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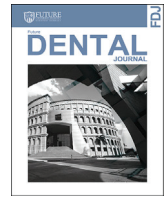
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Efficacy of Psychological Interventions in The Reduction of Orthodontic Pain at Its Peak of Intensity in Patients Undergoing Fixed Orthodontic Treatment: A Systematic Review and Meta- analysis

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ABSTRACT

Objectives: To investigate the efficacy of psychological interventions in the reduction of orthodontic pain at its peak of intensity.

Data sources: A search strategy was implemented using both manual hand search and electronic databases, including Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, ScienceDirect, Scopus and EBSCO.

Resources selection Randomized controlled trials involve 1) patients undergoing fixed orthodontic treatment 2) minimum age of 10 years old, 3) receiving a psychological intervention to control resulted pain and discomfort, 4) medically fit and 5) no previous orthodontic treatment, were included in the systematic review. All articles were checked against the inclusion and exclusion criteria independently and in duplicate by two authors. Risk of bias of the included trials was assessed using the Cochrane risk of bias tool.

Results: Only 7 RCTs met the inclusion criteria and were included in the final analysis. Meta-analysis showed a significant decrease in pain intensity in the cognitive behavioral therapy group, as compared to controls (mean difference [MD] -28.63 [95% confidence interval {CI} -34.24 to -23.02]), significant decrease in pain intensity in the structured phone calls group, when compared to controls (mean difference [MD] -7.55 [95% confidence interval {CI} -13.55 to -1.54]) and no difference in pain intensity between the text messages and control groups (mean difference [MD] -6.89 [95% confidence interval {CI} -17.08 to 3.31]).

Conclusions: Both 15 minutes self-practiced cognitive behavioral therapy and structured phone calls are effective non-pharmacological methods in the reduction of orthodontic pain after 24 hours of initial wire placement.

1. INTRODUCTION

One of the main disadvantages of orthodontic treatment is being lengthy, painful and expensive. Among these, pain is considered to be the major factor to cease treatment, discourage patients from treatment or affect their compliance.^[1,2] Approximately, one third of patients undergoing orthodontic treatment report pain as the major discouraging factor to discontinue treatment.^[2] Pain becomes more significant at 4 and 24 hours following the insertion of archwire and starts to decrease after 7 days.^[3] However, some reports suggest that more than 40 % of patients continued experiencing pain after one week of archwire insertion.^[4] When orthodontic force is applied to the teeth, a series of biological events take place to induce orthodontic tooth movement that results in the release of many inflammatory mediators including prostaglandin, histamine, bradykinin, serotonin and substance P.^{[5],[6]} These mediators are responsible to stimulate nerve endings and induce pain.

Orthodontists usually prescribe analgesics to control the resulted discomfort and pain mostly, ibuprofen, paracetamol and acetylsalicylic acid.^[7-9]

However, these analgesics can block the inflammatory pathway thus affecting the tooth movement.^[10] In addition, these drugs may have side effect and contraindications.^{[9],[10]} On the other hand, many non- pharmacological methods have been suggested to reduce patient discomfort and alleviate pain including low level laser therapy,^{[11],[12]} vibratory device^[13] and chewing adjuncts.^[14] Alternatively, researchers have suggested several psychological interventions to reduce orthodontic pain.^[15]

2. OBJECTIVES

Psychological interventions might be considered as promising non-pharmacological safe methods to reduce pain and discomfort for patients undergoing orthodontic treatment. Psychological factors play a major role in the pain process, since it has been clearly proved that pain threshold, intensity and tolerance are influenced by cognition, personality and past experience.^{[16],[17]} The efficacy of different psychological approaches to reduce orthodontic pain have not been fully explored yet. Therefore, by summarizing

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evidence from existing randomized clinical trials, the aim of this study is to investigate the effects of different psychological interventions on the intensity of pain at its peak in patients undergoing orthodontic treatment at peak pain intensity.

3. MATERIAL AND METHODS

In order to develop a well-structured design a PICOS methodology was used in this review as follows:

Participants— patients undergoing fixed orthodontic treatment and aged between 10 years old and above.

Intervention — psychological interventions;

Comparison — participants receiving treatment other than psychological interventions or no treatment (control);

Outcome — the reduction in pain intensity after 24 hours of orthodontic force application.

Study Design — RCTs.

Information Sources and Search Strategy A comprehensive search strategy was implemented using both manual and electronic search methods in order to identify both indexed and non-indexed articles in databases, as well as to reduce the possibility of excluding relevant studies by chance. The online database search strategy incorporated the following databases: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, ScienceDirect, Scopus and EBSCO, until June 2020.

The manual search incorporated the following journals:

1. Journal of Orthodontics (2000-2021);
2. European Journal of Orthodontics (2000- 2021);
3. American Journal of Orthodontic and Dentofacial Orthopedics (2000-2021);
4. Angle Orthodontist (2000-2021).

Eligibility Criteria

Articles were comprehensively examined against the inclusion and exclusion criteria and only randomized controlled trials involve patients 1) undergoing fixed orthodontic treatment 2) minimum age of 10 years old, 3) receiving a psychological intervention to control resulted pain and discomfort, 4) medically fit and 5) no previous orthodontic treatment, were included in the systematic review. Abstracts, titles and subsequently full texts of potential articles were examined carefully and independently by two authors to ensure the studies meet the eligibility criteria, and any disagreement between the authors were resolved by discussion. Furthermore, references from all of the reviewed articles were assessed carefully for their eligibility to meet the inclusion criteria. In case of any missing data or questions about the included papers, an attempt was made to contact the original study investigators. However, the reason behind excluding any paper due to missing data will be discussed in the review.

Data items

The primary outcome was the degree of pain intensity reported by patients 24 hours after the application of orthodontic force. The included trials assessed the intensity of pain using 10 cm visual analogue scale, a 100 mm VAS or a 10-points numeric rating scale. We assumed that the VAS (0-10) and the numerical rating scale are the same and 10 cm VAS was converted to 100 mm VAS by multiplying the pain score by 10. The same method of combining 10 cm visual analogue scale, a 100 mm VAS or a 10- points numeric rating scale into a single scale was used in recent study.^[18] Furthermore, if a study reported multiple measures (ex. biting, at rest, fitting front teeth or fitting back teeth) we combined these measures into a single estimate as recommended by the Cochrane handbook of systematic reviews of interventions.^[19]

Data Extraction and Meta-analysis

For the statistical analysis, data were extracted from each trial independently by two authors and were entered into a computerized database. Any disagreement between the authors were resolved by discussion. The extracted data included the mean visual analogue scale reported by patients in both experimental and control groups 1 day after the application of orthodontic force, sample size and standard deviation of both experimental and control group. In case of any missing data or questions about the included papers, an attempt was made to contact the original study's investigators. Meta-analysis was conducted using Revman 5.3 software by the Cochrane collaboration. Standardized mean difference (SMD) known also as Cohen's d or effect size was assessed and the corresponding 95% confidence interval was estimated for the effect sizes. Tests of heterogeneity were conducted using Q statistic; which is distributed as a chi-square variety (assumption of homogeneity of effect sizes). The between-study heterogeneity was assessed with the I-square statistic.

Risk of Bias in Individual Trials

All articles included in the study were reviewed independently by the two authors in order to assess the level of bias using the Cochrane risk of bias tool which is an assessment tool that entails quality assessment based on five factors including selection bias (allocation concealment and methods of randomization), detection bias, performance bias, reporting bias and attrition bias.^[20]

4. RESULTS

Study Selection

The flowchart in Figure 1 identifies the included and excluded articles at each stage.

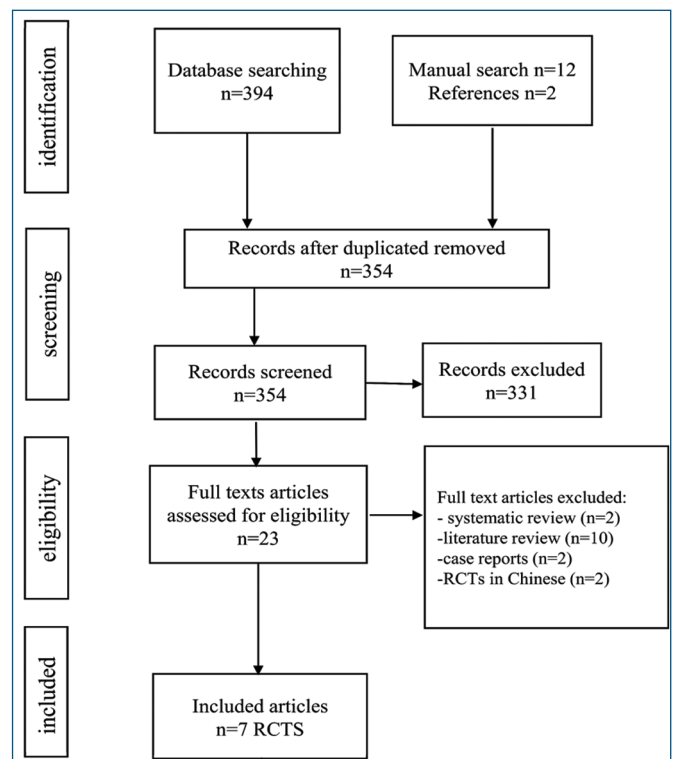


Figure (1): A flow chart describing the search methodology and numbers of articles included/excluded at each stage.

408 articles were assessed, including 394 articles from the electronic databases, 12 from the manual hand search and 2 articles from the reference lists. Forty articles were duplicates, and 331 did not relate to the research question, thus leaving 23 articles for potential inclusion in the study.

Following the inspection of the full texts of these articles, 16 articles were excluded including 2 systematic reviews, 10 reviews, 2 case reports and 2 randomized controlled trials not written in English. This means only 7 randomized clinical trials were included in the review for further analysis. The process of searching and selection of studies to be included in the review was carried out independently and in duplicate by the two authors and any disagreement was resolved through a discussion between them. The kappa statistic for the agreement between the reviewers was 0.87.

Risk of Bias within Studies

Using the Cochrane risk of bias tool, as depicted in Table 1, the quality of evidence of both the Sawada 2015 and the Teifer 2014 studies were evaluated of low quality due to the absence of allocation concealment, blinding of the outcome assessment and blinding of the participants and personals. On the other hand, the Huang 2016 study was assessed of low quality due to the absence of both blinding the outcome assessment and blinding of the participants and personals in addition to high risk of other bias due to not stating the gender distribution in the study. Furthermore, Keith study 2013 was assessed of low quality due to the absence of both blinding the outcome assessment and blinding the participants and personals. The Wang study 2012 was assessed of low quality due to the absence of blinding the participants and personals in addition to high risk of other biases due to not stating the gender distribution. The Bartlett study 2005 and the Cozzani 2015 study were assessed of medium quality due to absence of one of the following domains as seen in Table1, including allocation concealment, or blinding of the outcome assessment.

Table 1— Quality assessment of the studies included in the systematic review using “Cochrane risk of bias” tool

Bias domain	Wang et al., 2012 [21]	Huang et al., 2016 [22]	Sawada et al., 2015 [23]	Bartlett et al., 2005 [24]	Teifer et al., 2014 [25]	Cozzani et al., 2015 [26]	Keith et al., 2013 [27]
Random sequence generation (selection bias)	High risk	High risk	High risk	High risk	High risk	High risk	High risk
Allocation concealment (selection bias)	High risk	High risk	Low risk	High risk	Low risk	Low risk	High risk
Blinding of participants and personnel (performance bias)	Low risk	Low risk	Low risk	High risk	Low risk	High risk	Low risk
Blinding of outcome assessment (detection bias)	High risk	Low risk	Low risk	Low risk	Low risk	High risk	Low risk
Incomplete outcome data (attrition bias)	High risk	High risk	High risk	High risk	High risk	High risk	High risk
Selective reporting (reporting bias)	High risk	High risk	High risk	High risk	High risk	High risk	High risk
Other bias	Low risk	Low risk	High risk	High risk	High risk	High risk	High risk

Synthesis of studies

Cognitive Behavioral Therapy

Three randomized controlled trials [21],[22],[23] were included in this meta-analysis that evaluated the efficacy of cognitive behavioral therapy, as compared to a control group in the reduction of pain 24 hours after orthodontic force application. The values of $I^2 = 27\%$, $\chi^2 = 2.73$ and $P = .25$ indicate a non-significant study heterogeneity. Therefore, a fixed effect model was used and tested. The standard mean difference favors the cognitive behavioral therapy and its effects had a statistically significant difference with the control group ($P > .00001$). (Figure 2)

Structured Phone Calls

Three randomized controlled trials [24-26] were included in this meta-analysis to evaluate the efficacy of cognitive behavioral therapy, as compared to a control group in the reduction of pain 24 hours after orthodontic force application. The values of $I^2 = 0\%$, $\chi^2 = 2.00$ and $P = .37$ indicate a non-significant study heterogeneity. Therefore, a fixed effect model was used and tested. The standard mean difference favors the structured phone calls and its effects had a statistically significant difference with the control group ($P = .01$). (Figure 3)

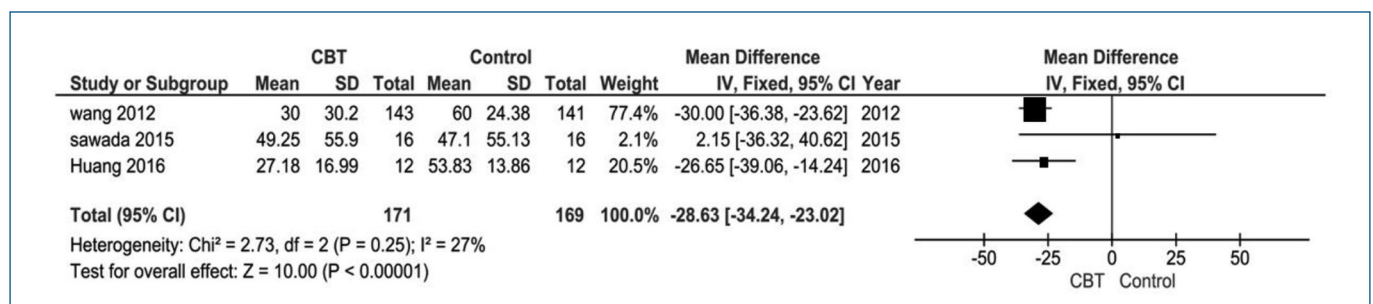


Figure 2. Forest plot comparing between cognitive behavioral therapy VS control

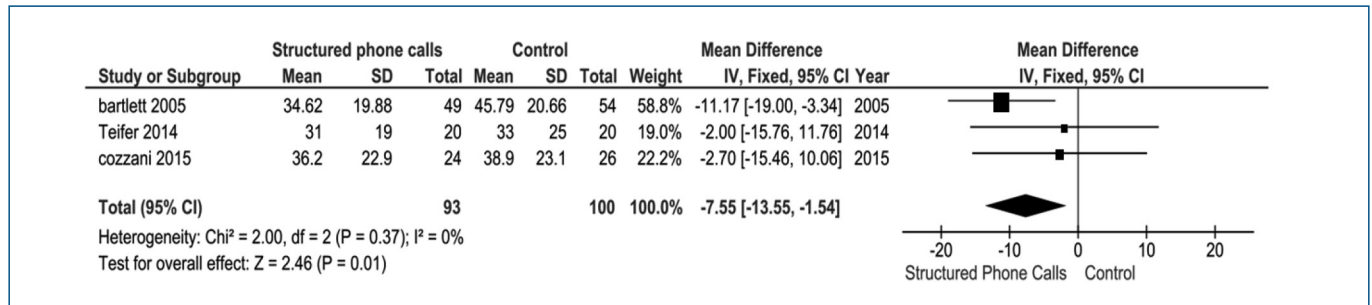


Figure 3. Forest plot comparing between structured phone calls VS control

Text Messages

Two randomized controlled trials [26,27] were included in this meta-analysis to evaluate the efficacy of text messages, as compared to a control group in the reduction of pain 24 hours after orthodontic force application. (Figure 4)

The values of I²= 0%, x²= 0.06 and P= 0.81 indicate a non-significant study heterogeneity. Therefore, a fixed effect model was used and tested. The standard mean difference favors the text messages intervention and its effects had a non- statistically significant difference with the control group (P= 0.19). (Table 2)

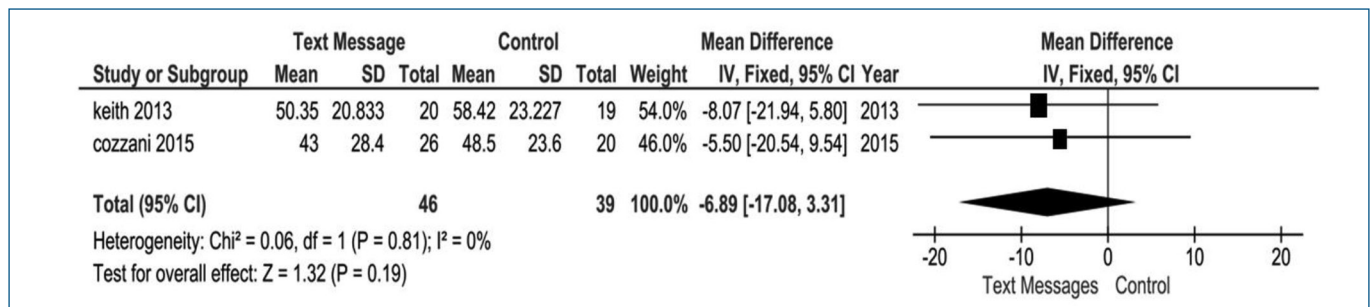


Figure 4. Forest plot comparing between text messages Vs control

Table 2 — Summarized published data of the studies included in the systematic review:

Study ID	Participants size, gender, age (years), dropout	Interventions	Mode of intervention	Method of pain assessment	Author’s conclusion
Bartlett et al., 2005 [24]	N=150 patients (69 males, 81 females) Mean age (years) 15.9 No drop out	Group 1 Structured telephone calls Group 2 Attention telephone Calls Group 3 Control	Group 1 Structured telephone calls daily and 4 hours after initial archwire placement Group 2 Attention telephone calls only made daily and 4 hours after initial archwire placement Group 3 Control	(VAS)	Structured phone calls significantly reduce orthodontic pain compared to the attention calls only and the control group
Wang et al., 2012 [21]	N=450 patients Mean age (years) 16.8 21 Drop out	Group 1 Cognitive behavioral therapy (CBT) Group 2 Ibuprofen Group 3 Control	Group 1 Self-practice CBT skills at home for 15 minutes Group 2 Ibuprofen 300 mg Group 3 Control	(VAS)	Cognitive behavioral therapy is as effective as ibuprofen in orthodontic pain management, indicating its clinical application potential.

Table 2 — Summarized published data of the studies included in the systematic review:

Study ID	Participants size, gender, age (years), dropout	Interventions	Mode of intervention	Method of pain assessment	Author's conclusion
Keith et al., 2013 [27]	N=39 patients (14 males, 25 females) Mean age (years) 13.4 No drop out	Group 1 Text messages Group 2 Control	Group 1 Text message sent daily and 4 hours after initial wire placement Group 2 Control	(VAS)	Text messages sent from orthodontic office was effective in the reduction of orthodontic pain
Teifer et al., 2014 [25]	N=120 (43 males, 64 females) 13 drop out	Group 1 Pre and post 600 mg acetaminophen Group 2 Pre-placebo and 600mg post-acetaminophen Group 3 Pre-600mg acetaminophen Post-placebo Group 4 Pre and post placebo Group 5 Pre and post courtesy phone calls Group 6 Control	Group 1 600 mg acetaminophen before arch wire placement and after recording VAS Group 2 Placebo before arch wire placement and 600 mg acetaminophen after recording VAS Group 3 600 mg acetaminophen before arch wire placement and placebo after recording VAS Group 4 Placebo before arch wire placement and placebo after recording VAS Group 5 Courtesy phone calls before arch wire placement and after recording VAS Group 6 Control	(VAS)	Acetaminophen, placebo, courtesy telephone calls, and no treatment were all equally effective in controlling orthodontic pain
Sawada et al., 2015 [23]	N=32 (16 males, 16 females) Mean age (years) 28.4 No drop out	Group 1 Cognitive behavioral therapy (CBT) Group 2 Control	Group 1 Self-practice CBT skills at home for 15 minutes Group 2 Control	(VAS)	Cognitive behavioral therapy was shown to be effective in the management of orthodontic pain and could merit clinical application.
Cozzani et al., 2015 [26]	N=150 (43 males, 41 females) mean age (years) 13.3 8 drop out	Group 1 Control Group 2 Text messages Group 3 Structures phone calls	Group 1 Control Group 2 Text messages were sent daily and 5-7 hours after bonding by the orthodontist. Group 3 Structured phone calls were made daily and 5-7 hours after bonding by the orthodontist	(VAS)	Patients in the structured telephone calls and the text messages groups reported less pain compared to the control group.
Huang et al., 2016 [22]	N= 36 Mean age (years) 22 No drop out	Group 1 Cognitive behavioral therapy (CBT) Group 2 Brainwave music therapy Group 3 Control	Group 1 Self-practice CBT skills at home for 15 mins Group 2 Brain wave music therapy for 15 mins Group 3 Control	(VAS)	Both cognitive behavioral therapy and brainwave music were effective in the reduction of orthodontic pain.

5. DISCUSSION

According to our knowledge this is the first systematic review to evaluate the efficacy of psychological interventions in the reduction of orthodontic pain at its peak intensity.

The results of this systematic review suggest a significant reduction of orthodontic pain at its peak intensity after initial wire placement in patients undergoing fixed orthodontic treatment.

Three randomized controlled trials compared patients treated with cognitive behavioral therapy to patients who did not receive any treatment (control group) and the results showed a significant reduction in the intensity of perceived pain after 24 hours. However, both the Huang study and the Sawada study had a relatively small sample size. Additionally, the gender distribution in the Huang study and the Wang study was not stated clearly. On the other hand, it is of great importance to compare the cost effectiveness of cognitive behavioral therapy to other non-invasive interventions, since adding more cost and sessions to the treatment may interfere with patient's compliance and willingness to commence treatment. Future studies evaluating the efficacy of cognitive behavioral therapy on the level of pain intensity in patients undergoing fixed orthodontic treatment could be ascertained by using functional magnetic resonance imaging rather than the patient's subjective perception of pain to accurately identify and compare the neural functional activities before and after treatment.

Three studies compared the efficacy of structured phone calls to patients who did not receive any treatment and emphasized a significant reduction in the level of pain intensity. However, the Cozzani and the Teifer studies had a small sample size.

Moreover, two studies compared the efficacy of text messages to patients who did not receive any intervention and revealed a reduction in the intensity of pain 24 hours after initial wire placement. However, both studies had a small sample size.

Furthermore, only one study compared between the efficacy of structured phone calls and the text messages and revealed that the structured phone calls are more effective in the reduction of orthodontic pain than the text messages. However, as previously mentioned, the sample size of this study was small. Therefore, to draw a better conclusion it is recommended to conduct better designed randomized controlled trials with large sample size in the future.

A systematic review was conducted in 2019 to compare between upper removable appliance and fixed appliance to correct anterior crossbite emphasized that patients who received fixed appliance therapy had greater pain intensity in the first few days of the treatment compared to those who received upper removable appliance therapy.^[28] Therefore, the use of psychological interventions in this case can be recommended to alleviate pain, improve the quality of life and reduce the consumption of analgesics in patients undergoing fixed orthodontic treatment.

Only one study described the perceived pain at different functions. Therefore, for better understanding of the role of psychological interventions in the reduction of pain intensity future studies should concentrate more on the level of perceived pain at different functions since sensation of pain during biting was different from the pain experienced when jaws at rest.

In order to avoid bias from being introduced during the study period. It's recommended to find a way to hide the previous VAS value by using telephone calls to report pain or by putting the old VAS on a new page.

Therefore, old VAS scores will not influence the patient's current perception of pain.

The limitation of this meta-analysis can be attributed to the fact that we synthesized the evidence at the pain peak intensity only. Our decision to include the intensity of pain at 24 hours is mainly because the included RCTs provided VAS scores at varying time points except for peak pain intensity. Therefore, we recommend future studies to investigate the pain intensity at multiple time points.

Another limitation of this study can be attributed to the exclusion of 2 randomized clinical trials that were written in Chinese language.

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Conflict of Interest

None to declare

7. CONCLUSION

By motivating patients and altering their attitude towards orthodontic treatment, 15 minutes self-practiced cognitive behavioral therapy and structured phone calls reduce orthodontic pain at its peak intensity (24hrs) without having any complications or side effects.

In order to base our practice on scientific evidence, better-controlled RCTs are needed to investigate the impact of psychological interventions on the intensity of orthodontic pain

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