ORIGINAL ARTICLE

Informed consent in orthodontics: A Prospective RCT comparing two methods of information delivery

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ABSTRACT

Objective: To assess the influence of two different methods of information delivery on recall of information during the consent process for orthodontic treatment.

Design and setting: A prospective randomized controlled questionnaire based study conducted at the Royal London Hospital and Central Middlesex Hospital.

Materials and Methods: 64 patients starting fixed appliance treatment aged between 10 and 15 years were recruited. The control group (*n* = 31) and their parents received verbal information only regarding fixed appliance treatment. The study group (*n* = 33) and their parents received verbal supplemented with written information concerning fixed appliance therapy. Supervised completion of questionnaires was conducted with subjects and their parents immediately after the consenting process and approximately 6 weeks later.

Results: 61 patients and their parents completed the questionnaire (control group *n* = 30; study group *n* = 31). The study group was more aware about the possibility of pain from braces, the need for emergency visits or the possibility of breakages compared with the control group (OR 0.92, CI 0.11-0.79). The study group was three times more likely to know the correct answer to how long treatment would take to complete compared to the control group (OR 3.20, CI 1.11-9.22). Furthermore, the study group was 3.5 times more likely to give the correct answer to why it is necessary to wear retainers compared to the control group (OR 3.65, CI 1.16-11.44).

Conclusions: Verbal information given to patients about fixed appliance treatment should be supplemented with additional written information.

Key words: Consent, comprehension, health education, informed consent, written informed consent

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Introduction

As in other areas of healthcare, issues relating to informed consent are becoming increasingly important in orthodontics although the importance of this seems not to be apparent to all as yet.[1] Research examining dental patients' understanding of informed consent is relatively sparse.[2]

King *et al.*[3] explored the process of obtaining informed consent in dentistry and highlighted the benefits for patients. These included: Creating greater awareness; "voicing" concerns; increasing empowerment; enhancing dignity; increasing motivation; increasing satisfaction and reducing anxiety. Furthermore, well-informed patients are believed to have more reasonable expectations from treatment and are less likely to file lawsuits for malpractice.[2]

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The value of obtaining informed consent in a manner that promotes the above is of particular importance in orthodontics. This is because, treatment is usually of long duration, involving a number of appointments and is extremely reliant on the patient's co-operation, in particular with appliance wear and maintenance of good oral hygiene. Various studies have highlighted the importance of patient compliance with reference to orthodontic treatment. [4,5] Furthermore, behavioral studies regarding patient co-operation in orthodontic treatment have concluded that the most important predictor is a good relationship with their parents.[6] Albino *et al.*[7] suggested that the parent's attitude towards orthodontic treatment was the strongest predictor of patient co-operation in the early stages of treatment. In the

later stages of treatment, their results suggest that the patient's attitude has a greater influence on co-operation.

It is clear from the above, that a process of communication that leads to patients and their parents being fully informed is of fundamental importance in orthodontics.

However, Mortensen *et al.*[2] suggest that informed consent appears to be a problem in orthodontics. They quote Pratelli *et al.*[8] who showed that parents themselves who had undergone orthodontic treatment were often unaware of treatment risks; just 41% of patients in their study knew that caries could occur beneath fixed appliances and 33% recalled the possibility of relapse following treatment.

Thomson *et al.*[9] found that both parents and patients exhibited poor recall of information regarding certain aspects of orthodontic treatment in both the short and long-term. This questionnaire-based study compared three methods of providing information regarding orthodontic treatment, namely, verbal, written and visual techniques. Twenty-eight patients and their parents were divided into groups to receive written, verbal or visual information about orthodontic treatment. Retention of this information by patients and parents was assessed in both the short (15 min after receiving the information) and long-term (8 weeks after receiving the information). The authors concluded that verbal information about orthodontic treatment should be supplemented by written or visual information being given to patients.

Mortensen *et al.*[2] investigated 29 orthodontic patients and their parents with reference to informed consent in orthodontics. Parents and patients were provided with verbal information relating to the reasons for treatment, the procedures to be used, the risks, the alternatives and the patients' and parents' responsibilities during treatment. Interviews were conducted immediately afterwards to assess patient and parent recall of the information provided. The authors concluded that, in general, both parents and patients recalled significantly less information than had been provided.

These findings raise concerns about the effectiveness of informed consent techniques employed in orthodontics and according to Mortensen *et al.*[2] research should focus on methods to improve the communication process for patients undergoing orthodontic therapy. To date, however, there have only been a few studies that have compared the understanding and recall of information given to orthodontic patients in various formats.

The aim of this study, therefore, was to assess the influence of two differing methods of information delivery (verbal and verbal supplemented with written information) to the consenting process.

Null hypothesis

- There is no difference in the response between patients who receive verbal supplemented with written information (study group) and those who receive verbal information only (control group) to questions about fixed appliance treatment.

Materials and Methods

Ethical approval

This two center, prospective, randomized, controlled questionnaire based study was conducted in the Orthodontic Departments of The Royal London Hospital and Central Middlesex Hospital. Ethical approval was obtained from the relevant Research and Ethics Committee for each center involved in the study.

Subjects

New patients starting fixed appliance treatment aged between 10 and 15 years, and their parents, were invited to participate. Patients who had previously undergone orthodontic treatment with fixed braces or those with learning disabilities were excluded from the study. Prior to enrollment, each subject and their parent were provided with verbal and written information about the study and written consent was obtained from each participant prior to entry.

Sample size calculation

A minimum overall sample size of 110 subjects, 55 in each group (control, study) was proposed to offer 80% power at the 95% confidence interval to demonstrate 0.5 standard deviation difference in understanding the information between the two groups (Nomogram by Altman, 1995).

Overall, 130 subjects were invited in the study to allow for drop out.

Study design

The main study was started after completion of a preliminary study to assess the suitability of the questionnaire for this study population. All the patients recruited for the study were due to start fixed appliance treatment with 1st or 2nd year orthodontic registrars in training. They were introduced to the investigator by the clinician and invited to participate in the study. Each patient and their accompanying parent were randomly allocated to either the control or study group. Random allocation gives all subjects the same chance of receiving either intervention, and thus the allocation is unbiased. Drawing concealed pieces of paper marked 'S' (study group) or 'C' (control group) from a box allowed for random allocation of subjects.

One investigator conducted the consent process for all subjects in the study. Guidelines were considered necessary forming a structured protocol on which the investigator based the informed consent process. For the purposes of this study

a model which defines the process of informed consent as a series of stages in practical terms as described by King *et al.*[3] was applied. Both groups, therefore, received information in a standardized manner.

Once the consenting process was complete all subjects were invited to complete the first part of the questionnaire during a structured interview (T1). Patients were interviewed in a large open clinic in full view of the parents who could not hear the answers being given to the questions. The accompanying parents were interviewed after the children in a similar manner as above. Patients were given appointments to return approximately 6 weeks later (T2) to complete the second part of the questionnaire that coincided with the first archwire change appointment.

The subjects in the control group were provided with standardized verbal information regarding fixed appliance treatment. This followed the normal procedure used within the departments. No additional supplementary forms of information were given. Patients and parents were invited to ask questions relating to the information provided.

The study group received the same information as the control group with the addition of a specially designed leaflet. This provided general information regarding fixed appliance treatment and was designed, illustrated and written in a way that made it visually appealing and comprehensible to children. A Gunning Fog test (Appendix 1) was applied to the information leaflet to assess its readability. Reading scores of higher than 12 suggest that the leaflet should be rewritten to make the text more comprehensible. Three separate sections of the leaflet were subjected to the test and 'reading scores' of 7.8, 4.8 and 8.6, implied the leaflet was reasonably simple to understand. Patients and parents were allowed adequate time to read the information leaflet and ask questions relating to its contents.

A CONSORT diagram showing the flow of participants through each stage of the study is [Figure 1].

Design of questionnaire

The questionnaire consisted of 35 closed and open-ended questions. Part of the questionnaire was compiled using extracts from the questionnaires from the Child Dental Health Survey[10] and from Alderson's study[11] on "Children's consent to surgery". In addition, the researcher added some additional questions that assessed recall of information given.

Questions in relation to recall of information were divided into four sections: Demographic details, general dental knowledge, previous dental experience (asked at T1) and issues of informed consent. The later explored disclosure and understanding of information (asked at T1); willingness and competence to consent to treatment (asked at T1); understanding and recall of information given at the start of treatment (asked at T2).

Data analysis

Data analysis was carried out using SPSS PC+ (SPSS Inc., Chicago, IL.), version 11.5 for Windows and involved descriptive and analytical statistics. The first stage of analysis summarized the baseline characteristics of the participants in order to ensure that the two groups were similar with respect to variables that may affect the outcome of measure. Cross

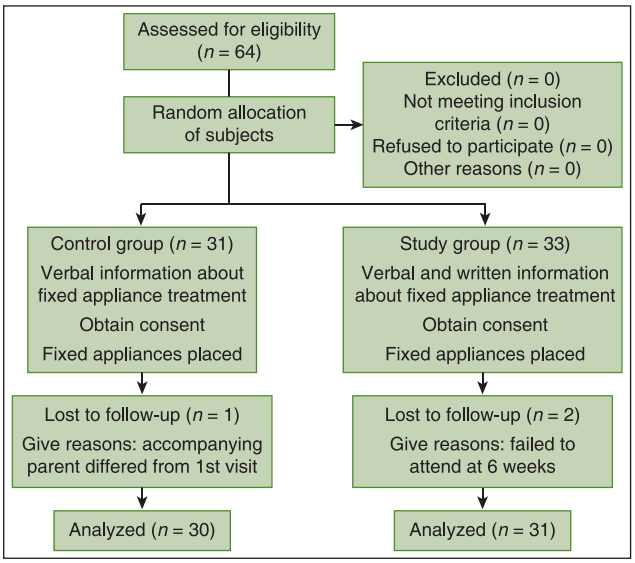

Figure 1: Consort chart showing the flow of participants through each stage of the trial

Appendix 1

The Gunning Fog Test

This test provides a simple numerical index of readability

The method outlined below is as described by Albert and Chadwick (1992)

1. Choose a passage of about 100 words, which must end in a full stop
2. Find the average sentence length by dividing 100 by the number of sentences.
3. Find the number of long words, defined as those of three syllables or more, excluding
   a. proper nouns;
   b. combination of easy words, like photocopy;
   c. verbs that become three syllables when "-es," "-ing," and "-ed" are added (for example, committed);
   d. jargon that the reader will know
4. Add the average sentence length to the number of long words
5. Multiply by 0.4 to get the "reading score"

For scores of 12 or above it is recommended that shorter sentences or simpler words should be used (Albert and Chadwick, 1992)

tabulations were used to calculate frequencies and percentages of correct and wrong answers to questions assessing recall of information for both groups.

Univariete analysis employing a logistic regression model was employed to investigate whether participants' correct answers to questions assessing recall of information were associated with the method of information delivery used for the study group in comparison to the control group.

An independent sample 't-test' was employed to compare the ages of the two groups of children.

The level of significance was set at 5% throughout.

Results

Response to questionnaire

Due to the time constraints 64 patients (control group $n = 31$; study group $n = 33$) and their parents were initially recruited for the study and completed the first part of the questionnaire. However, three patients (control group = 1; study group = 2) and their parents were unable to complete the second part of the questionnaire and were excluded from the analysis of the data. In two cases, the patients failed to attend for their appointment and in the third case the accompanying adult differed from the first visit. Results for 61 patients

(control group $n = 30$; study group $n = 31$) are presented. Questions relevant to the recall of information given for the two groups have been analyzed and presented.

Demographic characteristics of participants

Demographic details are presented in [Table 1].

The mean ages of patients in the control and study group were 13 years 8 months (range 11 years 10 months to 14 years 10 months) and 13 years 4 months (range 11 years 11 months to 14 years 11 months) respectively.

There were no significant differences between the study and control group of patients with respect to age ($P = 0.170$), gender ($P = 0.149$), ethnicity ($P = 0.923$), social class ($P = 0.860$) and accompanying adult ($P = 0.251$) [Table 1].

Table 1: Demographic data for control and study group of patients

	Control group *n* (%)	Study group *n* (%)	*P* value
Gender			
Male	14 (46.7)	16 (51.6)	$P=0.149$
Female	16 (53.3)	15 (48.4)	
Ethnicity			
Caucasian	19 (63.3)	20 (64.5)	$P=0.923$*
Afro-Caribbean	2 (6.7)	3 (9.7)	
Asian	5 (16.7)	7 (22.6)	
Other ethnic group	4 (13.3)	1 (3.2)	
Accompanying adult			
Mother	25 (83.3)	22 (71.0)	$P=0.251$
Father	5 (16.7)	9 (29.0)	
Social class			
Social class I	2 (6.7)	2 (6.5)	$P=0.860$**
Social class II	8 (26.7)	9 (29.0)	
Social class III	5 (16.7)	8 (25.8)	
Social class IV	10 (33.3)	8 (25.8)	
Social class V	5 (16.7)	4 (12.9)	

*Level of significance calculated by recoding Afro-Caribbean, Asian and other ethnic groups together as one group, **Level of significance calculated by recoding social classes I and II together as one group and social classes III, IV and V together as another group

Dental awareness and previous dental experience

Table 2 shows the data relating to dental awareness and previous dental experience.

In the control group, 15 (50%) patients reported having no treatment at their dentist while 15 (50%) patients reported having teeth filled or extracted. In the study group, however, only 3 (9.7%) patients reported having no treatment at their dentist while 28 (90.3%) reported having teeth filled or extracted. This represents the only significant difference between the groups ($P = 0.001$) in response to questions relating to dental awareness and previous dental experience.

Recall of information

Comparison of participants' answers on the recall of information for the control and study groups is presented in [Table 3].

At T1 all patients in both groups responded by saying "yes" when asked if they fully understood the information given to them [Table 3].

The remaining questions (asked at T2) assessed recall of information given. No significant differences were observed between the groups for questions 4, 5, 6, 7 and 9 [Table 3]. Significant differences between the control and study group of patients were observed for questions 2, 3 and 8 [Table 3].

Six weeks into treatment, in response to question 2 (what do wish had been explained that wasn't?) the study group was less likely to answer the possibility of either pain from braces, the need for emergency visits or the possibility of breakages compared to the control group (OR 0.92, CI 0.11-0.79). The study group was three times more likely to answer question 3 (how long will treatment take to complete?) correctly compared to the control group (OR 3.20, CI 1.11-9.22). Furthermore, the study group was 3.5 times more likely to answer question 8 (why is it necessary to wear retainers?) correctly compared to the control group (OR 3.65, CI 1.16-11.44).

Overall, recall of information relating to risks associated with poor cleaning was poorly recalled by both groups [Table 3].

Table 2: Dental awareness and previous dental experience data for control and study group of patients

Question	Regrouped responses	Control group *n* (%)	Study group *n* (%)	*P* value
Dental awareness				
How often should you visit the dentist?	3 months	24 (80.0)	28 (90.3)	*P*=0.301
	6 months			
	Once a year			
	Toothache/ Emergency	6 (20.0)	3 (9.7)	
How often should you Brush your teeth?	Twice a day	30 (100)	31 (100)	*
	Three times a day			
	Once a day	0 (0)	0 (0)	
Previous dental experience				
Have you ever been to the dentist before?	Yes	30 (100)	31 (100)	*
	No	0 (0)	0 (0)	
What do you think of the dentist? Is he/she	Friendly	30 (100)	28 (90.3)	*P*=0.238
	Not very friendly	0 (0)	3 (9.7)	
What kind of treatment did you have?	Check-up/ no treatment	15 (50.0)	3 (9.7)	*P*=0.001
	Teeth filled	15 (50.0)	28 (90.3)	
	Teeth taken out			
Do you think you were pressured into accepting treatment?	Yes	0 (0)	0 (0)	*
	No	30 (100)	31 (100.0)	

*No statistics computed because response is a constant

Less than 50% of patients in both groups knew "the dentist" is responsible for carrying out their routine dental check-ups during treatment [Table 3].

Discussion

Informed consent, especially in relation to children, is being more freely explored in orthodontics and has become a topical issue in recent years. As with other areas of dentistry, there has been a general increase in the numbers of children becoming exposed to and undergoing orthodontic treatment. Furthermore, issues relating to Clinical Governance demand that healthcare professionals strive to ensure that patients are well informed about all aspects of proposed treatment. There is, therefore, a need to establish which methods of information delivery are the most effective in conveying information that is understood and retained by children undergoing orthodontic treatment.

Overall, patients in the control and study groups were well matched with respect to demographic variables, dental awareness and previous dental experience. It is apparent from the findings that the use of a written information leaflet produces better-informed patients with respect to certain aspects of fixed appliance treatment. It is, however, also clear that much of the information given to patients in both groups is not remembered six weeks into treatment, and therefore, informed consent in principle is not valid. It is acknowledged that the sample size did not reach the minimum sample size requirements, thus compromising the power of the present study. As a consequence, the findings should be interpreted with some degree of caution given the wide confidence intervals attained. The sample size attained was, however, comparable to other published data in this field that has been referenced in the discussion. Furthermore, the use a homogenous sample of patients all undergoing fixed appliance therapy strengthens the internal validity of the study.

The findings of this study are similar to those reported by others within the orthodontic literature.[9] Furthermore, the results bear similarities to studies that have explored the use of written information in other areas of healthcare. Ley[12] highlights a review of 32 studies exploring the use of written information that concluded the most overwhelming effect of written information was to improve patient knowledge. However, others studies[13-15] have suggested little benefit for the use of written information as a supplement to verbal information, which is at variance with the findings in the present study. There is, however, one important difference between these studies and the present study, which is that the patients were all adults as opposed to children. Adults have been shown to respond to verbal information better than children[9] and this may explain the difference in observed findings. A concerning finding was that much of the information given to patients in both groups is not remembered 6 weeks into treatment. These results are even more worrying when considering all patients were aware of their involvement in a research study. These findings are not surprising in comparison to the findings of other studies exploring recall of information in orthodontics. Mortensen *et al.*[2] reported that children and parents recalled fewer aspects relating to issues of informed consent than had

Table 3: Comparison of control and study group of patients

Question	Regrouped response		Odds ratio	95% CI for odds ratio
T1				
Do you fully understand the information given to you?	yes	no		
Control group *n* (%)	30 (100%)	0 (0%)	*	*
Study group *n* (%)	31 (100%)	0 (0%)	*	*
T2				
What do you wish had been explained that wasn't?	Pain from braces, Breakages Emergency visits	Nothing		
Control group *n* (%)	8 (26.7%)	22 (73.3%)	1	
Study group *n* (%)	1 (3.2%)	30 (96.8%)	0.92	0.11-0.79
How long will your treatment take to complete?	About 2 years	About 1 year ,about 3 years, don't know		
Control group *n* (%)	13 (43.3%)	17 (56.7%)	1	
Study group *n* (%)	22 (71.0%)	9 (29.0%)	3.20	1.11-9.22
How often will you need to come for adjustments to your braces?	Every 4-6 weeks	Every 2 weeks, every 2 months ,Don't know		
Control group *n* (%)	23 (76.7%)	7 (23.3%)	1	
Study group *n* (%)	27 (87.1%)	4 (12.9%)	2.05	0.53-7.91
Poor cleaning around braces causes….				
Bleeding gums?	Yes	No, don't know		
Control group *n* (%)	15 (50.0%)	15 (50.0%)	1	
Study group *n* (%)	11 (35.5%)	20 (64.5%)	0.55	0.20-1.54
Tooth decay?	Yes	No, don't know		
Control group *n* (%)	30 (100%)	0 (0%)	*	*
Study group *n* (%)	31 (100%)	0 (0%)	*	*
White/ brown scars on the teeth?	Yes	No, don't know		
Control group *n* (%)	14 (46.7%)	16 (53.3%)	1	
Study group *n* (%)	20 (64.5%)	11 (35.5%)	2.08	0.74-5.81
Why is it necessary to wear retainers after fixed braces are removed?	To hold the teeth in their new position	To move the teeth into the correct position, don't know		
Control group *n* (%)	16 (53.3%)	14 (46.7%)	1	
Study group *n* (%)	25 (80.6%)	6 (19.4%)	3.65	1.16-11.44
Who will be carrying out your routine dental check-ups during your brace treatment?	The dentist	The orthodontist Don't know		
Control group *n* (%)	14 (46.7%)	16 (53.3%)	1	
Study group *n* (%)	14 (45.2%)	17 (54.8%	0.94	0.34-2.58

*No statistics computed because response is a constant

been provided by the orthodontist. Other studies[8,9] further highlight the problem of information retention and recall with respect to orthodontic treatment.

Written material as an adjunct to information given verbally would seem to offer a number of benefits.[16] Therefore, the use of written information as a supplement to information given verbally is recommended for orthodontic patients.[16] Written information in the form of a leaflet can be given to patients thus serving as a lasting source of information to which they may refer. This has clear advantages over information given verbally which may be forgotten. However, the design of any patient information leaflet must be carefully considered to ensure it is appropriate. Specifically, the information contained within the leaflet must be easy to read, understand, remember and targeted at the appropriate age group.

At present the consenting process is a procedure conducted formally at the start of treatment. It may be that supplementing the consenting process at various intervals during treatment with a "sustained consent process" will produce patients that are well informed. This is particularly relevant in orthodontics where treatment is elective, usually of long duration and requires excellent patient compliance in achieving desired treatment outcome.

Summary of findings

The use of written information as a supplement to verbal information produces better-informed patients in relation to

certain aspects of fixed appliance treatment. Specifically, the study group was more aware about the possibility of either pain from braces, the need for emergency visits or the possibility of breakages. Furthermore, the study group was better informed with respect to the duration of treatment and the need for retainer wear. The null hypothesis was rejected for these questions.

However, it is also apparent that neither method (verbal or verbal supplemented with written information) of information delivery was particularly successful with respect to possible risks of treatment and who will be carrying routine dental check-ups during treatment. The null hypothesis was accepted for these questions.

Conclusions

- Verbal information given to patients about fixed appliance treatment should be supplemented with additional written information.
- Clinicians should re-inform patients about aspects of treatment mentioned in the initial consent process at appropriate times throughout treatment.

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