European Journal of Orthodontics, 2020, 494–499
doi:10.1093/ejo/cjz068
Advance Access publication 27 August 2019

Randomized Controlled Trial (RCT)

Effect of verbal and written information on pain perception in patients undergoing fixed orthodontic treatment: a randomized controlled trial

Francesca Montebugnoli[1], Serena Incerti Parenti[2], Vincenzo D'Antò[1], Giulio Alessandri-Bonetti[2] and Ambra Michelotti[1]

[1]Department of Neurosciences, Reproductive Sciences and Oral Sciences, Section of Orthodontics, University of Naples 'Federico II', and [2]Department of Biomedical and Neuromotor Sciences (DIBINEM), Section of Orthodontics, University of Bologna, Italy

Correspondence to: Giulio Alessandri-Bonetti, Department of Biomedical and Neuromotor Sciences (DIBINEM), Section of Orthodontics, University of Bologna, Via San Vitale 59, 40125, Bologna, Italy. E-mail: giulio.alessandri@unibo.it

Summary

Background: Pain can discourage patients from seeking orthodontic treatment or compromise their compliance during therapy.
Objectives: To determine the effects of verbal and written information on orthodontic pain after fixed appliance placement.
Trial design: Two-arm parallel design randomized controlled trial.
Methods: Healthy adolescents with permanent dentition enrolled for orthodontic treatment were assigned to the study or control group using computer-generated random lists and allocation concealment with sealed envelopes. Participants completed baseline questionnaires to assess anxiety (State-Trait Anxiety Inventory Trait Version, Form X-2) and somatosensory amplification (Somatosensory Amplification Scale). Brackets were placed in the maxillary arch, from first molar to first molar, and an Australian archwire 0.012 inch was used for alignment. General verbal information on orthodontic treatment was given to all patients by the same clinician. Participants included in the study group received also detailed verbal instructions on orthodontic pain together with a take-home information leaflet by another clinician. Outcome included assessments of pain intensity with a Numerical Rating Scale (NRS) on the day of appliance placement (Day 1, bedtime) and twice a day for the following 6 days (Day 2 to Day 7, morning, bedtime), and analgesic consumption. Participants, statistician, and clinicians who gave general verbal information on orthodontic treatment and instructions about how to score pain intensity were blinded to group assignment.
Results: Sixty patients were assigned to the study ($n = 30$, mean age: 15.4 ± 1.3 years) or control group ($n = 30$, mean age: 14.7 ± 3.2 years). At baseline, no significant between-group differences were present in terms of anxiety and somatosensory amplification. Orthodontic pain scores were significantly lower in the study group compared with the control one, at bedtime on Day 1 ($P < 0.05$) and in the morning of Day 2 ($P < 0.01$). No significant between-group differences were found in following measurements. Overall, analgesic consumption was significantly lower in study compared with the control ($P < 0.01$).
Conclusion: A combination of verbal and written information on orthodontic pain after placement of fixed appliances reduced patient's self-reported pain in the early stages.
Registration: This study was not registered.

Introduction

The most common adverse effect of orthodontic treatment with fixed appliances is pain, a factor that can discourage some patients from seeking or continuing therapy and, also, adversely affects their compliance during treatment (1–3). Lack of cooperation may lead to disappointing treatment results, excessive treatment time, increased fees, greater incidence, and severity of white spots lesions or caries due to poor oral hygiene maintenance (4, 5). For these reasons, orthodontic pain and its management represent a major concern to both patients and clinicians (4). Pain induced by orthodontic tooth movement is one of the most common symptoms experienced during treatment; patient discomfort also refers to any painful sensation evoked by the presence of the appliances (e.g. mucosal ulcer, tongue discomfort and gingival lesion) (6, 7). This unpleasant feeling of pain generally begins within 4 hours, increases during the first 24–72 hours and then subsides gradually within a week after an active orthodontic appliance has been inserted (8–10), while the discomfort evoked by the presence of the appliances almost completely disappears after the first weeks of treatment (4).

The use of analgesics is the most common method to manage orthodontic pain (11–14). However, pharmacological interventions may produce some undesirable side effects, may interfere with the inflammatory process associated with orthodontic tooth movement, and some patients may be allergic to them (15, 16). For these reasons, a range of non-pharmacological approaches have been proposed as alternatives, including mechanical approaches (17–20), laser irradiation (21–25), and behavioural approaches (26–28). Among them, cognitive behavioural therapy (27), a psychological intervention consisting mainly of verbal instructions to alter patient pain-related thinking combined with behavioural training, seems to be effective for pain control during the early stages of orthodontic treatment (29). However, little is known regarding the combined role of verbal and written information on orthodontic pain perception.

This randomized controlled trial investigated the effects of verbal and written information on orthodontic pain after the placement of fixed appliances through detailed verbal instructions and counselling given by the clinician combined with a take-home patient information leaflet.

Subjects and methods

This two-arm parallel design randomized controlled trial was carried out in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement (30).

Trial design and participants

The study included healthy individuals enrolled for fixed orthodontic treatment at the Department of Orthodontics of the University of Naples, Italy.

Inclusion criteria were patients' age between 10 and 18 years, general good health conditions, presence of permanent dentition (second and third molars were not mandatory), and mild dental crowding, allowing the placement of brackets from first molar to first molar in the maxillary arch. Exclusion criteria were patients scheduled for fixed orthodontic treatment with extractions, previous orthodontic treatment, dental caries, chronic analgesic consumption, pain-related pathology, and self-reported pain prior to orthodontic treatment beginning [as measured on a Numerical Rating Scale (NRS) at baseline]. Eligible patients were randomly assigned to the study or control group. The study was approved by the Ethic Committee of University of Naples 'Federico II' (number of approval: 293/18) and subjects involved in the study or their parents/guardians gave voluntary informed consent to participate in the research.

Interventions

Metal brackets with 0.022″ × 0.028″ slot MBT prescription (Victory Series Low Profile, 3M Unitek, Monrovia, CA, USA) were placed in the maxillary arch and a 0.012″ Australian archwire (A. J. Wilcock, Whittlesea, Victoria, Australia) with elastomeric ligature ties were used for teeth alignment. The treatment followed a nonextraction protocol and a full engagement to all teeth was carried out from Day 1.

After the initial archwire was placed, general verbal instructions on the orthodontic treatment regarding dietary habits, oral hygiene maintenance, and general information on orthodontic pain were given to the patients included in both groups by the same operator who was blinded to the group allocation. Paracetamol consumption was recommended if needed.

Participants included in the study group received also written information on orthodontic treatment and, particularly, on orthodontic pain characteristics and management. To ensure consistency, the additional detailed verbal information was given by another clinician according to a written information leaflet that the patient was asked to take home and read thoroughly.

The information leaflet reported that everyone feels pain or discomfort after placement of fixed orthodontic appliances and illustrated the possible reasons for these unpleasant sensations. Particular emphasis was given to the fact that pain is most intensely felt 24–72 hours after initial archwire placement, then gradually subsides and finally disappears. Similarly, the discomfort evoked by the presence of the appliance commonly disappears after the first weeks of treatment. The patients were reassured that orthodontic pain could be controlled through the use of analgesics (paracetamol was recommended, if needed) and that discomfort could be relieved through the use of the orthodontic wax. The patients were also informed of possible difficulty in chewing hard food and appropriate changes in dietary habits were recommended. They also received instructions on oral hygiene procedures. Furthermore, the leaflet stressed the importance of a positive attitude towards orthodontic treatment and reassured the patient that a clinician would have been available for any doubt.

Outcomes

All participants completed baseline questionnaires to assess their level of pain using a NRS scale (0: no pain; 10: worst pain I can imagine). They were also invited to fill in the State-Trait Anxiety Inventory Trait Version (STAI-T, Form X-2) (31) and the Somatosensory Amplification Scale (SSAS) (32) to evaluate, respectively, their levels of anxiety and somatosensory amplification, because these factors can affect orthodontic pain perception (33).

Maxillary dental casts were digitized and a baseline evaluation of arch length discrepancy was carried out using a digital software (Delta-Dent, Outside Format, Spino D'Adda, Cremona, Italy), in order to determine the severity of dental crowding.

After the placement of fixed orthodontic appliances, each patient was instructed to score the intensity of pain using NRS as primary outcome measure and to record analgesic consumption as secondary outcome measure on the day of appliance placement (Day 1, bedtime) and twice a day for the following 6 days (Day 2 to Day 7, morning, bedtime). Written instructions on how and when to fill in the questionnaire were given to all participants.

Sample size

The study was powered to detect a minimum significant difference in visual analogue scale of 15 mm on the 100-mm visual analogue scale setting $\alpha = 0.05$, a power of 80 per cent, and a hypothesized within group sigma of 20 mm, obtained from a previous study (26); as a minimum, 29 patients would have been required in each treatment arm.

Randomization

Two computer-generated restricted random lists were used to create two groups with equal numbers of patients by an investigator with no clinical involvement in the trial. The allocation sequence was concealed in sequentially numbered, opaque and sealed envelopes. Corresponding envelopes were opened only after the enrolled participants completed baseline assessments and it was time to give the detailed verbal information.

Blinding

Participants were blinded to the group allocation and were not made aware that the verbal or written information were part of the study. The operator who gave general verbal information on the orthodontic treatment and the one who gave instructions about how to score the intensity of pain and how to record analgesic consumption were blinded to the group allocation. Data were analyzed by a statistician, which was also blinded to the patient allocation.

Statistical analysis

After evaluating that standardized skewness and standardized kurtosis were within the range expected for data from a normal distribution, a multilevel generalized model was fitted and a multiple regression analysis of variance (ANOVA) for repeated measures with split plot design was utilized to evaluate the presence of any significant difference in the pain perception between groups, moments, and the interaction groups * moments.

A one-way ANOVA was used to evaluate any between-group difference in STAI and SSAS. Differences in analgesic consumption were analyzed through a chi-squared test. The α level was a priori set at 0.05.

Results

Fifteen patients did not fulfil the eligibility criteria (congenitally missing maxillary lateral incisors, $n = 2$; congenitally missing maxillary second premolars, $n = 1$; patients scheduled for fixed orthodontic treatment with extractions, $n = 6$; patients scheduled for fixed orthodontic treatment in the mandibular arch, $n = 6$) and therefore were not included in the study. Sixty patients were randomly assigned to the study ($n = 30$; 17 females, 13 males; mean age: 15.4 ± 1.3 years) or control group ($n = 30$; 17 females, 13 males; mean age: 14.7 ± 3.2 years). Figure 1 shows the flow of participants through each stage of the randomized trial.

No significant between-group differences in STAI (44.8 ± 4.3 in the study group and 44.9 ± 6.1 in the control group $F = 1.0$; P = ns) and SSAS (24.6 ± 6.4 in the study group and 21.6 ± 5.5 in the control group; $F = 2.51$; P = ns) values were observed. None of the participants in either groups reported pain at baseline using NRS. No significant between-group difference in crowding was found in the study (–0.13 ± 2.46 mm) compared with the control (–0.61 ± 2.52 mm) group. This guaranteed comparability between groups in terms of anxiety, somatosensory amplification, baseline self-reported pain, and dental crowding.

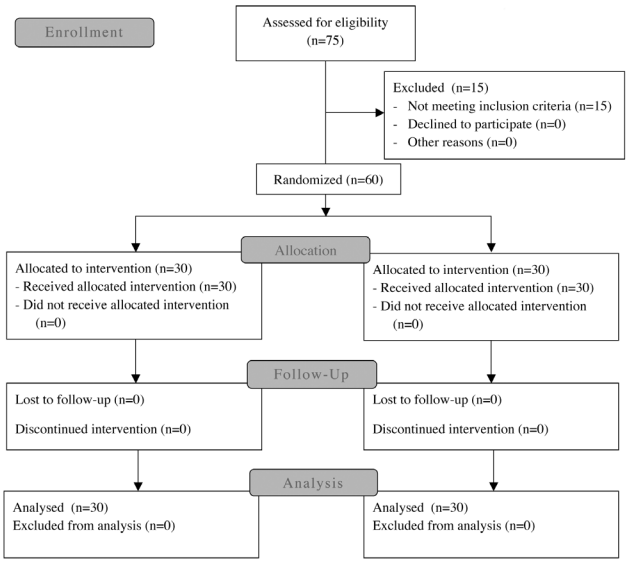

Figure 1. CONSORT diagram showing the flow of participants through each stage of the randomized trial (*n*, number of patients).

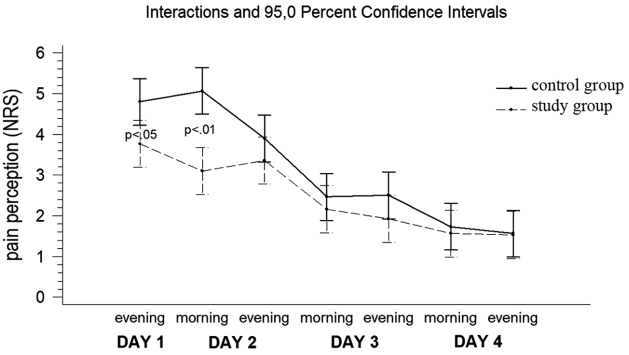

Figure 2. Mean pain intensity of the two groups over 4 days. No significant differences were found in the following measurements.

Pain perception was statistically ($P < 0.05$) higher in the control group at bedtime on the day of appliance placement (Day 1), and on the subsequent morning (Day 2; $P < 0.01$), whereas no significant differences were found in following measurements. Figure 2 show the NRS mean values in both groups over 4 days. A time-related significance with respect to the first value was found for both the study and the control group beginning from the morning of Day 3.

Twenty per cent of patients in the study group and 56.7 per cent of patients in the control group took analgesics. Overall, analgesic consumption was significantly ($P < 0.01$) lower in study group (6 tablets) than in control group (30 tablets). Table 1 reports analgesic consumption.

Discussion

This is the first study that aimed to investigate the effect of verbal and written information on orthodontic pain after placement of fixed appliances through detailed verbal instructions and counselling given by the clinician, combined with a take-home patient information leaflet. Verbal communication has a crucial role in building a therapeutic doctor–patient relationship and may have a profound impact on the patient's psychological state (34). Discussion with patients

Table 1. Analgesic consumption (*n*, number of tablets)

	Day 1	Day 2		Day 3		Day 4		
	Bedtime	Morning	Bedtime	Morning	Bedtime	Morning	Bedtime	Total
Control group	16	11	1	2	0	0	0	30
Study group	6	0	0	0	0	0	0	6

No analgesic consumption was detected from Day 4.

represents a useful opportunity to positively influence the physical, psychological, and social factors (the so called 'contextual factors') that characterize the multidimensionality of pain (35). A positive approach to pain can reduce the global pain experience through verbal suggestions. Verbal information given by clinicians about the expected pain or discomfort, combined with reassurance and encouragement can influence patient expectations, memories, and emotions that can contribute to the development of a positive context capable of reducing pain perception by triggering a placebo effect (35, 36).

For example, cognitive behavioural therapy, a psychological intervention consisting mainly of verbal instructions to identify and correct negative thinking, has been found to reduce pain during the early stages of orthodontic treatment (27).

Written communication has powerful effects as well. Reading written materials reinforces verbal information and enables patients to refresh their memory about information given by the clinician (37). The attempt should be to exploit the power of written words on the human psyche, similarly to bibliotherapy, a form of supportive psychotherapy in which the patient is given carefully selected material (appropriate books or other written materials) as an adjunct to psychological treatment, usually intended to be read outside of psychotherapy sessions (38). The basic assumption is to learn from high-quality written material for therapeutic benefit (39). In a study conducted on a sample of patients undergoing treatment for psychiatric disorders, those asked to read a psychological 'self-help' book demonstrated clinically significant improvement in their overall well-being, simply by reading and gaining a greater understanding of their condition (40).

In general health care, international treatment guidelines for patients before surgical intervention recommend both verbal and written information on pain relief, because it can be difficult to assimilate verbal information only, especially if it is too extensive and provided before surgery, which is a complex care situation for the patient (38). In orthodontic care, structured telephone calls and text messages from a health care provider after the placement of fixed appliances have been found to reduce post-operative pain through information about expected discomfort, patient reassurance, and encouragement (26, 28, 41), but no specific recommendations on preoperative information on pain are available.

Pain has been recognized as the most common adverse effect of orthodontic treatment with fixed appliances; this can significantly affect patient compliance (1–3). Missing or unrealistic information about possible pain or discomfort during treatment can have negative effects on patient compliance as well (4). Since poor cooperation can have negative effects on treatment outcomes and costs (4, 5), it is crucial that clinicians provide evidence-based information on pain characteristics and management prior to treatment beginning. The discussion with patients can help the clinician to evaluate patient's belief on pain and, if necessary, to discourage any unrealistic expectation, which may lead patients to rely on unproven or fake information delivered by the internet, social media, or peers.

In the present study, thanks to a combination of verbal and written information, patients were reassured that pain and discomfort were expected side effects after the placement of fixed orthodontic appliances, but they could be controlled and gradually disappear. A 1-week time period was chosen for observation, based on the fact that it represents the clinically meaningful time period in terms of change in pain intensity levels (13). A control group of patients who did not receive the information leaflet was used for comparisons. We decided to include only subjects who did not self-report pain before the intervention, because baseline pain can modify pain perception (13). Moreover, in order to avoid the influence of past experiences on pain perception, we enrolled only patients who had not received previous orthodontic treatment. The baseline anxiety levels and somatosensory amplification were also recorded using validated questionnaire, the STAI-T, X-2 Form, and the SSAS. It was possible to conclude that there were no significant differences between the groups for these variables, which could affect orthodontic pain perception (33). For the same reasons, arch length discrepancy was measured at baseline and no significant differences were found between the groups for crowding. Moreover, treatment was standardized by bonding the same brackets in the maxillary arch, from first molar to first molar, and by using the same archwire with elastomeric ligature ties for initial alignment. The primary outcome of interest was the patient-reported pain intensity assessed using a NRS. This is a validated instrument, easy to complete even by young patients (42–44), and was given to all patients with a simple and clear reminder regarding how and when to fill it out. Analgesic consumption was also recorded as a secondary form of assessment of the amount of discomfort experienced by patients. Patients were allowed to take analgesics in order to mimic the everyday clinical practice, in which the orthodontist recommends analgesic consumption for orthodontic pain relief. Our assumption was to keep both the study and the control group under the same experimental conditions, and, irrespective of group assignment, it would have been unethical to prevent any of the participants from analgesic consumption, if needed.

For the study group, the maximum mean pain intensity was observed at Day 1 (bedtime), while for the control group, it was observed at Day 2 (morning). The mean NRS scores gradually decreased in the following days and showed a time-related significant reduction of pain at Days 3 to 7 (morning and bedtime) compared to Day 1 (bedtime). These findings are in agreement with previous studies, which have shown mean pain intensity to peak around 4 and 24 hours following archwire placement and then to gradually subside (8–10).

Pain perception was statistically significantly lower in the study group at bedtime on the day of bonding (Day 1; $P < 0.05$), and the morning after the appliance placement (Day 2; $P < 0.01$) compared with controls, whereas no significant between-group differences were found in following measurements. A significantly lower analgesic consumption was observed in the study group compared with controls, which is in agreement with the results from the NRS scores. These findings highlight the importance of cognitive factors such

as patient's expectations on orthodontic pain perception, because receiving detailed information about both the characteristics of pain and the management of discomfort reduced self-reported pain and analgesic consumption.

A recent Bayesian network meta-analysis (29) reported that, among the behavioural therapy interventions for orthodontic pain relief at peak pain intensity, cognitive behavioural therapy (27) was more effective than structured phone calls and text messages in order to give patients reassurance about pain (26, 28, 41). This difference was ascribed to the fact that the cognitive behavioural therapy intervention offered an active psychological counselling (guided relaxation training and assistance in tackling pain-related anxiety) through a structured phone call made by a therapist on a daily basis.

This procedure involves significant burden for clinicians, patients, or both, with implications for costs and impact on daily life and also requires the presence of a therapist. The combination of verbal and written information presented in this study is a simple and less time-consuming procedure, that can be easily performed by an orthodontist in everyday clinical practice, aiming to improve patient compliance and to gain a more positive patient attitude towards treatment.

The main purpose of the information leaflet adopted in this study was to inform patients in detail on orthodontic pain characteristics and management. It was also decided to combine the leaflet with a specific verbal explanation in plain language provided by a knowledgeable person in order to ensure a proper understanding of the content by patients, thus refraining participants from accessing additional information from alternative sources such as consulting the internet as a strategy for clarification, as already reported in the field of medicine for leaflets of commonly prescribed medications (45). In fact, a lack of comprehension or a misunderstanding of medical information by patients may be associated with increased anxiety, decreased involvement of patients and, also, jeopardize patient–doctor relationship, which is essential for patient cooperation during treatment (46).

Limitations

A weakness of the present study is that it is not possible to know if the two verbal information sessions together (in the study group) are the reason for the findings of the differences between the groups, instead of the take-home written information leaflet. A third group which did not get the additional verbal information, but only a written leaflet, was not included. It cannot be excluded that the repeated verbal information (by another person than the one that gave general verbal instructions) could have influenced patient cooperation, thus being among the reasons for the findings of differences between the groups. Another limitation is that the study was powered to detect a minimum significant difference in visual analogue scale, likewise previous studies using cognitive behavioural therapies, phone calls, and text messages and evaluating orthodontic pain perception after initial archwire placement (26–28, 41), while participants were asked to fill in a NRS because it proved to be a valid measure for assessing pain intensity in children (42–44). A further weakness was the absence of trial registration.

Generalizability

The generalizability of study's results could be limited by the fact that brackets were placed only in the maxillary arch in subjects with mild dental crowding, who had no previous orthodontic treatment, and who did not report pain prior to orthodontic treatment beginning.

Conclusions

This randomized controlled trial demonstrated that a combination of verbal and written information on orthodontic pain characteristics and management reduced both the intensity of self-reported pain and analgesic consumption after placement of fixed appliances.

Acknowledgement

Warm thanks to Outside Format for providing the software for dental cast analysis.

Funding

No fundings were available for this study.

Conflicts of interest

None to declare.

References

1. Brown, D.F. and Moerenhout, R.G. (1991) The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. *American Journal of Orthodontics and Dentofacial Orthopedics*, 100, 349–356.
2. Sergl, H.G., Klages, U. and Zentner, A. (1998) Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *American Journal of Orthodontics and Dentofacial Orthopedics*, 114, 684–691.
3. O'Connor, P.J. (2000) Patients' perceptions before, during, and after orthodontic treatment. *Journal of Clinical Orthodontics*, 34, 591–592.
4. Krishnan, V. (2007) Orthodontic pain: from causes to management—a review. *European Journal of Orthodontics*, 29, 170–179.
5. Brown, M.D., Campbell, P.M., Schneiderman, E.D. and Buschang, P.H. (2016) A practice-based evaluation of the prevalence and predisposing etiology of white spot lesions. *The Angle Orthodontist*, 86, 181–186.
6. Long, H., Wang, Y., Jian, F., Liao, L.N., Yang, X. and Lai, W.L. (2016) Current advances in orthodontic pain. *International Journal of Oral Science*, 8, 67–75.
7. Rennick, L.A., Campbell, P.M., Naidu, A., Taylor, R.W. and Buschang, P.H. (2016) Effectiveness of a novel topical powder on the treatment of traumatic oral ulcers in orthodontic patients: a randomized controlled trial. *The Angle Orthodontist*, 86, 351–357.
8. Scott, P., Sherriff, M., Dibiase, A.T. and Cobourne, M.T. (2008) Perception of discomfort during initial orthodontic tooth alignment using a self-ligating or conventional bracket system: a randomized clinical trial. *European Journal of Orthodontics*, 30, 227–232.
9. Pringle, A.M., Petrie, A., Cunningham, S.J. and McKnight, M. (2009) Prospective randomized clinical trial to compare pain levels associated with 2 orthodontic fixed bracket systems. *American Journal of Orthodontics and Dentofacial Orthopedics*, 136, 160–167.
10. Fleming, P.S., Dibiase, A.T., Sarri, G. and Lee, R.T. (2009) Pain experience during initial alignment with a self-ligating and a conventional fixed orthodontic appliance system. A randomized controlled clinical trial. *The Angle Orthodontist*, 79, 46–50.
11. Xiaoting, L., Yin, T. and Yangxi, C. (2010) Interventions for pain during fixed orthodontic appliance therapy. A systematic review. *The Angle Orthodontist*, 80, 925–932.
12. Angelopoulou, M.V., Vlachou, V. and Halazonetis, D.J. (2012) Pharmacological management of pain during orthodontic treatment: a meta-analysis. *Orthodontics & Craniofacial Research*, 15, 71–83.
13. Sandhu, S.S., Piepho, H.P. and Khehra, H.S. (2017) Comparing the effectiveness profile of pharmacological interventions used for orthodontic pain relief: an arm-based multilevel network meta-analysis of longitudinal data. *European Journal of Orthodontics*, 39, 601–614.

14. Monk, A.B., Harrison, J.E., Worthington, H.V. and Teague, A. (2017) Pharmacological interventions for pain relief during orthodontic treatment. *The Cochrane Database of Systematic Reviews*, 11, CD003976.
15. Arias, O.R. and Marquez-Orozco, M.C. (2006) Aspirin, acetaminophen, and ibuprofen: their effects on orthodontic tooth movement. *American Journal of Orthodontics and Dentofacial Orthopedics*, 130, 364–370.
16. Fleming, P.S., Strydom, H., Katsaros, C., MacDonald, L., Curatolo, M., Fudalej, P. and Pandis, N. (2016) Non-pharmacological interventions for alleviating pain during orthodontic treatment. *The Cochrane Database of Systematic Reviews*, 12, CD010263.
17. Otasevic, M., Naini, F.B., Gill, D.S. and Lee, R.T. (2006) Prospective randomized clinical trial comparing the effects of a masticatory bite wafer and avoidance of hard food on pain associated with initial orthodontic tooth movement. *American Journal of Orthodontics and Dentofacial Orthopedics*, 130, 6.e9–6.15.
18. Alshammari, A.K. and Huggare, J. (2019) Pain relief after orthodontic archwire installation—a comparison between intervention with paracetamol and chewing gum: a randomized controlled trial. *European Journal of Orthodontics*, 41, 478–485.
19. Miles, P., Smith, H., Weyant, R. and Rinchuse, D.J. (2012) The effects of a vibrational appliance on tooth movement and patient discomfort: a prospective randomised clinical trial. *Australian Orthodontic Journal*, 28, 213–218.
20. Miles, P. and Fisher, E. (2016) Assessment of the changes in arch perimeter and irregularity in the mandibular arch during initial alignment with the AcceleDent Aura appliance vs no appliance in adolescents: a single-blind randomized clinical trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, 150, 928–936.
21. Turhani, D., Scheriau, M., Kapral, D., Benesch, T., Jonke, E. and Bantleon, H.P. (2006) Pain relief by single low-level laser irradiation in orthodontic patients undergoing fixed appliance therapy. *American Journal of Orthodontics and Dentofacial Orthopedics*, 130, 371–377.
22. Tortamano, A., Lenzi, D.C., Haddad, A.C., Bottino, M.C., Dominguez, G.C. and Vigorito, J.W. (2009) Low-level laser therapy for pain caused by placement of the first orthodontic archwire: a randomized clinical trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, 136, 662–667.
23. Nóbrega, C., da Silva, E.M. and de Macedo, C.R. (2013) Low-level laser therapy for treatment of pain associated with orthodontic elastomeric separator placement: a placebo-controlled randomized double-blind clinical trial. *Photomedicine and Laser Surgery*, 31, 10–16.
24. Kim, W.T., Bayome, M., Park, J.B., Park, J.H., Baek, S.H. and Kook, Y.A. (2013) Effect of frequent laser irradiation on orthodontic pain. A single-blind randomized clinical trial. *The Angle Orthodontist*, 83, 611–616.
25. Marini, I., Bartolucci, M.L., Bortolotti, F., Innocenti, G., Gatto, M.R. and Alessandri Bonetti, G. (2015) The effect of diode superpulsed low-level laser therapy on experimental orthodontic pain caused by elastomeric separators: a randomized controlled clinical trial. *Lasers in Medical Science*, 30, 35–41.
26. Bartlett, B.W., Firestone, A.R., Vig, K.W., Beck, F.M. and Marucha, P.T. (2005) The influence of a structured telephone call on orthodontic pain and anxiety. *American Journal of Orthodontics and Dentofacial Orthopedics*, 128, 435–441.
27. Wang, J., et al. (2012) Cognitive behavioral therapy for orthodontic pain control: a randomized trial. *Journal of Dental Research*, 91, 580–585.
28. Keith, D.J., Rinchuse, D.J., Kennedy, M. and Zullo, T. (2013) Effect of text message follow-up on patient's self-reported level of pain and anxiety. *The Angle Orthodontist*, 83, 605–610.
29. Sandhu, S.S., Cheema, M.S. and Khehra, H.S. (2016) Comparative effectiveness of pharmacologic and nonpharmacologic interventions for orthodontic pain relief at peak pain intensity: a Bayesian network meta-analysis. *American Journal of Orthodontics and Dentofacial Orthopedics*, 150, 13–32.
30. Moher, D., Hopewell, S., Schulz, K.F., Montori, V., Gøtzsche, P.C., Devereaux, P.J., Elbourne, D., Egger, M. and Altman, D.G. (2010) CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *British Medical Journal (Clinical Research Ed.)*, 340, c869.
31. Spielberger, C.D., Gorsuch, R.L. and Lushene, R.E. (1970) *Manual of the State-Trait Anxiety Inventory*. Consulting Psychologists Press, Palo Alto, CA.
32. Barsky, A.J., Goodson, J.D., Lane, R.S. and Cleary, P.D. (1988) The amplification of somatic symptoms. *Psychosomatic Medicine*, 50, 510–519.
33. Cioffi, I., Michelotti, A., Perrotta, S., Chiodini, P. and Ohrbach, R. (2016) Effect of somatosensory amplification and trait anxiety on experimentally induced orthodontic pain. *European Journal of Oral Sciences*, 124, 127–134.
34. Benedetti, F. (2013) Placebo and the new physiology of the doctor–patient relationship. *Physiological Reviews*, 93, 1207–1246.
35. Rossettini, G., Carlino, E. and Testa, M. (2018) Clinical relevance of contextual factors as triggers of placebo and nocebo effects in musculoskeletal pain. *BMC Musculoskeletal Disorders*, 19, 27.
36. Colloca, L. (2017) Hypoalgesic placebo effects can occur with transparent disclosures. *Pain*, 158, 2279–2280.
37. Andersson, V., Otterstrom-Rydberg, E. and Karlsson, A.K. (2015) The Importance of written and verbal information on pain treatment for patients undergoing surgical interventions. *Pain Management Nursing*, 16, 634–641.
38. Fitzgerald, J. A. Bibliotherapy. Encyclopedia of mental disorders. http://www.minddisorders.com/A-Br/Bibliotherapy.html (13 March 2019, date last accessed).
39. Glasgow, R.E. and Rosen, G.M. (1978) Behavioral bibliotherapy: a review of self-help behavior therapy manuals. *Psychological Bulletin*, 85, 1–23.
40. Grinder, J. and Bandler, R. (1975) *The Structure of Magic: A Book About Language and Therapy*. Science and Behavior Books, Palo Alto, CA.
41. Cozzani, M., Ragazzini, G., Delucchi, A., Barreca, C., Rinchuse, D.J., Servetto, R., Calevo, M.G. and Piras, V. (2016) Self-reported pain after orthodontic treatments: a randomized controlled study on the effects of two follow-up procedures. *European Journal of Orthodontics*, 38, 266–271.
42. von Baeyer, C.L., Spagrud, L.J., McCormick, J.C., Choo, E., Neville, K. and Connelly, M.A. (2009) Three new datasets supporting use of the Numerical Rating Scale (NRS-11) for children's self-reports of pain intensity. *Pain*, 143, 223–227.
43. Ferreira-Valente, M.A., Pais-Ribeiro, J.L. and Jensen, M.P. (2011) Validity of four pain intensity rating scales. *Pain*, 152, 2399–2404.
44. Pagé, M.G., Katz, J., Stinson, J., Isaac, L., Martin-Pichora, A.L. and Campbell, F. (2012) Validation of the numerical rating scale for pain intensity and unpleasantness in pediatric acute postoperative pain: sensitivity to change over time. *The Journal of Pain*, 13, 359–369.
45. Derevianchenko, N., Lvtovska, O., Diurba, D. and Leshchyna, I. (2018) Impact of medical terminology on patients' comprehension of healthcare. *Georgian Medical News*, 284, 159–163.
46. Herber, O.R., Gies, V., Schwappach, D., Thürmann, P. and Wilm, S. (2014) Patient information leaflets: informing or frightening? A focus group study exploring patients' emotional reactions and subsequent behavior towards package leaflets of commonly prescribed medications in family practices. *BMC Family Practice*, 15, 163.