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Published paper

Benson, PE, Razi, RM and Al-Bloushi, RJ (2012) *The effect of chewing gum on the impact, pain and breakages associated with fixed orthodontic appliances: a randomized clinical trial*. Orthodontics and Craniofacial Research, 15 (3). 178 - 187.

<http://dx.doi.org/10.1111/j.1601-6343.2012.01546.x>

The effect of chewing gum on the impact, pain and breakages associated with fixed orthodontic appliances: a randomized clinical trial

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Running title: Chewing gum and fixed appliances – an RCT

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Abstract: 246 words

Full manuscript: 4,497 words

Abstract

Authors - Benson PE, Razi RM, Al-Bloushi RJ

Objectives - To determine if the use of chewing gum reduced the impact and pain of fixed orthodontic appliances.

Setting and sample population - The Orthodontic Department of the Charles Clifford Dental Hospital, Sheffield, UK. Fifty-seven patients aged 18 years old or younger and who were about to start fixed orthodontic appliance treatment.

Subjects and Methods - A randomized clinical trial with two parallel groups allocated to either receive chewing gum after placement of their appliance or who were asked not to chew gum. The patients completed a previously validated Impact of Fixed Appliances questionnaire at 24hrs and 1wk following each visit up until the placement of the working archwire. A visual analogue scale (VAS) was used to assess the intensity of pain. Appliance breakages were recorded to the end of treatment.

Results - The difference between the median Total Impact Score of the two groups at 24hrs was 16, which was significantly different ($P=0.031$; Mann-Whitney U test). The difference between the median VAS between the two groups at 24 hours was 25 mm, which was significantly different ($P=0.038$; Mann-Whitney U test). There were no differences at 1 week. None of the risk ratios for appliance breakages were significant.

Conclusion - Chewing gum significantly decreased both the impact and pain from the fixed appliances. There was no evidence that chewing gum increased the incidence of appliance breakages.

Key words - Orthodontics; Randomized controlled trial; Chewing Gum; Fixed appliance; Impacts

Clinical relevance

Orthodontic appliances cause discomfort and can affect eating, speaking, smiling and other activities. Some patients give up treatment early because of the impact on their everyday life. We should therefore do all we can to minimize this impact. One simple intervention is to advise patients to chew gum when it suits them. However there are few clinical studies examining either the positive or negative effects in patients with fixed orthodontic appliances, which hopefully are addressed with this study. This found that chewing gum reduced the impact and discomfort of fixed appliances without the negative effects of causing more breakages.

Introduction

It has been shown that fixed orthodontic appliances lead to a deterioration in both adolescent (1, 2) and adult (3) oral health-related quality of life (OHRQoL), particularly in the first month after placement. This is related to the functional and social discomfort associated with wearing a fixed appliance (4), as well as the physical discomfort and pain.(5, 6) This impact on OHRQoL may affect compliance and may lead to patients failing to complete treatment.

The commonest method of controlling the pain and discomfort from orthodontic appliances investigated has been the use of systemic analgesics.(7, 8) The use of local pharmaceutical agents has also been investigated.(9) Non-pharmological methods include transcutaneous electrical nerve stimulation (TENS)(10) and lasers. (11)

It has been shown that the act of chewing leads to increased pulpal sensory thresholds to electrical stimulation.(12) Chewing has been recommended as a means of increasing the blood flow into and around the periodontal membrane, restoring lymphatic circulation and preventing, or relieving the inflammation and oedema.(13) It also stimulates salivary flow, increasing the bicarbonate concentration and consequently the pH and buffering capacity of saliva, as well as increasing the rate of clearance of oral sugar and plaque acid, hence reducing the incidence of demineralization and caries.(14)

There are few studies examining the effect of chewing on reducing the impact of fixed orthodontic appliances. Otasevic et al(15) undertook a randomized clinical trial to compare the effects of using a masticatory bite wafer compared with avoidance of hard

food to reduce pain and discomfort associated with initial orthodontic tooth movement. They reported significantly higher median pain scores in the bite wafer group for the first 4 days.

The aim of this study was to determine the effect of chewing gum on the impact and pain caused by fixed orthodontic appliances.

The specific research questions were:

- Does the use of chewing gum reduce the impact of a fixed appliance?
- Does the use of chewing gum reduce the pain following placement and adjustment of a fixed orthodontic appliance?
- Does the use of chewing gum increase the number of appliance breakages?

Subjects and Materials

Ethical approval for this study was obtained from South Sheffield Research Ethics Committee (reference number 07/H1309/96; November 2007). All participants or their parents gave written informed consent to take part in the trial.

The design was a randomized clinical trial with two parallel groups. The setting was the Orthodontic Department of a dental teaching hospital, the Charles Clifford Dental Hospital, Sheffield, UK.

Participants were recruited who fulfilled the following inclusion criteria:

- 18 years old or younger;

- About to start treatment with a fixed orthodontic appliance in at least one dental arch.

The following exclusion criteria were applied:

- Patients with a cleft of the lip or palate;
- Patients with phenylketonuria (those patients have to avoid products containing aspartame or artificial sweeteners which contain phenylalanine);
- Significant medical history;
- Poor dental or periodontal health precluding the use of fixed appliances.

Patients were screened at an initial records appointment and if deemed suitable for inclusion the study was explained verbally to the patient and their parent(s) and written information provided. They were allowed at least one week to consider whether or not to take part. If they agreed then written consent was subsequently obtained from patients and their parents.

Following consent participants were randomly allocated to one of two groups:

Chewing Gum (CG): received chewing gum (Wrigley's Orbit Complete®) to use when required at the bonding/separator appointment and subsequent appointments up to the visit after the placement of the working archwire (0.019×0.025 stainless steel).

Non-chewing Gum (NG): were specifically asked not to chew gum for the duration of the study.

Randomization was carried out by one of the authors (PEB) using computer generated random numbers. To ensure an equal number in the two groups a block design was used with randomly allocated blocks consisting of 4, 6, 8 or 10 participants. Enrollment into the trial was undertaken by two of the authors (RMR and RJA). The allocations were concealed in consecutively numbered opaque sealed envelopes, which were opened only after the patient and parent had agreed to enter the trial and had signed the consent form. Masking of the patient to group allocation was not possible because they were either asked to chew gum or not. Masking of the operator was undertaken where practical; however this was not always possible. Following an administrative error the first six patients in the chewing gum group received a diary that did not contain the 24 hour questionnaire; therefore one subsequent random block was weighted to contain more participants to be randomly allocated to the CG group.

The participants were treated by one of three orthodontic postgraduate students in the department using standard treatment mechanics. Upper and lower pre-adjusted edgewise appliances (0.022-inch slot, MBT prescription, Victory®, 3M, St Paul, MN) were placed using bonds on incisors, canines and premolars. Bands were placed on first molars. The initial aligning archwire was a round nickel-titanium (0.014-inch). Once alignment was achieved then a rectangular nickel-titanium (0.018 x 0.025-inch) was placed followed by a rectangular stainless steel (0.019 x 0.025-inch). After each visit up to and including following placement of the rectangular stainless steel participants were asked to complete a diary that included a previously validated Impact of Fixed Appliances (IFA) questionnaire designed to quantify the impact of a fixed appliance on a patient's daily life. (16) IFA consists of one global question and 32 questions in 9 subscales, including aesthetics, functional limitations, dietary impact and social impact.

The response options are on a 5 point scale from 1 (strongly disagree) to 5 (strongly agree). The responses of the 32 questions are summed to give an overall Total Impact Score (TIS).

Patients in the CG group were asked to use the chewing gum whenever they needed it, but in particular they were asked to chew gum for 10 minutes before filling in the questions. Patients in the NG group were specifically asked not to chew gum for the duration of the study.

Patients were given the diary to take home and asked to complete it at 24 hours and 1 week after placement or adjustment of their appliances. The patients were also asked to indicate on a 100 mm visual analogue scale (VAS) how much their teeth were hurting at that time, where the left side of the scale indicated “My teeth do not hurt at all” and the right side of the scale indicated that “My teeth hurt very badly” and whether they had taken any analgesics and had any other problem with the brace. Patients in the CG group were asked to make a note of how many sticks of gum they used.

Outcomes

The primary outcome was the TIS reported by the participants at 24 hours and 1 week after placement of the brace.

Secondary outcome measures included:

- Patients’ assessment of pain using the VAS measurements at 24 hours and 1 week after placement of the appliance;

- Reported use of oral analgesics;
- Recorded appliance breakages.

Statistical analysis

Data from a study using a similar methodology, but a different questionnaire were used. (17) The calculation determined that a sample size of 60 patients should be sufficient to detect a 20% difference in impact score (sd 14.4) to a power of 0.85 ($\alpha = 0.05$).

The data from each diary were entered into a spreadsheet (Excel® 2007, Microsoft Corp, USA). The frequency of the modal responses for each participant to the global question ‘How much does the brace affect your life overall?’ were determined at 24 hours and 1 week. The mode was used because examination of the data showed that many participants recorded the same global score over several visits, therefore this was considered the most appropriate summary measure. The five possible responses were collapsed into three groups. The difference in frequencies between the NG and CG groups was tested using the chi-squared test for trends.

The median TIS and VAS recorded at 24 hours and 1 week for each participant during the trial were analysed. The distributions of the TIS and VAS were examined and found not to be normal; therefore differences between the median scores recorded by the two groups at 24 hours and 1 week were tested using the non-parametric Mann-Whitney U test.

A frequency table of analgesic use was constructed to compare the participants who reported that they had and had not used analgesics. A chi-squared test was used to detect any difference in analgesic use between the chewing gum and the non-chewing gum groups at 24hrs and 1 week.

The total number of bands and brackets placed and the number of first time failures during the experimental period (up to and including the visit in which the 0.019 x 0.025-inch ss working archwire was placed) and the whole treatment was recorded contemporaneously on a data collection sheet placed in the patient notes. In addition the number of wire failures (defined as fracture or total loss of the archwire) was recorded, as well as the frequency and reason for any other problems with the appliance. The percentages of first time failures and the risk ratios (and 95% confidence intervals) for patients in the CG experiencing at least one failure of their appliance compared with patients in the NC group were calculated for both the experimental period and the whole of treatment.

The statistical tests were performed with PASW statistics (v18.0, SPSS Inc, USA) and the statistical significance was set at $P < 0.05$.

Results

Figure 1 shows the flow of patients through the.(18) Recruitment started in February 2008 and was completed in April 2009. Sixty eight patients were recruited and randomized. The numbers were slightly increased in the CG group due to an administrative error, which led to the first six patients receiving a diary that did not contain the 24 hour questionnaire. To compensate one of the randomization blocks later

in the trial was weighted to contain more participants randomly allocated to the CG group. One patient in the CG group dropped out of treatment. One patient in the CG group and three patients in the NG group were excluded from the analysis because they did not return any diaries and six patients from the CG group were excluded due to the administrative error. The final numbers of participants in each group included in the analysis were 28 patients in the NC group and 29 patients in the CG group.

The baseline demographics and treatment characteristics of the two groups are shown in Table 1. Overall 31 males and 26 females took part in the study. There were more males in the NC group compared with the CG group. The median number of returned diaries was 6 (sd; range 1 to 13).

Global rating of Impact

Table 2 shows the frequency of the modal responses for each participant to the global question. The statistical analysis suggests that the frequency of impacts was significantly lower for the CG group at 24 hours ($P=0.044$; chi-squared test for trend), but not at 1 week ($P=0.291$; chi-squared test for trend).

Total Impact Scores (TIS)

Figure 2 shows boxplots for the TIS. At 24 hours the median TIS was 89 (range 32 – 130) for the NC group and 73 (range 39 – 145) for the CG group, which was significantly different ($P=0.031$; Mann-Whitney U test). At 1 week the median TIS was 78 (32 – 130) for the NC group and 70 (range 36 – 148) for the CG group, which was not significantly different ($P=0.185$; Mann-Whitney U test).

Visual Analogue Scores (VAS)

Figure 3 shows boxplots of the VAS. At 24 hours the median VAS was 45 mm (range 0 – 84 mm) for the NC group and 20 mm (range 0 – 87 mm) for the CG group, which was significantly different ($P=0.038$; Mann-Whitney U test). At 1 week the median VAS was 21mm (0 – 69 mm) for the NC group and 9 mm (range 0 – 91 mm) for the CG group, which was not significantly different ($P=0.255$; Mann-Whitney U test).

Medication use

Table 3 shows the number of participants in the NC and CG groups who did and did not report taking painkillers during the experimental period. There were no statistically significant differences between the two groups at either 24 hours ($P=0.903$; Pearson Chi squared) or 1 week ($P=0.104$; Pearson Chi squared).

The median number of sticks of chewing gum used was 5 (range 2 – 19) at 24 hours and 6 (range 2 – 14) at one week.

Appliance failures

A total of 252 bands were placed in participants (NC 125; CG 127) and the number of first time band failures during the experimental period was 11 (NC 4; CG 7; failure rate 4.4%) and 15 (NC 7; CG 8; failure rate 6.3%) throughout treatment. A total of 1009 brackets were placed (NC 498; CG 511) and the number of first time failures was 72

during the experimental period (NC 36; CG 36; failure rate 7.1%) and 94 during the whole treatment period (NC 52; CG 42; failure rate 9.3%).

Table 4 outlines the proportions of patients experiencing first time band and bracket failures, as well as wire and other problems with their appliance. All the risk ratios and their 95% confidence intervals were within a value of 1, which denotes that there were no significant differences between the NC and CG groups for any of the appliance failures.

Discussion

This randomized controlled trial with two parallel groups of young people undergoing fixed orthodontic treatment found that chewing gum significantly decreased the impact and pain from the appliance. There was no evidence that chewing gum increased the incidence of appliance breakages.

This was the first study to use the impact questionnaire developed by Mandall et al (16) as a primary outcome in a randomized controlled trial. It is increasingly being recognized that the aim of healthcare is to improve an individual's health and that the patient is in the best position to judge this. It is hoped that researchers will increasingly consider using patient-based measures, rather than the more traditional cephalometric and occlusal outcomes when designing clinical trials in the future.(19)

Miller et al (17) used an impact questionnaire with two cohorts of adult patients undergoing fixed appliances and clear aligners, although the development and testing of the questionnaire for validity and test-retest properties are not described. The authors

did find that the patients receiving aligners suffering fewer impacts; however no randomization was undertaken and there were significant differences in the age, income and reason for treatment between the two groups at the start of treatment. In addition, it is not clear from the report whether the severity of the patient malocclusions was similar between the two groups. By randomizing to the intervention and non-intervention we hope to have addressed these confounders in our study.

The randomization did lead to a higher proportion of males in the NC group and a higher proportion of females in the CG group. Amongst those approached to take part in the study the proportions were similar to those undergoing treatment (56% female to 44% male). This was almost exactly reversed when patients were recruited to the study (46% female v 54% male). We can only speculate about the reasons for this, because ethical considerations meant that those approached did not have to give a reason why they did not want to take part, but perhaps chewing gum is more popular with boys compared with girls.

There are conflicting reports about whether there are differences in the reporting of pain between males and females. Some studies have found that gender has no significant effect on the impact of fixed appliances.(16) (20) Miller et al (17) found that females reported higher impacts than males, although gender was not a significant predictor of VAS values. We found no significant differences between males and females for the median TIS at 24 hours ($P=0.911$; Mann-Whitney U test) and 1 week ($P=0.779$; Mann-Whitney U test) or the median VAS scores at 24 hours ($P=0.785$; Mann-Whitney U test) and 1 week ($P=0.372$; Mann-Whitney U test). Our study was not designed to determine differences between genders, but if females were to score higher

than males (21-23) then the increased proportion of females in the chewing gum group would have reduced the difference between the NC and CG groups and decreased the possibility of finding a significant difference, therefore the true difference between the NC and CG groups might actually be greater.

The prevalence of impacts on the adolescents' life due to a fixed appliance was quite high according to the global question. Over one half of participants in the non-chewing gum group (54%) reported that the brace affected their life overall 'Some', 'A lot' or 'Very much' at 24 hours, which reduced to 36% at 1 week. In contrast the equivalent proportions for the chewing gum group were 24% and 25%, which concurs with Bernabe et al.(20)

We chose to use a single summary measure of impact and pain (the median score) at 24 hours and 1 week even though we collected serial data over a number of visits. We were interested in the differences between the NC and CG groups, rather than changes with time. Generally, 24 hours after fixed appliance placement/adjustment is considered the peak time for pain, which then reduces over the next week. (22, 24) One common statistical approach is to use linear regression to detect differences at different time points. On examination of the data we believe that a simplified approach was appropriate as interpretation of multiple p-values at different time points would have been difficult.(25) There was no simple linear relationship between the data at different time points and the participants returned different numbers of diaries due to the speed with which they progressed to the working archwire, as well as sometimes forgetting to return the diaries.

The overall bond failure rate (9.3%) was slightly higher than is reported in other studies. This might have been due to the treatments being carried out by three postgraduate students with limited experience of bonding appliances before starting the course. An appropriate statistical analysis was used which took into account clustering of teeth within the mouth. (26) Breakages were assessed both during the experimental period and throughout treatment. This was undertaken because it is possible that chewing gum led to weakening of a bond, which subsequently failed outside the experimental period; however we found no evidence for this. Most bracket and band failures occurred in the initial stages of treatment.

One interesting aspect of the diary was the comments placed in a box after the impact questions. Most of the comments made by the chewing gum group indicated that chewing gum helped with the pain and discomfort, for example:

“At first they were painful but now I am use (*sic*) to them, they do not hurt and chewing the gum helped heal the pain.”

Some mentioned that chewing gum distracts their attention from the discomfort:

“I feel the gum helps because you’re occupied and you do not fiddle about with the brace, it also helps you to forget about the brace and it releases the pain slightly.”

Others found that chewing gum did not help when the teeth were very sore:

“I used the chewing gum as it hurt a lot, however, this made it worse. I have found that if the pain is extreme the chewing gum hurts more; however, if the pain is slight then chewing the gum helps to loosen the jaw.”

A few noticed that it helped to keep the brace clean:

“I think sometimes the chewing gum does help release food that gets stuck in the brace.”

The additional potential benefit of chewing gum increasing salivary flow and helping to clean the appliance and possibly reduce demineralization would be an interesting avenue for future studies.

Conclusions

- Chewing gum reduced the impact and pain from fixed orthodontic appliances.
- There was no evidence that chewing gum increased the prevalence of appliance breakages.

Acknowledgements

The authors are grateful to Wrigleys UK who supplied the chewing gum used in this trial.

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Tables

Table 1

Baseline, treatment characteristics and mean number of returned diaries of the participants in the two groups.

		Non-chewing Gum N = 28	Chewing Gum N = 29
Gender	Males	19	12
	Females	9	17
Mean Age in Yrs (sd) at start of treatment		14.7 (1.5)	13.9 (1.6)
Treatment	Extraction	17	17
	Non-Extraction	11	12
	Mean length of time (mths) in the study (sd)	12.9 (4.8)	11.4 (6.7)
	Mean length of time (mths) in active treatment (sd)	22.1 (5.0)	21.9 (7.0)
	Mean number of visits in active treatment (sd)	16.2 (3.5)	15.1 (4.3)

Table 2

Frequency of responses (mode for each participant) to the global question ‘How much has your brace affected your life overall?’ for the two groups at 24 hours and 1 week (responses collapsed into three groups).

	Non-chewing Gum N=28				Chewing Gum N=29			
	24 hrs		1 wk		24 hrs		1 wk	
	N	%	N	%	N	%	N	%
‘Not at all’ or ‘Very little’	13	46.4%	18	64.3%	22	75.9%	22	75.9%
Some	9	32.1%	6	21.4%	4	13.8%	5	17.2%
‘A lot’ or ‘Very much’	6	21.4%	4	14.3%	3	10.3%	2	6.9%

Table 3

Number of participants who did and did not respond to the question ‘Have you taken any painkillers or other medications because of your brace today?’ at least once during the experimental period.

	Non-chewing Gum N=28				Chewing Gum N=29			
	24 hrs		1 wk		24 hrs		1 wk	
	N	%	N	%	N	%	N	%
Did not report using analgesics	13	46.4%	22	78.6%	13	44.8%	17	58.6%
Reported the use of analgesics at least once	15	53.6%	6	21.4%	16	55.2%	12	41.4%

Table 4

Numbers and proportions of participants, and risk ratios for the various appliance failures between the two groups during the experimental period and throughout treatment.

Type of Appliance Failure	Time period	Non-chewing gum (N = 28)		Chewing Gum (N = 29)		Total (N = 57)		Risk Ratio	95% Confidence Intervals
		N	%	N	%	N	%		
1 st time band failures	Experimental period	4	14.3%	5	17.2%	9	15.8%	1.21	0.36, 4.04
	Treatment period	5	17.9%	5	17.2%	10	17.5%	0.97	0.31, 2.98
1 st time bond failures	Experimental period	16	57.1%	18	62.1%	34	59.6%	1.09	0.71, 1.67
	Treatment period	18	64.3%	20	69.0%	38	66.7%	1.07	0.74, 1.55
Wire failures	Experimental period	5	17.9%	4	13.8%	9	15.8%	0.77	0.23, 2.58
	Treatment period	5	17.9%	6	20.7%	11	19.3%	1.16	0.40, 3.37
Other problems	Experimental period	13	46.4%	15	51.7%	28	49.1%	1.11	0.66, 1.89
	Treatment period	16	57.1%	17	58.6%	33	72.7%	1.03	0.66, 1.60

Figures

Figure 1

Flowchart of participants through the trial(18)

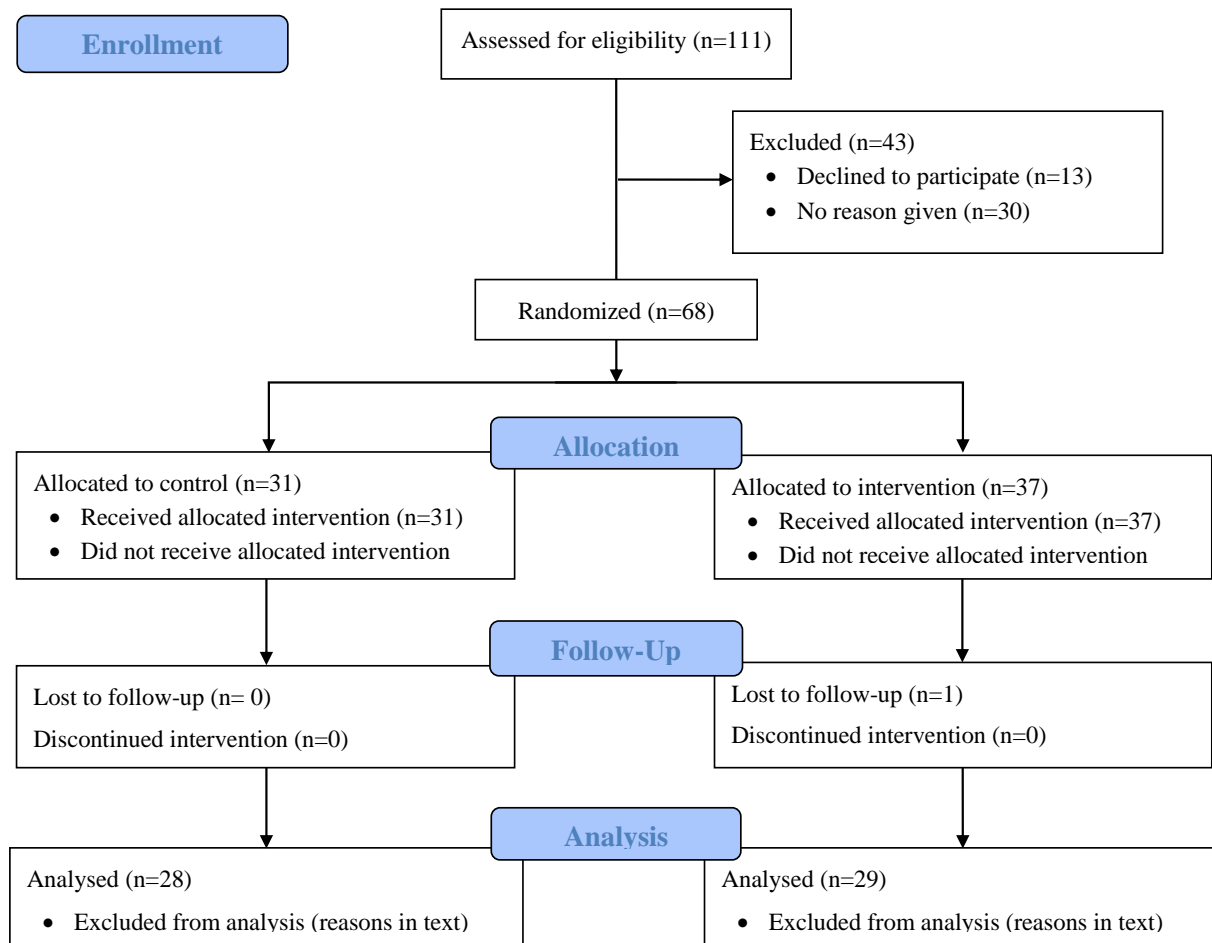


Figure 2

Boxplots of median Total Impact Scores for the two groups at 24 hours and 1 week.

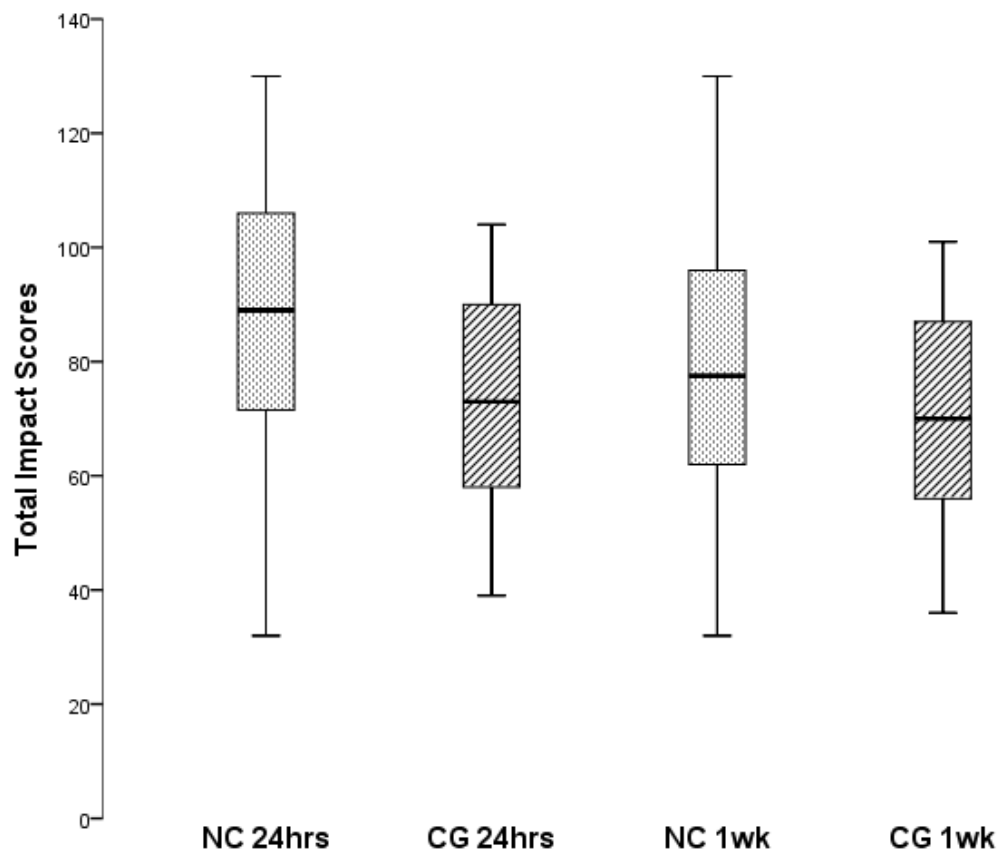


Figure 3

Boxplots of median Visual Analogues Scales for the two groups at 24 hours and 1 week.

