the United States Centers for Disease Control and Prevention, the three main conditions that cause daily life disability are heart disease, arthritis, and chronic back pain [1]. Myofascial pain syndrome (MPS) is a non-inflammatory syndrome that presents with symptoms of muscle pain and limited range of joint motion. MPS occurs in 11.9–44.8% of patients who complain of back pain [2, 3]. There is currently no standard treatment for patients with MPS [4]. Clinically available treatments are trigger point injections of a local anesthetic and dry needling [5, 6].

Ultrasound-guided interfascial injection (IFI) has recently been receiving increased attention as a therapy for treating MPS [7, 8]. In ultrasound-guided IFI, doctors use ultrasound to inject a drug solution into the interfascial space (including subcutaneous tissue, epimysial space, the space between the periosteum

and fascia, and the periphery of tendon) at the site where patients feel the most severe pain. The site is located at the periphery of the muscle diagnosed with MPS. The mechanism underlying the clinical efficacy of the method is unclear; however, pressure stimulation with drug solution injection, washout of pain-inducing substances, and acid-induced stimulation of acid sensing channels have been suggested.

We previously reported that MPS is a clinical symptom of psychosomatic disorder that occurs in approximately half of cancer patients. The results from a randomized controlled study suggested that biofeedback therapy, a psychosocial approach, is helpful in the treatment of MPS in cancer patients [9]. Clinically, visual feedback during ultrasound-guided IFI is expected to be effective as psychosocial approaches, whereby patients raise their expectations for treatment through real-time viewing of their ultrasound image (during the removal of fascial adhesions by saline injection) with doctors while receiving IFI. However, to date, there have not been any studies that have investigated whether visual feedback during ultrasound-guided nerve blocks, such as IFI, is effective as a psychosocial approach.

Expectations for treatment have a favorable effect on the subsequent course and behavior in patients. A systematic review has suggested that positive expectations for treatment are related to good health outcomes [10]. Furthermore, expectations for treatment have shown to play an important role in the placebo effect [11]. A previous study reported that positive expectations for pain treatment has a positive effect on the subsequent course of pain and behavior in patients [12].

We hypothesized that visual feedback would raise patients' expectations for pain treatment during ultrasound-guided IFI, which will lead to positive effects on the subsequent course of pain. To the best of our knowledge, there have not been any reports that have investigated the effect of visual feedback during ultrasound-guided IFI for MPS. Therefore, the aim of this study was to establish ultrasound-guided IFI as a therapeutic method by evaluating the effects of visual feedback during ultrasound-guided IFI.

Methods

Study design

This study was a prospective observational study that evaluated whether visual feedback during ultrasound-guided IFI influences the subsequent course of pain in patients with MPS, with expectations for treatment as a mediator. Visual feedback was defined as IFI administration while patients viewed the ultrasound image with their doctor.

Study Participants And Eligibility Criteria

This study was conducted from March 2019 to March 2020 at two facilities in Japan: Kansai Medical University Hospital and Omotesando Pain Clinic. During this period, we continuously enrolled outpatients who received ultrasound-guided IFI for MPS of the upper back. MPS was diagnosed based on the following criteria: 1) a tender spot located with palpation, with or without referral of pain; 2) recognition of

symptoms by the patient during palpation of the tender spot; and 3) at least three of the following: a) muscle stiffness or spasm, b) limited range of motion (ROM) of an associated joint, c) pain worsening with stress, and d) palpation of a taut band and/or nodule associated with the tender spot [13]. Diagnoses of MPS required careful manual examination, which is considered highly reliable [14]. The upper back was defined as the region below the neck and above the costal margin [15].

The exclusion criteria were: (1) patients who were younger than 20 years and (2) patients who had any comorbid psychiatric disease or condition that made communication difficult, such as cognitive impairment or delirium.

Intervention

IFIs (5 mL saline per injection) were administered by a doctor at each institution to four bilateral upper and lower sites at the boundary between the levator scapula and trapezius muscle. Doctors used ultrasound to confirm the following points in real-time: 1) boundary between the levator scapula and trapezius muscle; 2) position of the needle tip; 3) saline injection; and 4) removal of the fascia. A single IFI session was performed on the day of intervention.

Before starting treatment, a doctor at each institution verbally explained the ultrasound-guided IFI procedure (i.e., points 1) to 4) above) to the patients. Patients were then asked whether they would like to request to view the real-time ultrasound images during the procedure. The merits and demerits of visual feedback were not shared with the patients. Patients who viewed the real-time ultrasound images were defined as the visual feedback group, and patients who did not view the real-time ultrasound images were defined as the non-visual feedback group. Both groups spent equal amounts of time in each session. After the ultrasound-guided IFI, patients were instructed to perform two 3-minute sessions of a self-stretching exercise (right-left cervical rotation) per day. Assessments were carried out by a doctor in the outpatient department or clinic of each institution on the following days: before intervention (T0), the day of the IFI (T1), and 14 days after the IFI (T2).

Measures

Clinical demographic characteristics

Clinical demographic information was obtained from all subjects and included age, sex, institution (hospital or clinic), primary illness (cancer or non-cancer), pain numerical rating scale (NRS) before the IFI, NRS to assess expectations for treatment before IFI, and analgesic drug use.

Measures of pain intensity and criterion for pain reduction

Average pain intensity was assessed using an 11-point NRS for pain, which ranged from 0 (no pain) to 10 (worst possible pain) [16]. The questionnaire was self-administered and contained the following question:

“How intense was your average pain over the past 24 hours?” For patients with multiple MPS sites, we used the average pain NRS score. For pain at T1, pain intensity was evaluated as pain at the time. The reliability and validity of this scale have been established previously [17]. The criterion for pain reduction was determined as $\geq 50\%$ improvement in pain NRS score after the intervention. The optimal cut-off point for NRS rate of change has been reported to be 50% when determining the proportion of patients with clinically significant pain improvement [18].

Measures of expectations for treatment and criteria for increased expectations

Expectation intensity was determined using an NRS to assess expectations for treatment, which ranged from 0 (no expectations) to 10 (highest expectations). The questionnaire was self-administered and contained the following question: “How well do you expect this treatment to reduce pain?” The validity of this questionnaire is not clear, but it has frequently been used in research [10, 12]. The criterion for increased expectations was determined as an NRS score ≥ 8 or $\geq 33\%$ improvement in NRS score for expectations for treatment after IFI.

Measures of cervical ROMs

Cervical ROM for flexion, extension, lateral flexion, and rotation were measured using a goniometer (TAKUMED, Kyoto, Japan), which is an objective and reliable method [19]. All measurements were obtained by one doctor at each institution.

Outcomes

The primary endpoint was the proportion of patients who showed an improvement in pain NRS score by $\geq 50\%$ at 14 days after ultrasound-guided IFI, between patients with and without the visual feedback. The secondary outcomes were NRS score change for expectations for treatment and pain, cervical ROM, correlation between increased expectations and pain NRS reduction using path analysis, and adverse events.

Sample Size Calculation

Because previous studies on this subject are limited, sample size calculation was performed based on reports using similar therapeutic methodologies [2, 5–8]. We assumed that the response rates of IFI with and without visual feedback are 65% and 40%, respectively. The sample size required to achieve 80% statistical power at a 5% two-sided significance level was 62 patients per group, which was calculated using a chi-square test. Considering 10% rate of withdrawal, we determined a total sample size of 136 patients. The effective rate described here is the proportion of patients whose NRS scores reduced by $\geq 50\%$ after treatment.

Statistical analysis

Data are reported as means and standard deviations, medians with interquartile ranges, or frequencies (%), as appropriate. The proportion of study participants with visual feedback among all participants were estimated, including the exact 95% confidence intervals (95% CI). The rate of participants with pain reduction at 14 days after IFI for each group were estimated, including the exact 95% CI.

The study participants were classified into two groups: the visual feedback and non-visual feedback groups. Unpaired *t*-tests were used for comparisons of the dependent variables of age, pain NRS score before IFI, and NRS score for expectations for treatment before IFI. Pearson's chi-square tests were used to analyze the dependent variables of sex, institution, primary illness (cancer), and analgesic drug use.

The proportion of patients who showed $\geq 50\%$ improvement in pain NRS score at 14 days after intervention was analyzed using a chi-square test.

Changes in the course (T0, T1, and T2) of NRS scores for expectations for treatment, pain NRS scores, and cervical ROM scores were analyzed using one-way repeated measures analyses of variance (ANOVA) for each group. To conduct comparisons between groups, time course was used as the within-subjects factor and group was used as the between-subjects factor in a two-way repeated measures ANOVA. Multiple comparisons were corrected using the Bonferroni method. If participants withdrew from the study, NRS scores after withdrawal were substituted with scores immediately before withdrawal. Change in analgesic drug use during the period and loss to follow up were classified as withdrawals from the study.

Path analyses were conducted to estimate the direct and indirect paths with reference to correlation coefficients. A hypothetical model was created in which visual feedback, pain reduction at T1, expectations at T0, and increased expectation at T1 predicted pain reduction at T2. Visual feedback, age, analgesic drug use, NRS at T0, expectations at T0, pain reduction at T1, and increased expectations at T1 were mediators of increased expectations and pain reduction at T2. Figure 1 shows the hypothetical model (Akaike information criterion [AIC] = 116.832). Path analyses were performed by removing paths with $p < 0.05$, adjusting paths with reference to the modification index, repeating model correction while checking the goodness of fit index (GFI), and investigating correlations between factors specifying pain reduction at T2. To assess fit, we used model chi-square values, GFI, comparative fit index (CFI), root mean square error of approximation (RMSEA), and AIC. Smaller chi-square values, > 0.95 for GIF and CFI values, and ≤ 0.08 RMSEA values indicate good model fit [20]. The AIC was used to compare the hypothetical model with the modified model; a lower AIC value indicated a better model.

A value of $p < .05$ was considered statistically significant. Statistical analyses were performed using SPSS version 25.0 and Amos version 25.0 for Macintosh (SPSS, Inc., IBM, Chicago, IL, USA).

Results

Number of registered study participants

During the study period, 149 outpatients who received ultrasound-guided IFI for MPS were enrolled. Of these 149 outpatients, 13 patients were excluded for the following reasons: 1) aged < 20 years ($n = 5$) and 2) had a comorbid psychiatric disease or condition that made communication difficult ($n = 8$). A total of 136 patients were selected as study participants.

Clinical demographic characteristics

Of the 136 patients, 47.8% (95% CI: 39.4–56.2) received visual feedback during ultrasound-guided IFI. Patients were classified into the visual feedback ($n = 65$) or non-visual feedback ($n = 71$) groups. Table 1 shows the clinical demographic and characteristics of each group.

Ten patients withdrew from the study because of analgesic drug changes during the study period ($n = 3$) or loss to follow up ($n = 7$). Of these patients, four were in the visual feedback group and six were in the non-visual feedback group.

Between-group comparison of pain NRS score change

In the visual feedback group 67.7% of patients showed improvement in pain numerical rating scale score by 50% or more at day 14 (95% CI: 56.5–78.9), whereas such improvement was observed in only 36.6% in the non-visual feedback group (95% CI: 25.3–47.9; $p < .001$; Fig. 1). Overall, improvement was observed in 52.2% of patients (95% CI: 43.8–60.6).

Between-group comparison of NRS score change for expectations for treatment and pain

Compared with the non-visual feedback group, the visual feedback group had higher expectations for treatment immediately after IFI, and the higher expectations were maintained at day 14 ($p < .001$; Fig. 2). The comparison of NRS score change between groups showed a significant interaction between time course and group ($p < .001$). There was no significant difference for T1 between the two groups ($p = 0.186$). The visual feedback group showed a significant decrease in NRS score at T2 ($p < .001$; Fig. 2).

Within- and between-group comparisons of cervical ROM score change

In both groups, all measures of cervical ROM improved over time. There was a significant difference in time course between the two groups for right ($p = 0.028$) and left rotations ($p = 0.019$; Table 2).

Path diagram for the final model

The final model fit the data well (model chi-squared value = 0.001, CFI = 1.000, RMSEA = 0.000, and AIC = 26.001; Fig. 3). Visual feedback had the most influence on NRS reduction at T2 ($\beta = 0.356$). Furthermore, visual feedback had the largest influence on pain reduction at T2, indirectly through increased expectations for treatment after ultrasonic-guided IFI ($\beta = 0.434$). The adjusted R^2 values, which is the overall fit of the model, was 0.298.

Adverse events

There were no adverse events due to ultrasound-guided IFI. In addition, none of the patients in the visual feedback group experienced adverse events, such as feeling unwell.

Discussion

The first critical point of this study was the positive effect of visual feedback during ultrasound-guided IFI on expectations for treatment. Fifteen percent of psychosocial approach effects have been attributed to placebo effects which depend on patients' expectations for treatment [21]. To the best of our knowledge, this study is the first to investigate the effect of visual feedback during ultrasound-guided IFI as a psychosocial approach using a prospective observational study design. Placebo effects should be used actively as much as possible in clinical practice to improve patients' expectations for treatment and therapeutic outcomes [22].

In the visual feedback group, patients' expectations for treatment increased significantly immediately after the intervention. In a study on family caregivers of cancer patients, patients who became aware of comfort immediately after the introduction of relaxation had significantly higher expectations for treatment immediately after intervention compared with those of the control group [23]. Another study in advanced cancer patients with dizziness showed that awareness of muscle relaxation during hypnosis increased both expectation for treatment and implementation rate of self-care [24]. However, our study suggested that patients' expectations for treatment increased through awareness of vision during ultrasound-guided IFI.

In the visual feedback group, cervical ROM for rotation significantly improved in patients who were instructed to perform self-stretching exercises. However, other measures of cervical ROMs (flexion, extension, and lateral flexion) did not differ between patients who were and were not instructed to perform self-stretching exercises. These results indicated that in the visual feedback group, an increase in patients' expectation for treatment immediately after the intervention led patients to adhere more to self-stretching.

The second critical point was the effect of the visual feedback during ultrasound-guided IFI on the subsequent course of pain in MPS, which was mediated by increased expectations for treatment. The severity of upper back pain in MPS was 6.0 on the NRS, which reflects moderate pain [25]. At 14 days after ultrasound-guided IFI, there was a relatively high proportion of patients who achieved $\geq 50\%$ improvement in pain NRS scores. However, because there have not been any similar studies conducted previously, we cannot compare this result with other findings. One study reported that $\geq 50\%$ improvement in pain NRS score was observed in 48.8% of cancer patients with MPS, 1 week after receiving trigger point injections of a local anesthetic [2]. In our study we observed a 67.7% improvement rate in the visual feedback group, which is higher than the abovementioned study. Thus, visual feedback, a simple yet ingenious device, can offer considerable relief of moderate pain in patients with MPS, which

is of clinical significance. When considering the potential for an increase in subsequent analgesic effect on patients with MPS who request visual feedback treatment for upper back pain, our results may suggest evidence to recommend visual feedback treatment. Because our study was an observational study, negative effects could not be assessed for patients with MPS who received visual feedback treatment despite declining treatment.

Visual feedback had no direct effect on the subsequent course of pain. However, it had an indirect positive effect through increased expectations for treatment. We speculate that a placebo effect on pain in MPS patients was exerted by patients' expectations for treatment. A previous study reported that opioid-naïve cancer patients with high expectations for pain reduction before morphine treatment had significantly lower pain intensities at 7 days after treatment [12]. There have been two further reports that have indicated that the placebo effect is easily obtainable, particularly for pain in patients with MPS. One study investigated cancer patients with MPS [2], which showed that the proportion of cancer patients with MPS who also experienced psychological stress was 57.2%; the response rate to trigger point injection in these patients was significantly higher than that of cancer patients with MPS without psychological stress. The second study was based on MPS in family caregivers of cancer patients [26], which found that relative factors vary by back region and that MPS in the upper back is more easily affected by psychological stress. Therefore, the authors recommended psychosocial approaches for treating MPS in the upper back.

We also speculate that in the visual feedback group, the immediate increase in patients' expectations for treatment after the intervention increased the adherence rate of subsequent self-stretching, which resulted in MPS pain relief 14 days after the intervention. Efficacy of self-stretching on MPS in the plantar heel and stretching plus acupuncture on MPS in the upper back have been reported previously [27, 28].

The study has several limitations. First, self-selection bias was present because visual feedback was not allocated. Patients with high expectations for treatment may have requested visual feedback treatment. However, there was no significant difference between the two groups in NRS scores for expectations for treatment before IFI. Second, our results may not generalize to the general population because there was a large proportion of cancer patients. A recent review reported a high frequency of MPS in cancer patients [3]. Third, the timing of maximum effect and disappearance was obscure because of the two-point test (the day and 14 days after intervention). Even at 14 days after intervention, a more potent analgesic effect was probably attainable because patients' expectation for treatment remained high.

Conclusions

Visual feedback during ultrasound-guided IFI had an effect on the subsequent course of pain in patients with MPS, which was mediated by increased expectations for treatment.

Abbreviations

MPS
myofascial pain syndrome
IFI
interfascial injection
ROM
range of motion
NRS
numerical rating scale
95% CI
95% confidence intervals
ANOVA
analysis of variance
AIC
Akaike information criterion
GFI
goodness of fit index
CFI
comparative fit index
RMSEA
root mean square error of approximation

Declarations

Ethics approval and consent to participate

The study received approval from the Medical Ethics Committee of Kansai Medical University (reference number: 2018177). Informed consent was not obtained in this study because usual clinical practice was observed, including assessments and treatment. An opt-out method was used so that patients and their families could refuse to participate in the study. The procedures performed in this study were in accordance with the Declaration of Helsinki (as revised in 2013).

Consent for publication

Not applicable.

Availability of data and materials

The datasets analyzed in the current study are available from the corresponding author upon reasonable request.

Competing interest

The authors have declared that there is no conflict of interest.

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Author's contributions

HH was responsible for the conception and design of this study and wrote the article. HH and HO were responsible for data collection and for clinical evaluations. HH was responsible for data analysis. MF provided advice on the composition of the manuscript. All authors have approved the final version of this manuscript.

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Tables

Due to technical limitations, table 1 and 2 is only available as a download in the Supplemental Files section.

Figures

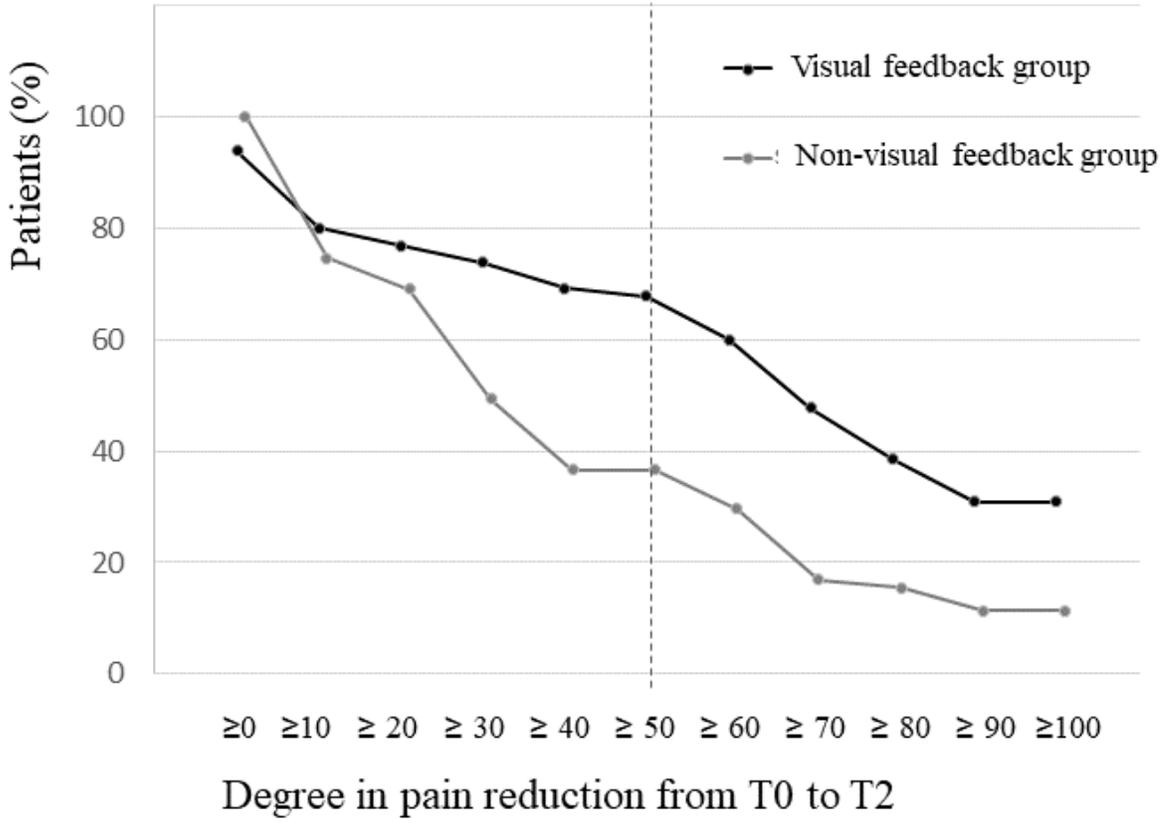


Figure 1

Between-group comparison of pain numerical rating scale score change

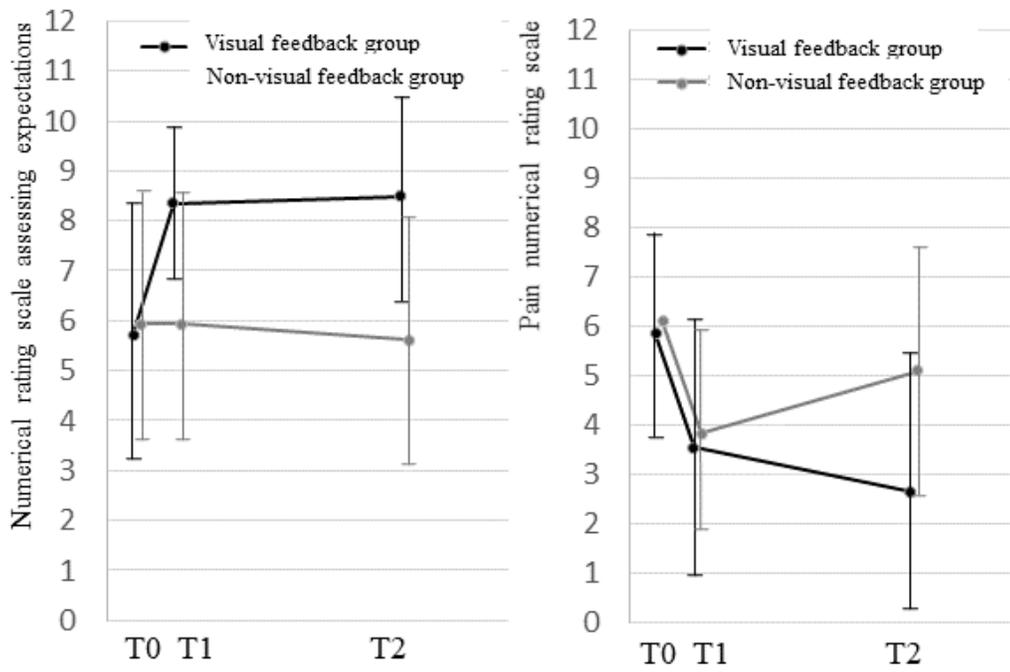


Figure 2

Between-group comparison of numerical rating scale score change for expectations for treatment and pain

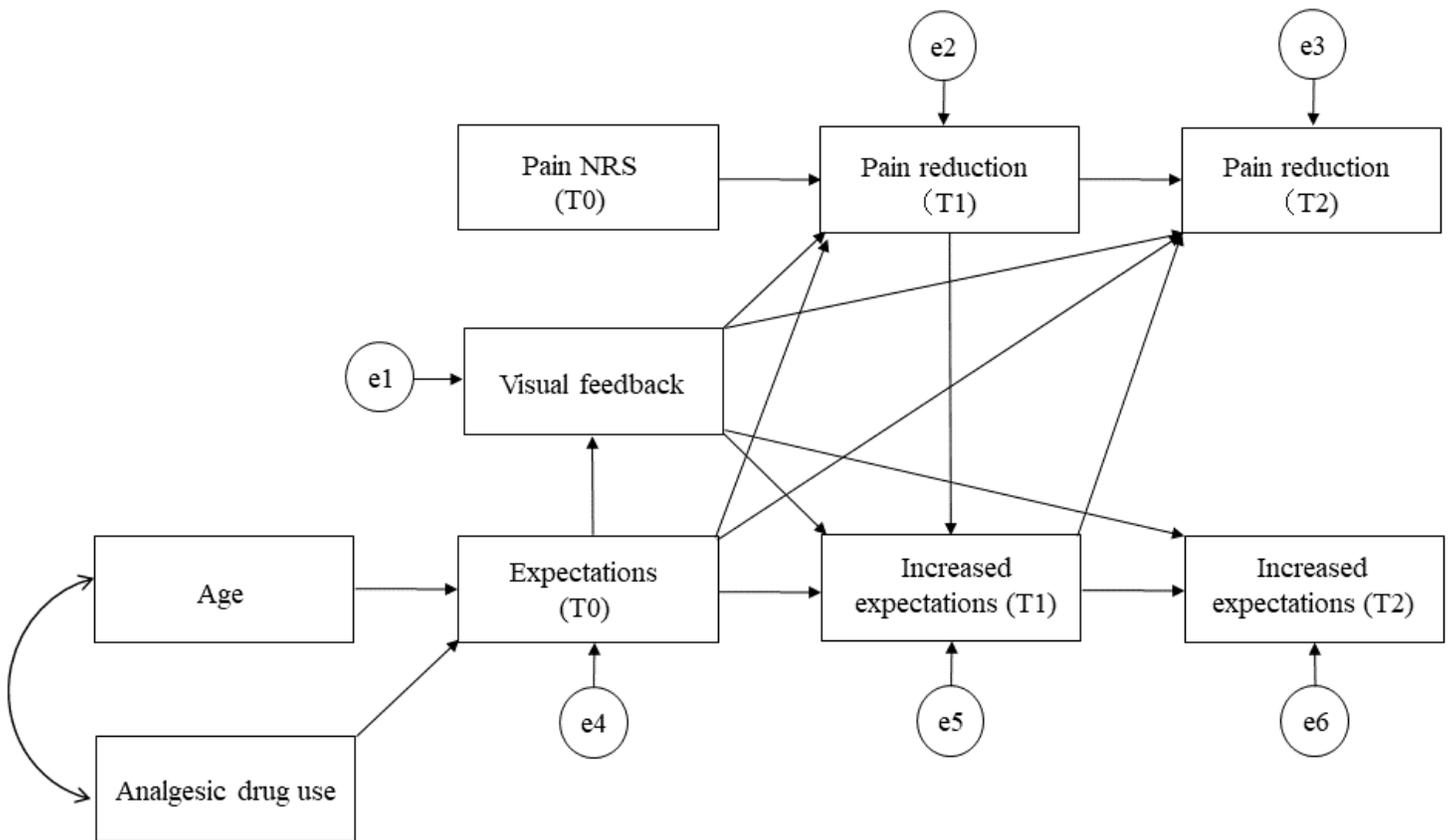


Figure 3

Path diagram for the hypothetical model

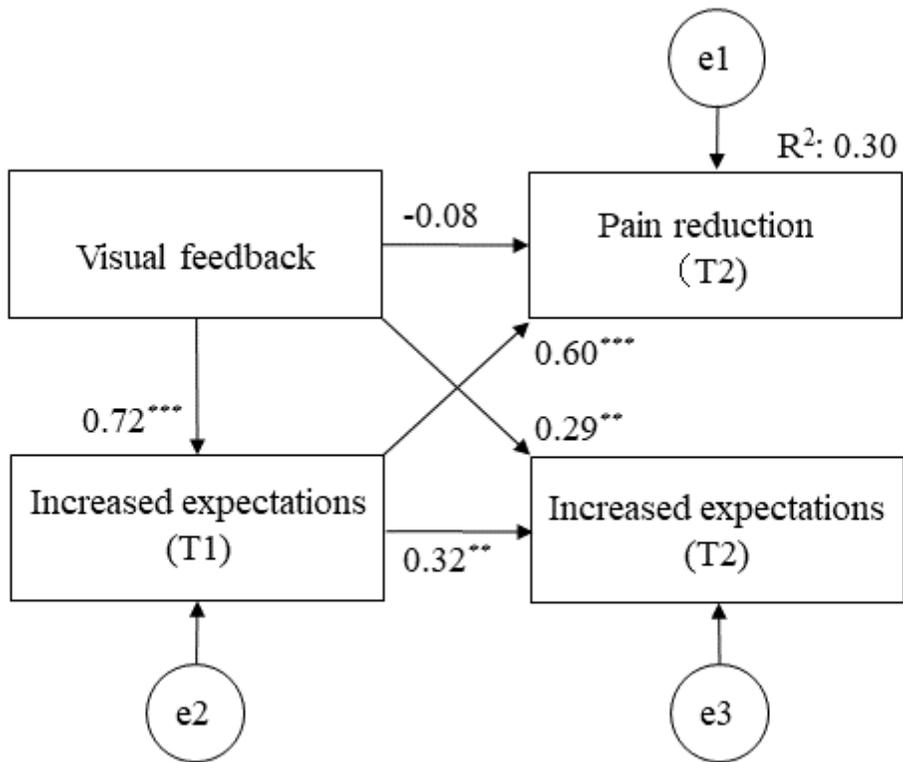


Figure 4

Path diagram for the final model

Supplementary Files

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