In patients undergoing fixed orthodontic treatment, does the use of a Waterpik® in addition to a manual toothbrush, compared to using a manual toothbrush alone, improve oral hygiene? A randomised controlled trial.

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1 Intellectual Property and Publication Statements

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My own contributions, fully and explicitly indicated in the thesis have been overall management and set up of the trial, training of nursing staff, acquiring trial materials, trial recruitment, collection of trial indices, statistical analysis, and thesis production.

The other members of the group and their contributions have been as follows:

Mr Hock-Hoe Goh – Supervisor, author of protocol, IRAS coordinator, author of trial literature
Mr Jay Kindelan – Supervisor
Dr Jing Kang – Statistician
Ms Amanda White, Ms Katie Friend, Ms Natalie Nickson, Ms Sharon Kelly – Trial nurses
Ms Deborah Phillips – Trial registration coordinator and NHS Trust research advisor
Mr Tom Szczerbicki – Risk assessment coordinator

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3 Abstract

Aims: To assess whether the use of a Waterpik® in addition to a manual toothbrush improves oral hygiene in patients wearing fixed orthodontic appliances.

Design: single-centre, single-operator, two-arm, parallel-group, stratified, single-blind, randomised controlled clinical trial with a 1:1 allocation ratio.

Setting: A single orthodontic department in an NHS District General Hospital in York (UK).

Subjects: 40 fit and well patients aged 10-20 accessing upper and lower fixed orthodontic therapy.

Methods: Participants were randomly allocated to the control group (manual toothbrush) or intervention group (manual toothbrush and Waterpik®). Plaque index, gingival index and interdental bleeding index were recorded as primary outcomes at baseline, 8-weeks, 32-weeks, and 56-weeks. Secondary outcome measures assessed were soft tissue trauma, adherence with oral hygiene regime and satisfaction with oral hygiene regime. A mixed model analysis was used to assess differences between groups.

Results: Interim analysis is performed due to COVID-19 disruption of the project progress. 34 participants have been recruited. 4 participants have completed the trial. The remaining patients are at various points with approximately 50% of data collected. The overall differences between the groups were as follows:

Orthodontic modification of plaque index: 0.02 (p = 0.85, 95% CI: -0.2, 0.2)

Gingival index: -0.06 (p = 0.45, 95% CI: -0.21, 0.09)

Interdental bleeding index: -5.5 (p = 0.418, 95% CI: -19.29, 8.21)

There was no difference in terms of soft tissue trauma.

It was not possible to assess adherence with and satisfaction with oral hygiene regime in the interim analysis.

Conclusions: There is no statistical or clinical benefit in the use of a Waterpik® in addition to a manual toothbrush for patients wearing fixed orthodontic appliances.

However, as the data for the trial is incomplete and the analyses were performed on limited sample size, any conclusions should be interpreted with caution.

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8 List of Abbreviations

BOP	**Bleeding on probing**
BPE	**Basic periodontal examination**
CAL	**Clinical attachment loss**
CCT	**Controlled clinical trial**
CHX	**Chlorhexidine**
CONSORT	**Consolidated standards for reporting trials**
DN	**Dental nurse**
DT	**Mr Daniel Tyler (Investigator)**
ETB	**Electric toothbrush**
GDP	**General dental practitioner**
GI	**Gingival index**
HbA1C	**Haemoglobin A1c**
HCRW	**Health and Care Research Wales**
HG	**Mr H.H. Goh (Supervisor)**
HRA	**Healthcare Research Authority**
IBI	**Interdental bleeding index**
ICC	**Intraclass correlation coefficient**
IL	**Interleukin**
IMF	**Intermaxillary fixation**
IRAS	**Integrated Research Application System**
JDK	**Mr J. D. Kindelan (Supervisor)**
JK	**Dr J. Kang Kang (Statistician)**
MTB	**Manual toothbrush**
NHS	**National Health Service**
OHE	**Oral health education**
OI	**Oral irrigation**
OMPI	**Orthodontic modification of plaque index**
PDL	**Periodontal ligament**
PG	**Prostaglandin**
PI	**Plaque index**

PIL	**Patient information leaflet**
PPD	**Periodontal pocket depth**
PSI	**Pounds per square inch**
RCT	**Randomised controlled trial**
RSD	**Root surface debridement**
T0	**Appointment 1, baseline indices**
T1	**Appointment 2, 8-week indices**
T2	**Appointment 3, 32-week indices**
T3	**Appointment 4, 56-week indices**
TNF-α	**Tumour necrosis factor alpha**
WHO	**World Health Organisation**
WP	**Waterpik**
WP+MTB	**WP and manual toothbrush**
WPPF	**Waterpik Power Flosser**

9 Introduction

Oral hygiene practices have been performed by humans for millennia. Almost 10,000 years ago Scandinavian settlers chewed birch pitch, a sticky substance produced from the bark of the birch tree (Kashuba et al., 2019). Remains of this ancient 'chewing gum' has been found in many archaeological sites. However, despite its antiseptic properties, historians think it more likely that it was chewed to make it useable as an adhesive, than for the purposes of oral health (Jensen et al., 2019). Toothpicks are thought to have been the first devices used to deliberately remove debris from between the teeth. They were initially just pieces of wood, but became more complicated. For example, a gold toothpick was found in the tomb of a Mesopotamian King, dating from 3,000 BC (Fischman, 1997).

A more modern approach to removing debris from between the teeth is the Waterpik® (WP) (Water Pik, Inc, Fort Collins, CO, USA). The WP is a water irrigation device designed for home use. It was invented in the early 1960s by an American dentist, Gerald Moyer, together with a patient of his, John Mattingly, who was a hydraulic engineer. The WP produces a pulsing jet of water to remove debris, whereas previous similar devices had produced a single steady stream (Jahn, 2019).

The pulsing water jet is believed to remove debris and bacteria in two phases. The first phase is the compression phase, in which the water jet contacts the tooth surface under pressure. The second phase is the interpulse decompression phase. This is the period in which the spray deflects from the tooth and debris is flushed away (Bhaskar et al., 1971). These phases have also been described in terms of alternating between an impact zone and a flushing zone (Lyle, 2012).

10 Literature Review

10.1 Effectiveness of Plaque Removal

The degree to which WP devices remove plaque has come under much scrutiny over the years. Ex-vivo and animal studies using the WP have shown mixed results. For example, Brady et al. (1973) used a WP on seven rhesus monkeys, and then examined the plaque microscopically in a single use, split-mouth study. After one use, two out of seven monkeys (28.6%) had no plaque to collect on the intervention side of the mouth, but five out of seven (71.4%) still had visible plaque. Of those with plaque to collect, widespread evacuation of bacterial cell contents was seen with and without rupture of the cell membrane, with far fewer viable bacteria present. However, this was an animal study, with the device professionally used for a single use. These same outcomes can not necessarily be expected in humans using the device at home.

Gorur et al. (2009) carried out a similar trial into the plaque removal efficacy of the WP assessed microscopically. They took eight extracted teeth and thoroughly cleaned half of them before inoculating them with saliva to produce what they termed 'ex-vivo plaque'. On the other half, they left the plaque which was already in-situ and termed this 'in-vivo plaque'. They cleaned the teeth with a WP for three seconds before examining the teeth microscopically. The authors stated that 99.84-99.99% of ex-vivo plaque was removed, depending on the tip used. However, they did not present percentages for the in-vivo plaque, just stating that 'significant amounts' were removed. The in-vivo plaque is clearly more clinically important to be able to remove, and so the fact that figures were not given for this group is concerning. This trial was also commissioned by Water Pik, Inc. and therefore is at risk of outcome reporting bias.

Regarding clinical plaque removal, a number of clinical trials have attempted to establish whether this is effective with a WP. Husseini et al. (2008) performed a systematic review of the efficacy of oral irrigation (OI). The group identified six randomised controlled trials (RCT) and one controlled clinical trial (CCT) which assessed the use of an oral irrigator in addition to regular oral hygiene. Three of these trials used the WP, and four used other pulsing oral irrigators. All trials followed-up patients for a minimum of eight weeks with five of the seven

following the patients up for six months or more. None of the studies found a significant difference in terms of the amount of visible plaque between patients who used an oral irrigator and those who did not. However, three studies showed a significant difference in terms of gingival inflammation and three showed a significant difference in terms of bleeding on probing (BOP). The authors concluded that OI does not improve visible plaque but may improve gingival health.

Since this systematic review, there have been several small studies sponsored by Water Pik, Inc. which *have* shown a statistically significant improvement in plaque levels. For example, an RCT by Goyal et al. (2018a) took 72 patients with gingivitis and allocated them to either a manual toothbrush or a manual toothbrush with a WP. Participants had BOP, gingival index (GI) and plaque scores measured by a blinded examiner at two and four weeks. Both groups had statistically significant improvement in all full mouth indices at both two and four weeks ($p<0.001$). The WP group was significantly more effective than the toothbrush group in all full mouth indices at both two and four weeks ($p<0.001$). The same team found similar results when they looked at WP over four weeks used alongside a sonic toothbrush (Goyal et al., 2012). However, the outcomes of these short studies commissioned by Water Pik, Inc. must be interpreted with caution.

Worthington et al. (2019) carried out a Cochrane review on the use of interdental cleaning devices in addition to toothbrushing. As part of this review, they selected five RCTs which assessed whether oral irrigation plus toothbrushing was more effective than toothbrushing alone. Although these trials met the Cochrane inclusion standards, they did state that they were 'at unclear risk of bias'. One of these studies investigated the use of the WP (Goyal et al., 2012). In the other four, the irrigation was carried out by similar, but not identical devices, such as the Phillips® AirFloss® (Koninklijke Phillips N.V, Eindhoven, Netherlands) (Jenkins, 2010) and the Braun Oral-B® OxyJet (Gillette Company LLC, Boston, MA, USA), (Frascella et al., 2000). The meta-analysis concluded that, compared to brushing alone, there was no difference in plaque over one, three or six months. In terms of gingival inflammation, it concluded that water irrigation plus toothbrushing may reduce this in the short-term, but there was no evidence for the long-term. The certainty of the evidence was all either 'low' or 'very low'. However, different oral irrigators have different modes of action. For example, the

OxyJet stream of water contains around five percent air, which is intended to form microbubbles to remove plaque (Frascella et al., 2000). Therefore, it may not be useful to compare all oral irrigators all under the same umbrella.

10.2 Why might the Waterpik® affect gingival health but not plaque?

It is widely accepted that dental plaque is the main causative factor for gingival inflammation (Murakami et al., 2018). Therefore, the fact that the WP has repeatedly been shown to improve gingival condition without reducing levels of visible plaque is somewhat surprising. Several authors have suggested possible mechanisms for this being the case.

Rosema et al. (2011) suggested that the WP may reduce the thickness of the plaque, remove the loosely adherent soft matter, and stop the plaque maturing. This could possibly reduce gingival inflammation, but, in the simple two-dimensional methods used for measuring plaque, not be picked up.

It has also been suggested that the WP might alter the proportion of key pathogens responsible for causing gingival inflammation (van der Weijden and Slot, 2011). However, an RCT which compared irrigating with chlorhexidine (CHX); irrigating with water; rinsing with CHX; and rinsing with sodium fluoride over six months found that water irrigation had no significant effect on any of the bacterial groups they assessed. They did, however, find changes in bacterial populations when the patients irrigated or rinsed with CHX (Newman et al., 1990).

Chaves et al. (1994) performed a similar RCT, again over six months, comparing irrigating with CHX; irrigating with water; rinsing with CHX and no rinse or irrigation. They found similar results to Newman et al. in terms of microbiological outcomes. They again found an improvement in gingival health, but not plaque score for the water irrigation group. They hypothesised that the WP may alter the inflammatory interaction between bacteria and host.

Cytokines are chemical messenger molecules produced by gingival epithelial cells in response to plaque bacteria (Stathopoulou et al., 2010). Cutler et al. (2000) looked at the volume of

different cytokines in gingival crevicular fluid between patients who did not clean their teeth for two weeks, patients who performed routine oral hygiene for two weeks and those who performed routine oral hygiene together with a WP for two weeks. They found mixed results with the WP group producing significantly less IL-1β (a pro-inflammatory cytokine) at two weeks compared to the other two groups. IL-10 is considered an anti-inflammatory cytokine. Levels of IL-10 were higher in both the WP and the no oral hygiene group compared to the routine oral hygiene group at two weeks. Other cytokines such as TNF-α, showed no difference between the three groups. These findings suggest that the host-bacteria response is complicated. The paper only followed patients for two weeks and they were not randomised because the no oral hygiene group were paid volunteers. This infers that this research study was at risk of selection bias.

Another possible explanation is that the mechanical stimulation of the gingiva could affect gingival health. Mechanical stimulation by the WP has been shown to increase capillary strength, which could reduce the incidence of bleeding. Kozam (1973) performed a split-mouth study in which participants massaged the labial mucosa of half of their mouth for four minutes a day with a WP. A suction stress test was performed weekly for four weeks, and the number of petechiae formed was counted. They found that there was a 54.96% increase in capillary strength (calculated by a reduction in petechiae when suction tested) of the labial mucosa following the massage. However, the WP is not generally used on the labial mucosa, nor is it used for this length of time. The authors stated that the stress test could not be performed on gingiva, hence choosing the labial mucosa, but care must be taken to generalise these findings to normal daily use around the teeth.

10.3 Depth of Irrigation

The gingival sulcus in health is no deeper than 3.5mm when measured with a World Health Organisation (WHO) probe (British Society of Periodontology, 2011). Inflammation associated with gingivitis can cause an increase in the depth of the gingival sulcus known as ‘pseudo pocketing’. In periodontitis, the junctional epithelium transforms to pocket epithelium and migrates apically down the root. This also causes an increase in depth of the sulcus (British

Society of Periodontology, 2012). As the sulcus contains plaque, bacteria, debris, and cytokines, it may be beneficial for the pulsing water to enter.

Several studies have assessed how far subgingivally the WP irrigates. Braun and Ciancio (1992) took 14 patients, who were due to have one or more teeth extracted, and randomised them into either an irrigation or a rinse group. A pocket charting was completed on the teeth due for extraction. Patients then either rinsed with erythrosine dye or had this irrigated around the teeth and into the pockets with a WP. Erythrosine dye stains plaque. A handpiece was used to cut a groove at the gingival margin of the teeth before they were extracted. The depth to which the dye had penetrated from the groove was then measured and a percentage depth of penetration calculated. They found that in pockets of 1-6mm depth, the WP delivers its solution to around 90% of the pocket depth, significantly more than the 21% achieved with rinsing ($p < 0.01$). The mean depth of penetration for pockets >7mm was 64%. However, the irrigation was performed professionally and at 45 degrees to the tooth, whereas the manufacturers recommend 90 degrees. This reduces the external validity of this study. However, other similar studies have shown that there is no statistically significant difference between irrigating at 90 degrees and 45 degrees in terms of depth of penetration (Eakle et al., 1986).

The potential method error in this study was high. The probe tip will penetrate the junctional epithelium of inflamed tissues and overestimate the pocket depth (Preshaw, 2015). This may explain the lower percentage penetration in pockets >7mm and brings into question the internal validity of this study. Other similar studies have stained the residual PDL on extracted teeth with crystal violet in an attempt to determine the depth of the sulcus once extracted (Eakle et al., 1986). Interestingly, this group divided pockets into 0-3mm, 4-7mm and >7mm and found the lowest penetration in the 4-7mm group. They found on average that the WP penetrated to around half the depth of the actual pockets. An issue with depth of irrigation trials is that although the fluid may be reaching into the pocket, it is clearly not removing the plaque as the plaque staining dye is present and visible following extraction.

10.4 Tip Design

The WP uses a removable tip, which the manufacturers recommend are replaced every three to six months depending on the type of tip. There are currently six types of tips on the market. The standard tip is the 'Classic Jet Tip' which is a simple hollow tube. Other tips available include an 'Orthodontic Tip' with a tapered brush on the end to clean around fixed appliances; the 'Pik Pocket® Tip' which is designed to go into the pockets of patients with periodontal disease; and the 'Plaque Seeker® Tip' which has three thin tufts of bristles on the end and is designed to clean around prosthodontic work (Water Pik, 2020b).

Little evidence for the efficacy of any of the tips other than the standard tip has been published. In the previously mentioned Rosema et al. (2011) paper a four-week, three-group parallel clinical trial was used to compare the standard tip, with dental floss, and a prototype jet tip. The prototype jet tip (or one very similar) appears to have been subsequently manufactured as the 'Plaque Seeker® Tip' following this trial. However, in this trial, mean plaque score worsened over four weeks in the prototype tip group. There was no statistically significant difference between the two tips in terms of bleeding on probing at four weeks.

Boyd et al. (1992) assessed whether there was a difference in depth of irrigation between the 'Pik Pocket® Tip' and the standard tip. In a trial relatively similar to those of Eakle et al. (1986) and Braun and Ciancio (1992) described in the previous section, the authors allocated patients requiring extractions to one of three groups. They received either subgingival irrigation with a 'Pik Pocket® Tip' inserted halfway into the gingival sulcus, the same irrigation with a 'Classic Jet Tip' or an oral rinse. A plaque staining dye solution was used in all three groups and irrigation was professionally performed. The gingival margin was notched, and the teeth were extracted and examined microscopically. The distances from the connective tissue attachment to the apical extent of the stained plaque and the gingival margin notches were measured to calculate depth of penetration. On average, the 'Pik Pocket® Tips' penetrated 70-75% of the depth of the pocket, compared to 29-54% with a standard tip and only 0.1mm with the oral rinse. The 'Pik Pocket® tips' penetrated significantly deeper than the standard tips in pockets of >3.5mm ($p<0.01$). Using a microscope to visualise the connective tissue attachment on the teeth improves the internal validity compared to similar trials previously

described. However, only patients who had not had a professional clean for at least one year were recruited. These patients are perhaps less likely to invest in a WP.

10.5 Safety

10.5.1 Damage to soft tissues

From the published literature, the WP appears to be safe to use. Adverse effects from using the Waterpik® have not been reported in any recent papers, although some older papers mention cases of them being blamed for causing acute periodontal infections. For example, Romans and App (1971) quote Arnim (1967) describing patients who have used them at a high power directed down the gingival sulcus, developing periodontal abscesses. Selting et al. (1972) describe observing the clinical formation of 'gum boils' when the stream of water is directed apically and suggest that this may be due to excessive pressure in the pocket. However, this is low quality evidence and no recent reports have been published.

WPs currently on the market have adjustable pressure settings which vary from 10 pounds per square inch (PSI) to 100 PSI depending on the model (Water Pik, 2020a). Due to the relatively high pressure of the devices, research has been carried out to ensure that they are safe to use without causing damage to the oral soft tissues. Several of the early experiments into the safety of the WP were carried out by the United States Army as they were interested in the possibility of using the devices for cleaning facial wounds inflicted during combat. They published the results of several histological experiments on rats and dogs, using pressures of up to 200 PSI. They concluded that, if used at a very high pressure on free gingiva, the WP did have the potential to cause haemorrhage, oedema, and ulcerations. However, the WP is designed for use on the attached gingiva. When used here, there was no damage with pressures up to 70 PSI, and only minimal changes seen at pressures up to 200 PSI which quickly healed. Research has found that WPs effectively remove debris and help with the clearance of bacteria (Bhaskar et al., 1971). However, the results of rat and dog studies cannot be seamlessly transferred to humans, as there are structural differences between the oral soft tissues of the three species (Struillou et al., 2010).

It would have been unethical to perform the U.S. Army experiments on humans, but Cobb et al. (1988) were able to carry out some similar research. This group took 32 teeth planned for extraction in 12 patients and allocated them to a control or an intervention using a single coin toss. The intervention teeth were cleaned with a WP at 60 PSI for eight seconds prior to extraction, whereas the control teeth were not. All teeth were then extracted and had an excisional biopsy of the gingival sulcus performed. Half of the samples were examined under a scanning electron microscope, whilst the other half were examined with a transmission electron microscope. They found that there was no damage to the soft tissues, and a qualitative difference in plaque up to 4mm, which reduced at the 5-6mm pocket level. Although these patients were due to undergo an extraction, research of this design type may struggle with attaining ethical approval today.

Recently published evidence on whether the WP damages soft tissues is lacking. In a trial commissioned by Water Pik, Inc., Goyal et al. (2018b) asked patients to use the WP at an increasing pressure from 40 to 100 PSI over six weeks. They measured the periodontal pocket depth (PPD) and clinical attachment loss (CAL), compared to a group using floss and a group using no interdental cleaning aid. There were very small changes in the two outcome measures over six weeks and the paper failed to report whether there were any statistically significant differences between the three groups. The paper stated that it aimed to assess the safety of the WP as measured by CAL and PPD levels, and appears to suggest that it is safe to use because it does not increase CAL and PPD values. This is potentially a questionable surrogate method to measure the safety of the device.

10.5.2 Bacteraemia

Another area of concern which has been raised regarding the safety of the WP, is whether it has the potential to force bacteria through the soft tissues of the gingival sulcus and cause a bacteraemia. In susceptible individuals with structural abnormalities of the heart, a bacteraemia has the potential to cause infective endocarditis. This is a potentially life-threatening illness which is often linked to oral bacteria (Lockhart et al., 2009). The literature on the potential of WP to cause bacteraemia has shown mixed results.

One area of research has focused on using the WP with a solution filled with dye particles. The theory of this approach is that if dye particles can permeate through the soft tissues under the force of the WP, then bacteria, which are much smaller, could do too. Kancir and Krajewski (1972) used the WP with a solution of India ink (a carbon solution) on the gingiva of dogs. They also had two control groups, one which received no India ink, and another which had it swabbed on to the floor of their mouth. They then performed biopsies on adjacent lymph nodes and the livers of the dogs. Carbon was found in all the liver samples and some of the lymph node samples of the intervention group, but in neither of the control groups. This does suggest that the WP generates sufficient force to push debris through the soft tissue into the blood stream. However, the pressure used was not specified in the paper and being an animal study, we must be wary of drawing conclusions.

It would be unethical to take liver and lymph node biopsies from human subjects for this type of research. However, similar research has been carried out to assess whether dye is pushed into the gingival tissues of humans. O'Leary et al. (1970) used the WP containing a solution of India ink on patients who required a gingivectomy. He assessed the excised gingiva under a microscope of WP patients and found that many of this group had carbon in their sections, whereas the control group had none. There also appeared to be a relationship between inflammation and carbon uptake, with the more inflamed sections containing more carbon. To ensure that the carbon had not made its way into the sections during the biopsy procedure, the investigators repeated the experiment. However, this time they irrigated with India ink and then took the biopsy one to five weeks later. Again, carbon was found in many sections.

Contradicting the earlier findings, Manhold et al. (1978) carried out a similar experiment to that of O'Leary et al. (1970), but concluded that the idea of permeation of debris through the gingival epithelium was more theoretical than clinical. They argued that the knife blade tended to drag particles from the surface through the tissue during the biopsy procedure, and also found penetration of carbon in their control groups. However, this does not account for the carbon found in the patient’s in the delayed biopsy participants in O'Leary et al. (1970) or in the livers of the dogs used by Kancir and Krajewski (1972).

Research into the development of a microbiologically detectable bacteraemia has also shown mixed results. Felix et al. (1971) and Romans and App (1971) both examined blood samples of 30 patients before and after the use of the WP. Neither group demonstrated any bacteraemia before the use of the WP. Participants in the Felix et al. (1971) study had periodontal disease, with 15/30 (50%) having a detectable bacteraemia after the use of the WP. Participants in the Romans and App (1971) study had gingivitis, with 2/30 (6.67%) having a detectable bacteraemia after use of the WP.

Berger et al. (1974) saw 60 patients with 'healthy appearing gingiva'. Thirty used a WP, and thirty used a normal manual toothbrush. None of the participants had a bacteraemia before the interventions. Post-operatively, 8/30 (26.67%) of the WP group developed a bacteraemia, compared to 1/30 (3.34%) of the toothbrush group. Reinforcing the results of Felix et al. (1971) and Romans and App (1971), they found a statistically significant positive correlation between bleeding after irrigation or brushing and the development of a bacteraemia ($p<0.05$).

However, other research has concluded that patients do not develop a bacteraemia following the use of a WP. Tamimi et al. (1969) assessed 30 patients: 10 with healthy gingivae, 10 with gingivitis and 10 with periodontal disease. The participants either brushed their teeth or brushed their teeth and used a WP. They had blood samples taken before, and at regular intervals during the experiment period for up to 60 days. They analysed 2,160 plates of the 30 participants and found growth on 19 plates. Eleven of these plates were from WP patients, and eight were from control. However, all the plates had already been duplicated and there was no growth on any of the duplicate plates. The authors, therefore, concluded that the plates must have been inadvertently contaminated and none of the participants had actually developed a bacteraemia.

From the evidence available, it seems possible that the WP can cause a bacteraemia. On the other hand, reviews of the literature have shown that toothbrushing can also cause a bacteraemia up to 57% of the time (Lockhart et al., 2008), as can the process of mastication itself (Seymour et al., 2000). Poor oral hygiene and bleeding after brushing has been demonstrated to be a risk factor for the development of infective endocarditis (Lockhart et

al., 2009). Based on the available evidence, it does seem that the WP is more likely to cause a bacteraemia than toothbrushing alone (Berger et al., 1974), but whether its use should be avoided in patients at risk of infective endocarditis is unproven.

10.6 Compared to Other Methods of Interproximal Cleaning

The WP is designed for interproximal cleaning. Conventional toothbrushing does not reach the interproximal areas between the teeth. Interdental plaque can cause gingivitis and caries (Claydon, 2008). Although the literature does not support the plaque removal efficacy of the WP, several published clinical trials have compared the performance of the WP compared to other methods of interproximal plaque removal, in terms of plaque scores and gingival health.

One method of interproximal plaque control which is commonly employed is the use of dental floss which is passed into the embrasure spaces. The Cochrane review carried out by Worthington et al. (2019) investigated whether oral irrigation is superior to dental floss in terms of plaque scores and gingival health. They identified two RCTs, both of which had used the WP as the oral irrigator, Barnes et al. (2005) and Rosema et al. (2011). Both trials lasted only one month. Combining the results of the two studies in a meta-analysis, they concluded that the plaque levels in the WP groups was on average higher than the dental floss group, suggesting that the WP is inferior to floss at removing plaque. They did find there is some evidence that the WP may be better than flossing for reducing gingivitis, however the differences were small. For example, the mean score for gingival index in the floss groups after one month was 1.14. The mean score in the WP groups were just 0.06 lower (95% CI: -0.12, 0.00) This is unlikely to be of any clinical significance. Again, the certainty of the evidence was graded as ‘low’ or ‘very low’. A recent RCT found no significant difference between regular floss and a WP in terms of plaque removal after a single use (Abdellatif et al., 2021).

Another common method of interdental cleaning is the use of interdental brushes. These may be superior to floss when it comes to improving gingival health (Worthington et al., 2019). In a published pilot study for an RCT commissioned by Water Pik, Inc., Goyal et al. (2016) looked at 28 participants with periodontal disease, giving one group WPs and the other interdental

brushes. Both groups showed statistically significant improvements in plaque index and bleeding scores at two weeks. In terms of plaque, the authors state that the study was underpowered (according to a post hoc power calculation) so a difference between the groups could not be ascertained. For full mouth bleeding scores, there was a statistically significant difference between groups (P<0.001) in terms of change in mean bleeding score. However, the WP group on average reduced their bleeding score by 0.19, compared to 0.12 in the interdental brush group. This reduction is of questionable clinical significance. To date, no follow-up study has been published from the original pilot, and so no conclusions can be drawn.

The Phillips® AirFloss® is a competitor product to the WP. The AirFloss® uses rapid bursts of air with water droplets contained in it in order to attempt to disrupt the biofilm. It is different to the WP in that it uses a much smaller volume of water combined with air under pressure, as opposed to much higher volumes of pulsing water in the WP (Sharma et al., 2012a). Water Pik, Inc. have commissioned three separate trials in which they have compared the WP to various models of the Phillips® AirFloss® ((Sharma et al., 2012b; Goyal et al., 2015; Goyal et al., 2018a). The trials were all very similar, giving patients either a WP or an AirFloss® to use alongside a manual toothbrush for four weeks. In all the studies, both groups showed a statistically significant improvement in terms of bleeding on probing, gingival index, and plaque index at the four-week stage.

These studies appear to show that the WP performs better than the AirFloss®. However, in some parts of the papers the statistics are presented in such a way to maximise the superiority of the WP, which may be because of the research being commissioned by Water Pik, Inc. For example, in Goyal et al. (2018a), the mean facial proximal gingival index score in the WP group reduces from 2.07 to 1.66 over four weeks, compared to 2.08 to 1.86 in the AirFloss® group. This is statistically significant (p<0.001), but unlikely to be clinically significant. This is presented as a 19.8% improvement in the WP group compared to a 10.7% improvement in the AirFloss® group, and is then presented as an 86% difference between the two devices. Although mathematically correct, it could be argued that this is misleading to the reader.

10.7 Specific Patient Groups

Over the years, various focused research papers have investigated whether the WP is useful in specific patient groups.

10.7.1 Periodontal Disease

In patients with periodontal disease, who do not respond to non-surgical periodontal therapy, some periodontists advocate the topical application of adjuvant antibiotics into the periodontal pocket. The efficacy and necessity of this treatment has been questioned, particularly considering the modern day concern for antimicrobial resistance (Cortelli et al., 2008). Genovesi et al. (2014) performed an RCT in which patients with periodontitis either received root surface debridement (RSD) and then minocycline placed into the pockets, or had RSD and then used a WP twice daily at home. The patients were seen after 30 days to record their periodontal indices and a microbiological assessment. There were no statistically significant differences between the two groups. This does suggest that a WP is as effective as minocycline placed topically into the pockets, but other studies which look at the effects of minocycline have tended to follow-up patients for a longer duration (Cortelli et al., 2008).

The link between glycaemic control, diabetes mellitus and periodontal disease is well established with some evidence to show that it may be bidirectional. This suggests that not only does poorly controlled diabetes predispose to periodontal disease, but that poorly controlled periodontal disease may make glycaemic control more challenging for a patient (Taylor et al., 2004). Al-Mubarak et al. (2002) performed an RCT using participants with periodontal disease together with Type 1 or Type 2 Diabetes. Fifty-two patients were randomised to either scaling and root planning; or scaling and root planing together with a WP to use at home. Patients were seen at baseline, six weeks and 12 weeks for clinical indices and venous blood samples to analyse their levels of specific systemic cytokines. At 12 weeks, both groups had a statistically significant improvement in terms of gingival index, plaque index and bleeding on probing ($p<0.02$). The WP group was significantly better than the control group in these three indices ($p<0.03$). The 12-week mean GI was 0.69 in the WP group compared to 1.15 in the control group and PI was 0.86 compared to 1.45 in the control group, which are likely to be clinically relevant differences. There was no difference in terms of CAL

or PPD from baseline in either group. However, as it has been established that the WP does not improve plaque control in many other studies, there is the possibility that the WP group cleaned their teeth to a higher standard by chance, thus also improving the GI and bleeding index. On the other hand, it is accepted that the composition of plaque in patients with diabetes is different to the norm (Hintao et al., 2007), so it may be that 'diabetic plaque' is more susceptible to removal with the WP.

In terms of systemic cytokines, the results were varied. There was no statistically significant difference at 12 weeks in levels of HbA1C, TNF-Alpha or IL-10 for either group. The levels of IL-1β significantly improved in both groups at 12 weeks ($P<0.05$). The levels of PGE2 significantly improved from baseline in the WP group only at 12 weeks ($p<0.05$). Although these figures were statistically significant, it is not clear whether the results are clinically significant. In addition, the study was sponsored by Water Pik, Inc. which does make it susceptible to outcome reporting bias.

10.7.2 Peri-Implant Diseases

Like natural teeth, dental implants are susceptible to inflammatory conditions affecting their supporting structures. Inflammation affecting the soft tissue surrounding an implant in the way gingivitis would affect a tooth is termed peri-implant mucositis, whereas once the condition affects the supporting bone it is known as peri-implantitis (Lindhe and Meyle, 2008). These diseases are common, with a recent meta-analysis calculating a weighted mean implant-based prevalence for peri-implant mucositis of 29.48%. The same prevalence for peri-implantitis was 9.25% (Lee et al., 2017).

Magnuson et al. (2013) carried out an RCT in which they randomised 30 patients to either use of string floss around their implants or use of a WP. The patients who completed the study had 40 implants altogether. The patients were examined at 14 and 30 days by a blinded examiner. BOP was defined as at least two of the six sites probed on the implant bleeding. At baseline, 40/40 (100%) of the implants had BOP. At 30 days, four of the implants in the WP group had BOP, compared to 12 in the string floss group. This was presented as an 81.8% reduction in the WP group compared to 33.3% in the floss group. This was statistically significant ($p<0.001$). However, this was a short study with a small number of participants and

implants. Therefore, care must be taken when generalising the results. Further research into the use of the WP around implants would be beneficial.

10.7.3 Intermaxillary Fixation

Intermaxillary fixation (IMF) is a method used in maxillofacial surgery to assist with stability of the repositioned of the maxilla and mandible following trauma or reconstructive surgery. The dental occlusion of the patient is held together to help reduce the bones to the correct position (Coletti et al., 2007). In modern practice, this tends to be performed intraoperatively using self-tapping screws. Wire is placed between the screws, the fractures are fixated with screws and plates, and the wires and screws are then removed (Sahoo and Mohan, 2010). Previously to this, IMF has been used as the sole treatment for mandibular fractures, using rigid arch bars to fix the jaws together and allow them to heal. In some fractures, such as those severely comminuted and in the severely atrophic mandible, this technique is still used. However, patients then require a liquid diet for six weeks and oral hygiene can be very challenging (Mukerji et al., 2006).

Phelps-Sandall and Oxford (1983) used WPs in a clinical trial to investigate methods of oral hygiene in patients in IMF. Twenty-one patients were randomised to one of three groups. Group 1 used a WP, Group 2 used a WP and a Perio-Aid® toothpick holder (Marquis Dental Manufacturing Company, Denver, CO, USA) and Group 3 used a WP, a Perio-Aid® toothpick holder and were shown to brush the gingival sulcus with a toothbrush. Patients were seen at two, four and six weeks and had simplified debris and gingival health indices completed. The study found significantly better oral hygiene and gingival health in Group 1, using the WP alone. The authors suggested that adding more than one device or technique may have caused patient confusion or further discomfort.

However, this study had a high dropout rate with only 15 of the 21 patients completing it. The reasons for the dropouts were not given. Furthermore, patients who had their IMF removed before the end of the six-week period were left in the study, but the paper does not report how many of these patients there were. The final individual group numbers were low, with no power calculation carried out by the researchers. There were also no baseline indices

taken to establish whether the initial oral hygiene of the groups was similar, and there was no control group for comparison purposes.

10.7.4 Orthodontics

It is widely accepted that it is more difficult to maintain good oral hygiene when wearing orthodontic appliances. Most patients will develop some degree of gingival inflammation during their fixed appliance treatment. There is little attachment loss. Bollen et al. (2008) carried out a meta-analysis and found that a course of fixed appliance orthodontic treatment on average increases PPD by 0.23mm (95% CI 0.15-0.30mm) and recession by 0.03mm (95% CI 0.01-0.04). However, inflamed gingivae can be uncomfortable and lead to gingival hypertrophy. Although the hypertrophy usually resolves after appliances have been removed (Zachrisson and Zachrisson, 1972), this can make the appliance and teeth more difficult to clean around. There is also a change in the microbiome of the mouth during fixed appliance therapy with an increase in periodontopathic (Naranjo et al., 2006) and cariogenic (Marda et al., 2018) bacteria. The oral microbiome has been shown to remain 'abnormal' even two years after debond (Ghijselings et al., 2014).

As well as the effect on the periodontium, stagnating plaque around orthodontic appliances predisposes to decalcification. This can leave permanent, unsightly white or brown marks on the teeth which can progress to decay and cavitation. The incidence of decalcification varies depending on the diagnostic techniques and criteria used, but a meta-analysis reported an incidence of 68.4% (Sundararaj et al., 2015).

The literature contains mixed results as to whether the WP can be useful for plaque control and periodontal health in patients wearing fixed orthodontic appliances.

An early clinical trial by Hurst and Madonia (1970) was carried out on patients wearing banded fixed appliances. The 60 participants were divided into a group who used a manual toothbrush with a WP to clean their teeth and a second group who used a manual toothbrush and water rinses. Saliva samples were taken at 21, 42 and 63 days and assessed microscopically to assess the number of anaerobes and lactobacilli. On average, the WP group

had 65% less lactobacilli and 86% less anaerobes than the water rinse group. However, it is unclear whether these results are significant clinically.

In terms of contemporary bonded, buccally-placed fixed appliances the results have also been mixed. Burch et al. (1994) recruited 47 patients wearing upper and lower fixed appliances. They were randomised to either a control group who were advised to continue with their normal manual toothbrushing regime, a group who were provided with a WP to use in addition to their manual toothbrush or a group who were provided with a WP and an electric toothbrush. All three groups had a statistically significant improvement in terms of plaque, GI, and BOP. This is likely to be because of the Hawthorne effect. This is the phenomenon by which study participants modify their behaviour because they are aware that they are being observed (Landsberger, 1958). No statistically significant difference was found between the 3 groups. The authors then combined the results of WP and the WP with electric toothbrush groups and were able to show that the combined results were statistically significantly better than the control group in terms of plaque, GI, and BOP scores. However, it is not clear whether this improvement is due to the electric toothbrush or the WP. Jackson (1991) completed a similar trial, comparing manual toothbrush; electric toothbrush; manual toothbrush & WP; and electric toothbrush & WP. Each participant followed each of the routines for 4 weeks, and no significant difference between the groups was demonstrated in terms of plaque or gingival health indices.

More recently, in a trial commissioned by Water Pik, Inc., Sharma et al. (2008) investigated the use of the WP in fixed orthodontic patients using the Orthodontic Tip. A total of 106 patients wearing conventional bonded fixed appliances with at least 50% BOP were recruited and randomly assigned to one of three groups. They were either provided with a WP with an Orthodontic Tip and a manual toothbrush, floss with a floss threader and a manual toothbrush or a manual toothbrush only. The patients were examined by a blinded examiner at 14 and 28 days and assessed for bleeding index and plaque scores. All three groups showed a statistically significant improvement in plaque from baseline to 28 days. The mean reduction in plaque score for the WP group was 1.45, compared to 0.38 in the floss group and 0.25 in the toothbrush group. The difference between the groups was statistically significant ($p<0.05$) and likely to be clinically significant. In terms of bleeding index, the mean reduction at 28 days

for the WP group was 0.59 compared to 0.46 in the floss group and 0.38 in the toothbrush group. The difference between the groups was statistically significant ($p<0.05$) but unlikely to be clinically significant. This trial, however, only lasted four weeks and it is unknown whether these effects would last long-term.

10.7.4.1 Use of Similar Devices in Orthodontic Patients

Investigators have also carried out research to assess whether similar devices to the WP can be of benefit for orthodontic patients. Mazzoleni et al. (2019) carried out a single blind, split mouth RCT in which patients were asked to clean one side of their mouth with a Phillips® AirFloss® as well as traditional brushing and only carry out traditional brushing on the other side. Patients had PI and GI measured at baseline, one month after bond up, three months after bond up and six months after bond up. No significant differences between the sides of the mouth which had the AirFloss® used on them and those which did not were found. However, as previously mentioned, the AirFloss® has a different mechanism of action to the WP. Furthermore, in a split-mouth trial such as this one, it is difficult to ensure that the participants are indeed only using the intervention on one side of the mouth.

Water Pik, Inc. also produce an alternative device to the WP units for interdental cleaning. The Waterpik® Power Flosser (Water Pik, Inc, Fort Collins, CO, USA) (WPPF) is a hand-held unit which does not use water, but instead uses a vibrating Nylon tip which the patient inserts into the spaces between their teeth to clean them. Hohoff et al. (2003) assessed use of the WPPF in 32 patients wearing lingual appliances. This was a split-mouth trial in which patients were asked to clean half of their mouth with a WPPF and toothbrush and the other half with just a toothbrush. A significant improvement in terms of approximal plaque and BOP from baseline to 46 days was found for both groups, but with no statistically significant difference between the groups. This trial, therefore, suggests that the addition of the WPPF did not make a difference in their plaque control or gingival health compared to brushing alone. At baseline, the investigators found statistically significant differences in plaque control and BOP per quadrant, in terms of gender and dominant hand. Therefore, they made the decision to only include right-handed, female participants. This clearly reduces the external validity of the trial.

Kossack and Jost-Brinkmann (2005) also used the WPPF in a 6-month single-blind repeated measures randomised controlled trial. Patients used a manual toothbrush; an electric toothbrush; an electric toothbrush with a WPPF; or an electric toothbrush with dental floss. Each patient used each of the four combinations of oral hygiene aids for four weeks each over the six-month period. They had plaque and bleeding indices measured at baseline, two-weeks, and four-weeks of each four-week period, with a two-week 'wash out' period between each. The only group with a statistically significant improvement in plaque control and bleeding index compared to the manual toothbrush at four-weeks was the electric toothbrush and WPPF group. The mean difference between this group and the manual toothbrush group in terms of plaque index was 0.217 and bleeding index was 0.033. The investigators attributed the improvement to the WPPF, as a significant difference was not seen in the electric toothbrush and dental floss or electric toothbrush alone groups. However, the investigators used a Modified Quigley Hein Index (Quigley and Hein, 1962) for plaque scoring which scores 0 - 5, and the Papillary bleeding index (Mühlemann, 1977) which scores from 0 - 4. With such small differences demonstrated, the differences may have been statistically significant, but they are unlikely to be clinically significant.

10.8 Conclusion

Previous research has failed to consistently find an improvement in plaque control when using a WP. Improvements in gingival health have been reported in some groups. However, the published literature has nearly all described the use of a WP with a standard tip which has no mechanical means of removing plaque. Instead, it relies purely on the action of the ejected water.

The Orthodontic Tip features a tapered brush through which the ejected water is delivered. If used appropriately, the orthodontic tip could mechanically remove plaque alongside the cleaning action of the pulsing water (Gorur et al., 2009). Evidence exists that suggests that over four weeks, using a WP with an Orthodontic Tip improves the plaque control of patients wearing fixed orthodontic appliances (Sharma et al., 2008). However, a course of fixed orthodontic treatment takes on average 24.9 months (Papageorgiou et al., 2017b). A suitably

designed RCT which assesses orthodontic patients for a longer period using a WP with the Orthodontic Tip would be a valuable addition to the current knowledge base.

11 Aims

The aim of this study was to establish whether the use of a WP alongside a manual toothbrush (WP+MTB) is more effective for maintaining oral hygiene compared to the use of a manual toothbrush alone (MTB), in patients wearing fixed orthodontic appliances.

The primary outcome measures were:

1. Plaque levels
2. Gingival health
3. Interdental gingival bleeding

The secondary outcome measures were:

1. Soft tissue trauma
2. Adherence with oral hygiene regime
3. Patient reported satisfaction with oral hygiene regime

12 Null Hypotheses

1. There is no difference in plaque levels between patients using WP+MTB compared to using MTB alone.
2. There is no difference in overall gingival health between patients using WP+MTB compared to using MTB alone.
3. There is no difference in interdental gingival bleeding between patients using WP+MTB compared to using MTB alone.
4. There is no difference in experience of soft tissue trauma between patients using WP+MTB compared to using MTB alone.
5. There is no difference in adherence to oral hygiene regime between patients using WP+MTB compared to using MTB alone.
6. There is no difference in patient reported satisfaction with oral hygiene regime between patients using WP+MTB compared to using MTB alone.

13 Methods

13.1 Trial Design

This study was a single-centre, single-operator, two-arm, parallel-group, stratified, single-blind, randomised controlled clinical trial with a 1:1 allocation ratio.

Since trial commencement there has been a change to the trial protocol in terms of the randomisation method used because of the COVID-19 pandemic. This is detailed in Section 13.9 (Randomisation).

13.2 Participants

Participants for the trial were recruited from patients booked with Mr Daniel Tyler (DT) for placement of fixed orthodontic appliances. All patients who met the selection criteria were invited to take part in the trial until the required number of participants was recruited. The selection criteria were as follows:

1. Patients had to be:
    a. Between the ages of 10 and 20 years.
    b. In good general health. Free of medical conditions or medications which may alter the oral tissue's response to fixed appliance treatment. Examples include diabetes mellitus, immunosuppressant drugs, steroids, hormonal therapy.
    c. Free of reduced manual dexterity due to disability, or poor compliance with oral hygiene instruction.
    d. Not using a toothpaste on prescription from their GDP.
    e. Free of poor initial periodontal health.
    f. Brushing teeth at least twice a day.
    g. Not already using a WP regularly.
2. The Orthodontic treatment planned had to be:
    a. Brackets as opposed to bands, except from permanent molars which could be banded.
    b. Full upper and lower arch treatment.

c. Pre-adjusted edgewise appliances with American Orthodontics® MBT prescription brackets (American Orthodontics Corporation, Sheboygan, WI, USA).
d. Bonded with Transbond® XT (3M Company, Maplewood, MN, USA)

A checklist was used to ensure that patients met the inclusion criteria prior to them being recruited into the trial, as shown in Appendix 1.

13.3 Study Setting

The study was carried out in the Orthodontic Department at York Hospital, York, YO31 8HE (UK).

The orthodontic treatment and all trial indices were performed by a single Specialty Registrar in Orthodontics, DT.

The clinical supervision for the trial was provided by Consultant Orthodontists Mr J. Kindelan (JDK) and Mr H. H. Goh (HG).

Recruitment for the trial began on 14th October 2019.

13.4 Interventions

13.4.1 Oral Health Education Given to Both Groups

Both groups received a 30-minute oral health education (OHE) appointment with a qualified dental nurse (DN) with further training in OHE. This appointment was given prior to the appointment to have their fixed appliances placed. At this appointment diet advice was given, as well as a demonstration of toothbrushing around fixed appliances.

Immediately after placement of the fixed appliances, both groups received further detailed oral hygiene instruction on models. Participants were shown to clean above and below the brackets, and to turn the toothbrush end on to pass the bristles underneath the wire and in between the brackets. They were asked to do this at least twice a day for at least two minutes using a pea size amount of toothpaste. All participants were also asked to rinse with 10ml of

fluoride mouthwash for at least 30 seconds at a different time to brushing. A standard script was used for both control and intervention groups, and each patient was given a copy of the script to take away with them to act as an aide memoire. These are shown in Appendix 2 and Appendix 3. These scripts were adapted from those of a similar trial (Saini, 2016).

Participants were provided with their toothbrushes, toothpaste, and mouthwash for the duration of the trial. The toothbrushes and the fluoride concentrations in the toothpaste and mouthwash were chosen to be in line with the Delivering Better Oral Health Toolkit (Public Health England, 2017)

The toothbrushes which the participants were provided with were Oral-B® 1-2-3 Classic Care Manual Medium (Gillette Company LLC, Boston, MA, USA), which is a standard manual toothbrush with a small head and medium bristles. Participants were advised that these should last two to three months. The toothpaste which the participants were provided with was Colgate Triple Action® (Colgate-Palmolive Company, New York, NY, USA) 100ml Tubes, which contains 1,450ppm of Fluoride. Participants were advised that each tube should last eight weeks. The mouthwash which the participants were provided with was Wisdom® Fresh Effect Coolmint Mouthwash (Wisdom Toothbrushes Limited, Haverhill, UK) 500ml Bottles. This contains 225ppm fluoride. The participants were advised that each bottle should last seven weeks. Participants were provided with enough of their consumables at the start of the trial to last eight weeks, and these were replenished at every eight-weekly appointment. Participants were asked to ensure that nobody else used their oral hygiene consumables apart from them. Participants were informed that if they were to run out of consumables between appointments to contact the department for more to be posted to them.

13.4.2 Oral Health Education Given to Intervention Group

The intervention group received OHE, toothbrushes, toothpaste and mouthwash as previously described, together with a Waterpik® Water Flosser Model WP-560 (Water Pik, Inc, Fort Collins, CO, USA) (see Figure 1). Following the OHE provided after placement of their fixed appliances, they were shown how to use the WP on models. They were advised to use the orthodontic tip only and were provided with four spare orthodontic tips to change every three months. They were shown to fill the reservoir with warm water and to use the unit over

the sink with their mouth slightly open. They were shown to clean around the brackets and between the teeth systematically, starting at a low pressure and increasing if they felt comfortable. The participants were asked to do this once a day at night for around one minute.

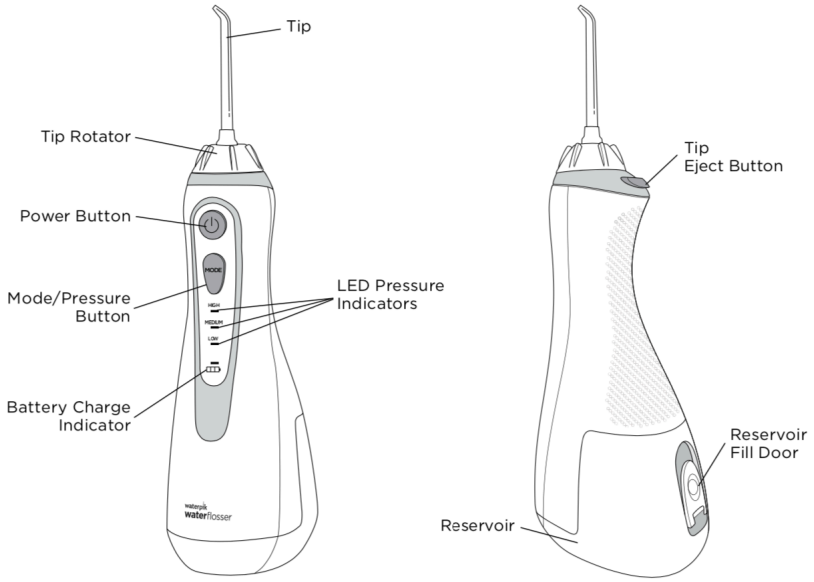

Figure 1: Diagram of WP-560 which was used in the trial.

Image from Water Pik (2017).

The WP-560 was chosen as it is a cordless model. Following preliminary discussions with potential participants on clinic, it transpired that several patients did not have the 2-pin shaver sockets in their bathrooms which corded models require to run. Using a corded model would mean that these patients could not take part. The WP-560 runs from a built-in rechargeable battery which is charged using a two-pin shaver socket. To ensure that any participants without a shaver socket in their home were able to charge the WP, all patients in the intervention group also received an adaptor which allowed the two-pin plug to be plugged into a standard UK three-pin socket (B&Q White Shaver socket, B and Q Plc, Eastleigh, UK). It would have been unsafe for participants to use a corded model plugged in to a three-pin socket and an adapter due to the high volumes of water ejected from the tip.

13.5 Outcomes

13.5.1 Baseline Indices

To ensure that there were no significant differences between the control and intervention groups in terms of oral hygiene prior to the trial, a set of baseline indices were performed immediately prior to placement of the fixed appliances.

Some patients have one arch of fixed braces placed some time before the second arch. Patients for whom this was the case were only recruited into the trial when they were ready to have the brace fitted to their second arch. In these patients, their baseline indices were only recorded from the arch which did not yet have the brace fitted.

Some patients have an orthodontic appliance attached to the first molars in either the upper or lower arch placed some time before their braces. These include appliances such as a Transpalatal arch (TPA), TPA with a Nance button (TPA Nance) or Quadhelix. These are usually held in place with metal bands placed around their first molars, which can interfere with oral hygiene and cause gingival inflammation. For patients who had these in place, the banded first molars were left off the baseline indices.

The baseline indices were collected on a paper data collection form adapted from a similar trial (Saini, 2016). This is shown in Appendix 4.

The baseline indices recorded were as follows:

13.5.1.1 Plaque Index

The Plaque Index (PI) (Silness and Loe, 1964) was used to measure the plaque coverage on six index teeth, one in each sextant of the mouth. The index teeth are the UR6, UR2, UL4, LL6, LL2 and LR4 (upper right first molar, upper right second incisor, upper left first premolar, lower left first molar, lower left second incisor, lower right first molar). The six index teeth were painted with plaque disclosing solution (TePe PlaqSearch™ Advanced Disclosing Solution, TePe Munhygienprodukter AB, Malmö, Sweden) and the patient was then asked to rinse with water.

A single score from 0-3 was allocated for four surfaces (mesial, distal, buccal and lingual) of the six teeth using a probe. The scoring criteria are shown in Table 1.

Score	Description
0	No Plaque
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.
2	Moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin

Table 1: Scoring criteria for the Silness and Loe Plaque Index

(Silness and Loe, 1964)

The mean score for the mouth was then calculated to give a single score from 0-3.

The index was slightly altered from the original description. The original description of the index states that missing teeth should not be substituted. However, first premolars are commonly extracted for orthodontic treatment, and therefore the decision was made to substitute first premolars with their adjacent second premolar if it had been extracted for orthodontic treatment. If both premolars were missing, this was not substituted.

This index has been shown to be valid (Mander and Mainwaring, 1980), but criticised for being subjective (Fischman, 1988). However, by having only one examiner perform all the measurements the issue of subjectivity is reduced.

13.5.1.2 Gingival Index

The health of the gingival tissues was recorded using the Gingival index (GI) (Loe and Silness, 1963). This was used to record the gingival health of all upper and lower permanent teeth from first molar to first molar. A periodontal probe was gently inserted into the gingival

crevice of four sites on each tooth (mesial, distal, buccal and lingual), and a score of 0-3 allocated to each surface. The scoring criterion are shown in Table 2.

Score	Description
0	Absence of inflammation
1	Mild inflammation – slight change in colour and little change in texture
2	Moderate inflammation – moderate glazing, redness, oedema and hypertrophy. Bleeding on pressure.
3	Severe inflammation – marked redness and hypertrophy. Tendency to spontaneous bleeding. Ulceration.

Table 2: Scoring criteria for the Gingival Index

(Loe and Silness, 1963)

The mean score for the mouth was then calculated to give a single score from 0-3.

Whereas the original description of the GI only measures the gingival condition of the six index teeth used in the PI, all permanent teeth present from first molar to first molar were examined.

13.5.1.3 Interdental Bleeding Index

The presence of gingival inflammation in the interproximal regions was assessed using the Eastman Interdental Bleeding Index (IBI) (Caton, J.G. and Polson, 1985). To perform this examination, a wooden interdental stick was used to depress each of the interdental papillae from first molar to first molar in both arches. The interdental stick was inserted buccally and the papillae depressed 1-2mm four times. The presence of bleeding within 15 seconds recorded as a 1, or lack of bleeding recorded as a 0.

A percentage bleeding score was calculated as $\frac{Number\ of\ bleeding\ sites}{Total\ number\ of\ sites} \times 100$.

Where a tooth was missing, or significantly displaced so much that an obvious papilla was not present (such as in the case of a palatally ectopic canine), the sites mesially and distally to the tooth were not recorded.

13.5.2 Primary Outcome Measures

Patients were seen at 8, 32 and 52 weeks at their appointments to adjust their braces. At these appointments clinical indices to assess oral hygiene and gingival health were again completed.

Historically, orthodontics was performed by placing metal bands cemented around all the teeth. In contemporary fixed orthodontics, these have largely been superseded by brackets which are bonded to the buccal aspect of the teeth. However, in some circumstances it is still necessary to use a band. Cemented bands accumulate more plaque and lead to more gingival inflammation than bonded brackets (Boyd and Baumrind, 1992). Therefore, any banded teeth were not included in the recall indices.

Any teeth which were not attached to the fixed appliance at the recall appointments, either due to a breakage or them not yet being 'picked up', were also not included in the recall indices.

The recall indices were collected on a paper data collection form adapted from a similar trial (Saini, 2016). This is shown in Appendix 5.

The 3 recall indices recorded were as follows:

13.5.2.1 Orthodontic Modification of the Plaque Index

To assess the plaque coverage around the orthodontic appliances, the Orthodontic Modification of the Plaque Index (OMPI) (Williams et al., 1991) was used. This is similar to the PI previously described, but specifically for patients wearing fixed appliances. All teeth from first molar to first molar in both arches were painted with the same disclosing solution as used for the baseline PI, and the patient was asked to rinse with water. Clinical photographs were then taken for assessment of intra-rater reliability.

Four sites on each tooth (mesial, distal, gingival and incisal to the bracket) were scored from 0-3. The location of each site is shown in Figure 2. The scoring criteria are the same as the PI and shown in Table 1. A mean score for the mouth was calculated.

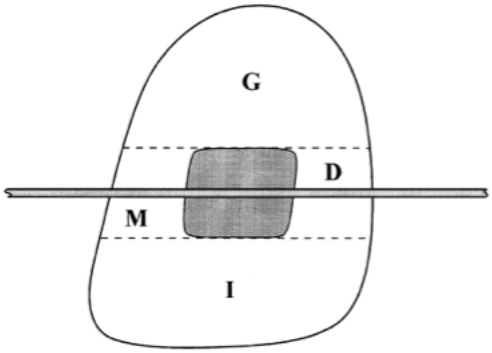

Figure 2: Diagram of the division of the tooth into mesial, distal, gingival and incisal used in the OMPI

Image from Clerehugh et al. (1998)

13.5.2.2 Gingival Index

The GI was performed at recall in the same manner as at baseline.

13.5.2.3 Interdental Bleeding index

The IBI was performed at recall in the same manner as at baseline.

13.5.3 Secondary Outcome Measures

13.5.3.1 Soft Tissue Trauma

At each appointment, a full soft tissue examination of the oral cavity was performed. Any soft tissue trauma secondary to oral hygiene regime was recorded.

13.5.3.2 Adherence with oral hygiene regime

To assess patient adherence with the prescribed oral hygiene regime, patients were given Oral Hygiene Diaries to take home and complete for the duration of the trial. The oral hygiene diary can be seen in Appendix 6.

Patients were asked to complete the oral health diary every time they cleaned their teeth, estimating in minutes for how long their teeth were cleaned, and state whether the WP was used. Patients were asked to return these at every eight-weekly appointment. This data was to be used to assess frequency of toothbrushing, time spent toothbrushing, and frequency of WP use.

13.5.3.3 Satisfaction with oral hygiene regime

To assess patient satisfaction with the allocated oral hygiene regime, patients were asked to complete a patient satisfaction questionnaire following their appointment at 8 weeks and 56 weeks. Two separate questionnaires were completed to avoid the control group being asked questions about using the WP. The intervention group answered all the questions on the control questionnaire, with additional questions regarding the WP. The 48-week space between the completion of the two questionnaires allowed for an assessment of change in satisfaction over time. The questionnaires for the control and intervention group are shown in Appendix 7 and Appendix 8 respectively. The questionnaires were adapted from those used a similar trial (Saini, 2016), but are not validated.

13.6 Sample size

To establish sample size, a power calculation was performed by the trial statistician Dr Jing Kang (JK) based on OMPI. The significance level of the study was decided to be 5% ($\alpha = 0.05$). The smallest effect size of clinical relevance in PI has been set at 0.5 in previous studies (Sreenivasan and Prasad, 2017), and therefore the minimum effect size was set at 0.5. The standard deviation of OMPI found in similar studies is around 0.3 (Clerehugh et al., 1998), and therefore this figure was used. The intended power of the test is 0.9 (90% ($\beta = 0.10$)).

JK used PASS (Power Analysis and Sample Size) Version 11 (NCSS LLC, Kaysville, UT, USA), to calculate the sample size using the function 'Tests for two means (two-sample T-Test on differences)'. Using the above figures, the minimum sample size for each group was calculated to be 7, so 14 participants in total are required. Based on an unpublished audit, the proportion of patients in the study population who do not complete their orthodontic treatment is around 15%. Therefore, the minimum sample size was increased to 8 participants in each group (16 in total) to account for dropouts.

We planned to recruit 20 patients into each group, 40 patients in total, which is more than sufficient to satisfy the power calculation.

13.7 Recruitment

At an appointment prior to placement of their fixed appliances, consecutive patients commencing fixed orthodontic treatment with a single operator (DT) at York Hospital were assessed against the trial inclusion criteria (see 13.2) using the aforementioned patient suitability checklist (Appendix 1).

Patients for whom the inclusion criteria were met were invited to take part in the trial. The trial was verbally explained to the patient and their parent (if under 16) by DT. It was explained to the patients that participation in the trial was entirely voluntary and would have no bearing on their orthodontic treatment.

Patients who expressed an interest in taking part in the trial were given a patient information leaflet (PIL) to take away and read. Patients over 16 years old received a PIL for adults. This is shown in Appendix 9. Patients who were younger than 16 received a PIL for young people to be read by the patient, and a second PIL for their parent or legal guardian. These are shown in Appendix 10 and Appendix 11.

The PILs explained the purpose of the trial and how it would be conducted. It had contact details for both HG and the Research and Development Unit at York Hospital to allow the potential participants to ask any further questions before their next appointment. Patients were given at least a week between being given the verbal information and PILs and their appointment to place their fixed appliances to consider whether they would like to participate.

Patients who had been given the PILs and had expressed an interest in taking part were added to a table in order to keep track of them. It was also used to record the reasons given by patients who chose not to take part. This table is shown in Appendix 12.

13.8 Consent

At the beginning of the appointment to have fixed appliances placed, potential participants were asked whether they had any questions following reading the PIL. Any questions were answered, and if patients were willing to take part, they were recruited into the trial.

Written consent was obtained for all participants. Patients over 16 years old were asked to read and sign the consent form shown in Appendix 13. Patients who were younger than 16 years old were asked to sign the consent form shown in Appendix 14 and a parent or legal guardian was asked to sign the consent form shown in Appendix 15. Three copies of each consent form were signed. The participant was given one, one was kept in the patient notes, and the third was kept in the site file.

The consent form also obtained consent to inform the participant's general dental practitioner (GDP) that they were taking part in the trial. It was important that GDPs were made aware, as if they were to prescribe toothpaste to the patient which was different to the one provided for participants, this could theoretically act as a confounder. A standard letter was sent to GDPs and is shown in Appendix 16.

Participants were also informed that a limited number of patients could be recruited to the trial, dependent on age, gender, and gingival health at baseline. It was explained that their baseline indices would allocate them into a block, and if recruitment in this block had already filled, they would not be able to take part in the trial.

13.9 Randomisation

To attempt to achieve a balance between the control and intervention groups at baseline, participants were allocated using stratified block randomization. Stratified block randomization attempts to achieve equal group sizes and balance between measurable prognostic characteristics of the participants. The participants were stratified based on three prognostic characteristics: gender, age, and bleeding on probing at baseline.

Gender was chosen for several reasons. Firstly, it has been shown that female orthodontic patients report cleaning their teeth more often than males (Kudirkaite et al., 2016). Furthermore, female patients have been shown to have lower levels of plaque and have a greater level of knowledge of oral health (Furuta et al., 2011).

Age was chosen as it has been shown that older orthodontic patients report cleaning their teeth more often than younger patients (Kudirkaite et al., 2016). As the inclusion criteria allowed for patients aged 10 to 20, participants were split in to younger than 15 and older than or equal to 15 years old.

To attempt to attempt to evenly distribute the participants based on their baseline oral hygiene, the third prognostic characteristic used was baseline IBI. Patients were split into less than or equal to 20% IBI or higher than 20% IBI.

Using three prognostic characteristics resulted in eight blocks in which patients could be placed in to. These eight blocks are shown in Table 3.

Block Number	Description
1	Female, <15 years old, ≤20% IBI
2	Female, <15 years old, >20% IBI
3	Female, ≥ 15 years old, ≤20% IBI
4	Female, ≥ 15 years old, >20% IBI
5	Male, <15 years old, ≤20% IBI
6	Male, <15 years old, >20% IBI
7	Male, ≥ 15 years old, ≤20% IBI
8	Male, ≥ 15 years old, >20% IBI

Table 3: Blocks used in the stratified block randomisation process.

As the trial aimed to recruit 40 participants, it was planned that up to six participants in each block could be recruited. Once this number of participants had been reached, recruitment into that block would cease.

For each block, six sealed opaque envelopes were produced by DT. Inside each envelope was a paper slip which read either 'Intervention' or 'Control'. There were three intervention and three control envelopes produced for each block. A folder was produced for each block and labelled with the block number and description. The six envelopes were placed inside each of the eight block folders. These were kept in a secure location on the clinic.

At the end of the appointment to place the fixed appliances, DT calculated the IBI from the baseline indices. DT then allocated the participant into one of the eight blocks based on their IBI, gender and age and informed the DN of which block they were in. DT then left the room and left the participant with the DN to allocate them into the intervention or control group.

Once DT had left the room, the DN took out the relevant block folder. The patient was then asked to choose an envelope from the folder, and this was opened by the nurse. This would allocate the patient into intervention or control. If there were no envelopes remaining in the folder, it was planned that the participant would be informed that recruitment in their group was filled, and unfortunately, they would not be taking any further part in the trial.

However, due to the COVID-19 pandemic there was reduction in the number of patients being seen in the department. Therefore, the pool of potential patients to be recruited from was reduced and there was a concern that we may be unable to recruit the patients required if we turned patients away because their block was filled. In a change to the initially planned protocol, it was therefore decided, with the statistician (JK), that once a block was filled patients would be allocated into intervention or control by a single coin toss. A single coin toss was performed by the DN once DT had left the room, with heads signifying the patient was to be placed into the intervention group, or tails the control group. This was carried out from participant 30 onwards. The DN then provided specific OHE based on their allocation, as described in 13.4.

13.10 Blinding

This was a single blind trial. The operator carrying out all the measurements (DT) was blinded to the patient allocation. Clearly, the patient could not be blinded to their allocation. The

patients were told that they must not tell DT whether they had a WP or not, and this was also included on the OHE scripts given to the patients (see
Appendix 2 and Appendix 3)

A list of participants and whether they were part of the intervention or control groups was recorded on a table which was kept separately to other trial paperwork and only seen by the DNs. This is shown in Appendix 17.

The DNs were also asked to affix a patient identification sticker to the back of the allocation or control slip and keep these in a separate folder to facilitate cross referencing at the end of the trial.

13.11 Appointments

Following the initial discussion appointment prior to recruitment, data was collected at four appointments during the 56-week trial period. The nature of orthodontic treatment means that patients are usually seen every eight weeks, and therefore data was collected at 0, 8, 32 and 56 weeks. A checklist was completed at each appointment as an aide memoir to ensure all tasks were completed. This is shown in Appendix 18.

At every eight-weekly appointment, patients were given more trial consumables and diaries to complete, and their diaries were collected by the DN. However, indices were only completed at these four intervals. A summary of each appointment is shown in Figure 3.

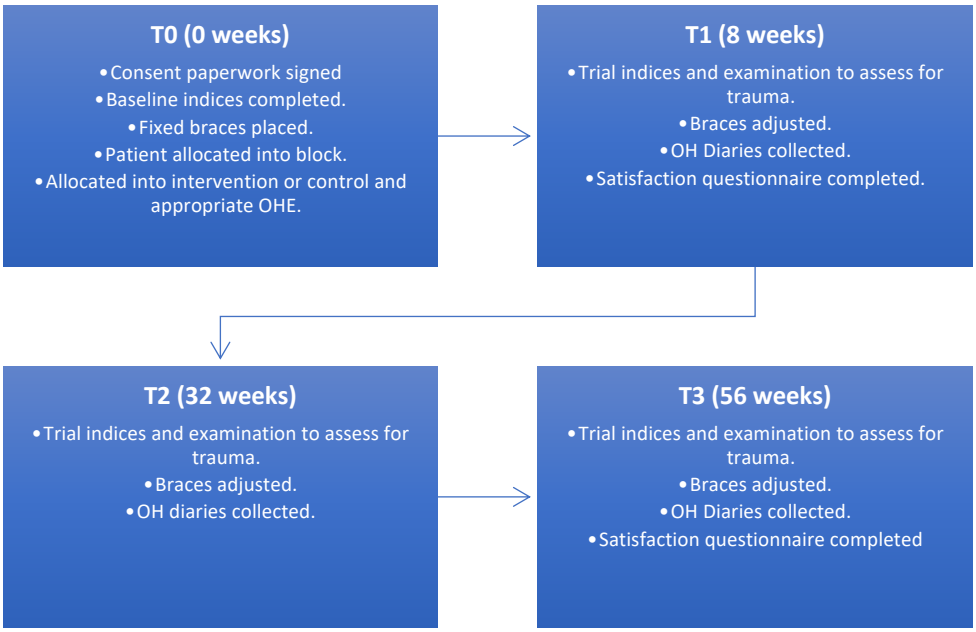

Figure 3: Flow chart summary of the data collection appointments during the trial period.

13.12 Statistical analysis

Statistical analysis was performed using IBM® SPSS® software (International Business Machines Corporation, Armonk, NY, USA). Summary descriptive statistics were produced to illustrate demographic features and for each oral health variable.

A mixed model was used to assess whether there was a difference between the intervention and control groups in terms of OMPI, GI and IBI. A mixed model is the ideal statistical test as it allows comparison of groups over time with non-normally distributed data and missing data (Ibrahim and Molenberghs, 2009). Traditional statistical models such as ANOVA eliminate participants with missing data, which would have reduced the sample size significantly in this trial.

An intraclass correlation coefficient (ICC) was generated to assess intra-rater reliability in the measurement of the OMPI. The comparison was made between the clinical score and a repeated measurement taken on the clinical photographs taken.

Incidence of trauma was analysed by a comparison of frequency between the two groups.

Compliance with oral hygiene regime was analysed by comparing the frequency of oral hygiene practices over the trial period between the two groups.

Participant satisfaction with oral hygiene regime was analysed by frequency of response to each question. The responses were compared both between groups and within groups between the two time points. This would allow assessment of whether satisfaction varied between groups or changed over the trial period.

13.13 Ethical Approval

Ethical approval was sought for the trial through the Integrated Research Application System (IRAS) by HG. This was approved by the Health Research Authority and Health and Care Research Wales (HRA & HCRW) on 23rd of August 2019. The approval letter is shown in Appendix 19.

The trial was registered with York Teaching Hospital NHS Foundation Trust who acted as the sponsor. The risk assessment completed in order to achieve this is shown in Appendix 20.

The confirmation from the Trust that it has capacity and capability to deliver the study is shown in Appendix 21.

13.14 Protocol Registration

The trial was registered with ClinicalTrials.gov Protocol Registration and Results system. The Unique Protocol ID was 266235. The registration receipt is shown in Appendix 22.

Due to an administrative error, the trial was not registered until 09/10/2020. Recruitment for the trial had already begun at this point.

13.15 Funding

Water Pik, Inc. funded the WPs, orthodontic tips, plug adaptors, toothbrushes, toothpaste, mouthwash, and paper bags to give the patients their trial consumables in.

DT was employed and paid by Leeds Teaching Hospitals NHS Trust.

HG and JDK were employed and paid by York Teaching Hospital NHS Foundation Trust.

JK was employed and paid by The University of Leeds.

14 Results

14.1 Decision to present interim analysis of results

Due to delays in the recruitment of patients because of the COVID-19 pandemic, the decision was made to write up this thesis with incomplete data to meet the submission deadline.

Data collected up to 13/04/2021 has been included, with an interim analysis of results presented. At this point, data collection was approximately 50% complete.

14.2 Participant Flow

A diagram of participant flow through the trial to this point is shown in Figure 4.

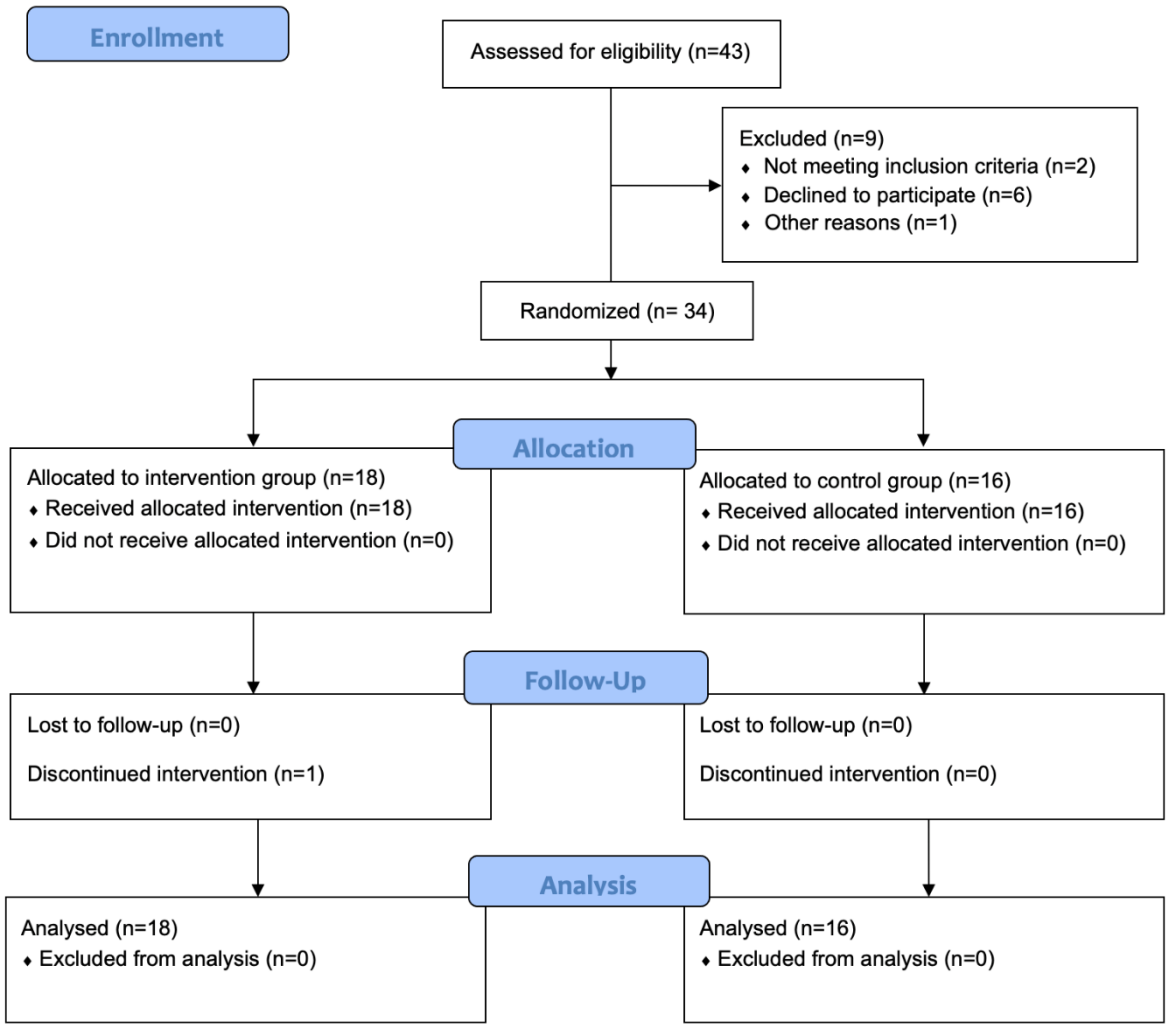

Figure 4: CONSORT participant flow diagram.

Adapted from CONSORT (2010)

The patients who did not meet the inclusion criteria failed on account of already regularly using a WP (n=1) and using a prescription toothpaste (n=1).

Patients declined to participate for several reasons. The most common was that they did not wish to stop using an electric toothbrush (n=4). Others stated that they did not want longer appointments (n=1) or did not want the 'pressure' of repeated close examination of their cleaning (n=1).

One potential participant's parents were living abroad, and we were unable to gain the appropriate written consent from them (n=1). This patient is categorised in Figure 4 as excluded for 'Other reasons'.

A single patient in the intervention group withdrew from the study after the 32-week indices, as he wished to start using an electric toothbrush.

14.3 Recruitment

Recruitment for the trial began on 15/11/2019. The first patient to be recruited started the trial (T0 as per Figure 3) on 06/01/2020. The most recent participant to be recruited started the trial on 06/04/2021.

Although 34 patients had been recruited up to 13/04/2021, only four patients had completed the trial. The number of patients to progress to each time point in the trial up to this point is shown in Figure 5.

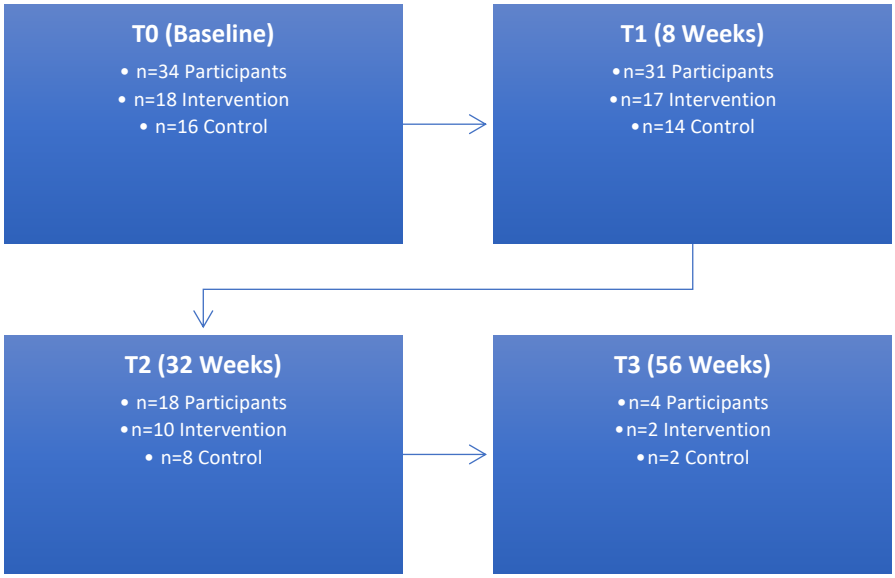

Figure 5: Diagram demonstrating number of patients progressing to each point in trial up to interim analysis of results.

Recruitment is ongoing with 34 of 40 participants having been recruited.

14.3.1 Disruption due to COVID-19

There was a delay in recruiting patients due to the COVID-19 pandemic. From 23/03/2020 to 15/06/2020 the Orthodontic Department at York Hospital was closed completely. On reopening, patients already in active treatment were prioritised for appointments over those who had not yet started treatment.

When the department closed on 23/03/2020, seven patients were already enrolled into the trial. Four of these patients were in the intervention group, with three in the control group. Two patients (one intervention and one control) had returned for T1 (8-week indices), whereas the other five had only attended for T0 (baseline indices). All participants received a standard letter advising them to continue with their allocated oral hygiene regime and completing their oral hygiene diaries. This letter is shown in Appendix 23.

The participants were also posted trial consumables and oral hygiene diaries.

14.4 Baseline data

Baseline data is presented for all 34 patients who have been recruited up to 13/04/2021.

14.4.1 Age

Participant age at baseline is presented in Table 4. Histograms for age split between intervention and control group are shown Figure 6. Box plots for age split between intervention and control group are shown in Figure 7.

Table 4 shows that the mean and median values are similar both between and within the groups, suggesting that the data is normally distributed. This fits with the visual appearance of the normal distribution curves on the histograms. The appearance of the box plots is also similar, with no outliers in either group. The data shows that age was similarly distributed between the intervention and control groups. Although the inclusion criteria of the trial allowed for patients from 10 to 20 years old, participants were between 11.7 and 17.81 at baseline.

	Intervention	Control	Total
N	18	16	34
Mean	14.79	14.55	14.68
Std. Dev.	1.73	1.31	1.52
Median	14.78	14.86	14.85
Min	11.7	11.98	11.7
Max	17.81	16.18	17.81

Table 4: Participant age at T0.

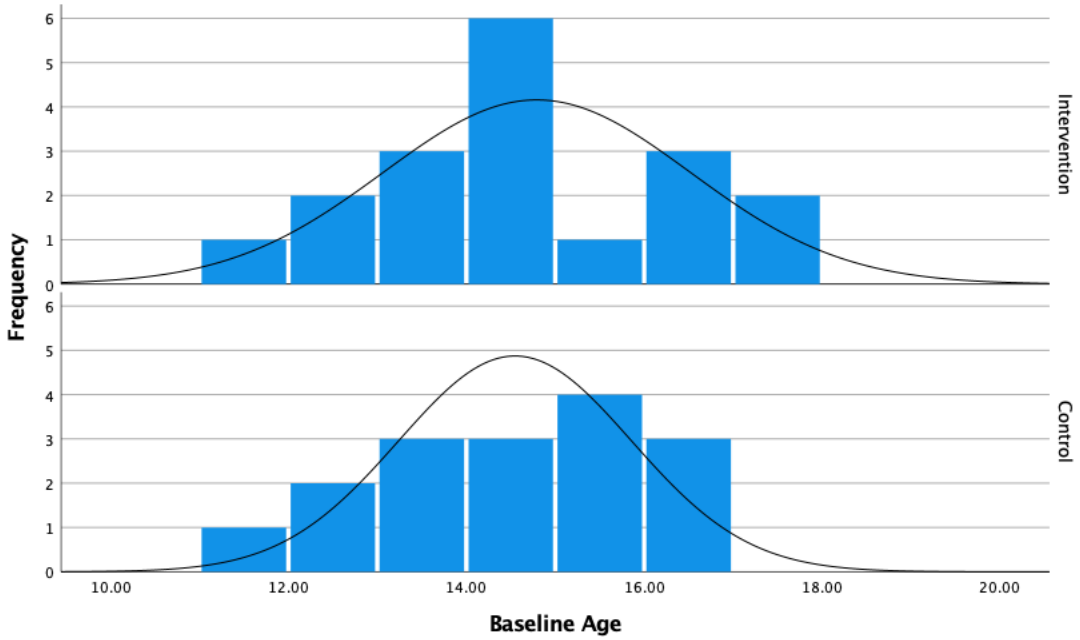

Figure 6: Histogram of patient age at baseline split by intervention or control group.

Normal distribution curves have been traced.

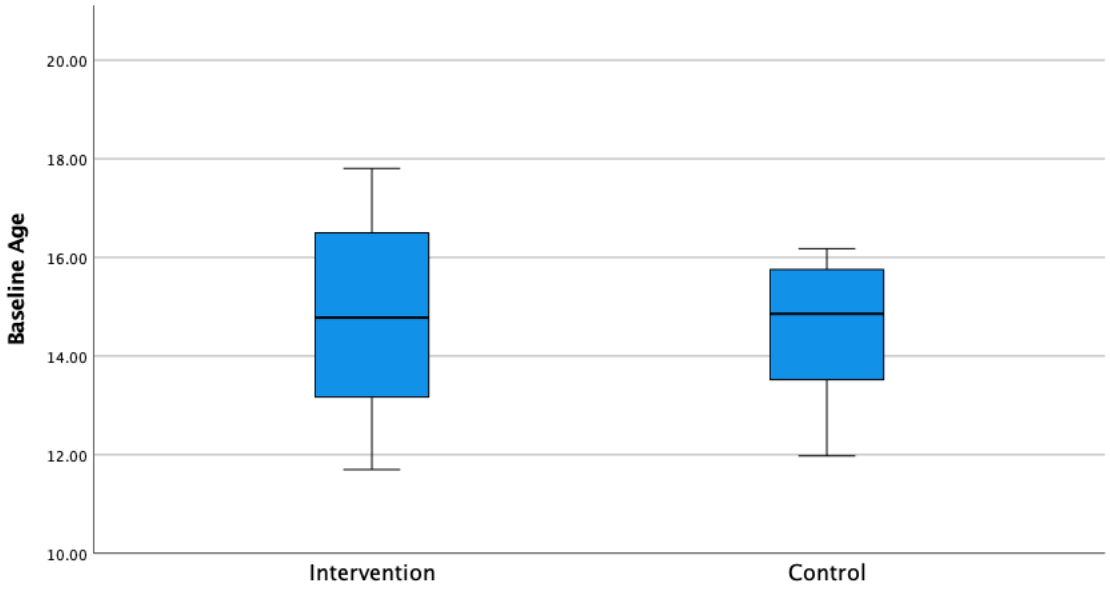

Figure 7: Box plot of patient age at baseline split by intervention or control group.

14.4.2 Gender

Participant gender is shown in Figure 8. The data demonstrates that between all participants there was a slightly higher proportion of females. Within the intervention group, there was an even split between male and female participants. There was a higher proportion of female patients in the control group.

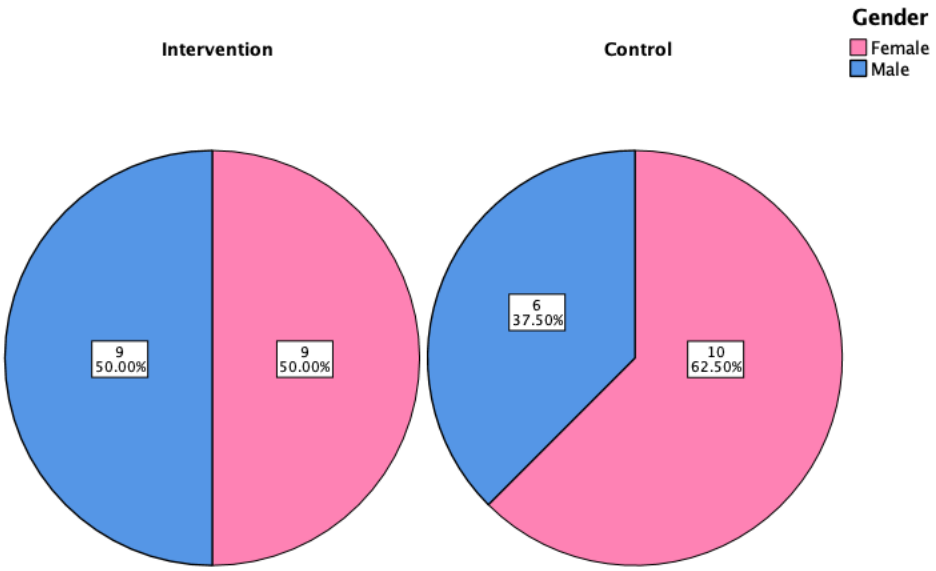

Figure 8: Pie charts of gender split by intervention and control group.

14.4.3 Orthodontic appliances

As described in in 13.5.1, the baseline indices recorded were slightly different if a participant already had an orthodontic appliance in situ. The appliances already in situ were either appliances which only attach to the first molars in either the upper or lower arch, or a fully bonded arch which had previously been placed. As previously mentioned, appliances attached to the first molars only are held in place by circumferential bands which make oral hygiene more difficult and cause gingival inflammation. Fully bonded arches are not likely to give a fair indication of baseline plaque control. Therefore, these teeth were left off the baseline indices.

Details of any appliances already in place at T0 are presented in Table 5 and Table 6. Figure 9 shows what the individual appliances were if present.

		Intervention	Control	Total
	N	18	16	34
Was there already an appliance present attached to bands on first molars at T0?	No	10 (55.6%)	10 (62.5%)	20 (58.8%)
	Yes	8 (44.4%)	6 (37.5%)	14 (41.2%)

Table 5: Proportion of patients with appliances present attached to bands on first molars at T0.

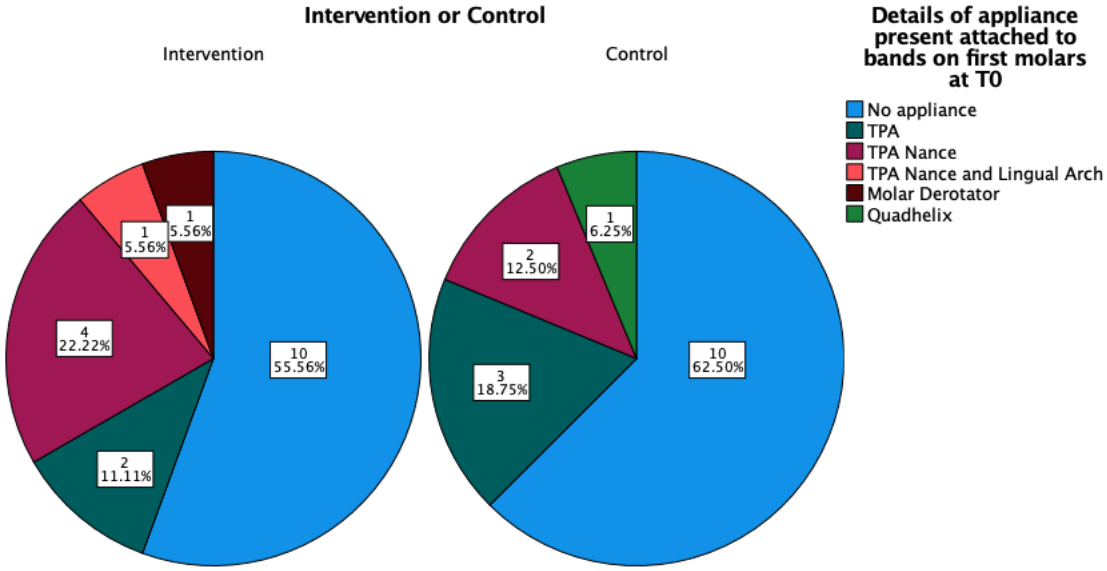

Figure 9: Pie charts of appliances present attached to bands on first molars at T0

		Intervention	Control	Total
	N	18	16	34
Was there already a single arch bonded at T0?	No	17 (94.4%)	15 (93.8%)	32 (94.1%)
	Yes	1 (5.6%)	1 (6.3%)	2 (5.9%)

Table 6: Proportion of patients who already had one arch with a fixed brace in situ at T0.

14.4.4 Oral hygiene indices

Baseline measurements of PI, GI and IBI are presented in Table 7.

		Intervention	Control	Total
	N	18	16	34
T0 PI	Mean	.927	.921	.9212
	Std. Dev.	.338	.290	.312
T0 GI	Mean	.747	.741	.741
	Std. Dev.	.284	.255	.267
T0 IBI (%)	Mean	25.79	35.53	30.37
	Std. Dev.	25.85	27.77	26.82

Table 7: Baseline PI, GI and IBI.

14.5 Number of Patients Analysed

All patients randomised were analysed for the data collected up to the point at which the interim analysis was completed. The numbers analysed at each time point are as per Figure 5. The single participant who dropped out had data collected at T1 and T2, however dropped out before T3 so no indices could be completed.

14.6 Outcomes

14.6.1 Duration between data collection points

The planned durations between T0 and T1, T2, T3 were 8 weeks, 32 weeks, and 56 weeks respectively. However, as described in 14.3.1, as result of the COVID-19 pandemic there were delays in being able to arrange appointments for indices to be completed due to a departmental closure. Furthermore, once the department had reopened, several participants cancelled appointments at short notice due to self-isolation. Due to the backlog of patients caused by the pandemic, patients cancelling appointments would experience delays in finding another appointment. This has meant that patients were often not seen at the planned durations. Table 8 shows the data for the duration between follow-up appointments.

The table shows that at all 3 time points there is a tendency for patients to have been seen later than planned. At T1, there is a large range of values from 49 to 140 days overall. On

average, the control group attended later than the intervention group. However, the mean values at T1 for the intervention and control group are within a week of each other and the standard deviations are similar. These suggest a similar spread of data.

At T2, there is again a large range of values from 210 to 280 days. On average, the control group attended later than the intervention group. The standard deviation for the control group is lower than that of the intervention group, demonstrating a wider spread of data in the intervention group.

Only 4 patients have progressed to T4 so far. On average, the intervention group have attended later.

		Intervention	Control	Total
Days from T0 to T1 (56 planned)	N	17	14	31
	Mean	73.41	79.0	75.94
	Std. Dev.	22.139	23.367	22.494
	Median	69	70	70
	Min	49	56	49
	Max	126	140	140
Days from T0 to T2 (224 planned)	N	10	8	18
	Mean	246.3	237.75	242.5
	Std. Dev.	21.198	14.636	18.58
	Median	241.5	238	238
	Min	223	210	210
	Max	280	258	280
Days from T0 to T3 (392 planned)	N	2	2	4
	Mean	420.5	395.5	408
	Std. Dev.	19.092	24.749	23.108
	Median	420.5	395.5	410
	Min	407	378	378
	Max	434	413	434

Table 8: Days elapsed between T0 and T1, T2, T3.

14.6.2 Orthodontic Modification of Plaque Index (OMPI)

Baseline data was not included in the mixed model for OMPI, as at baseline PI was recorded rather than OMPI. These scores are not directly comparable.

For OMPI the estimated effect size was 0.02 (p = 0.85, 95% CI -0.2, 0.2), demonstrating that overall, there was no statistical difference between the Intervention and Control groups over time. The mean values at each time with 95% CI error bars is shown in Figure 10.

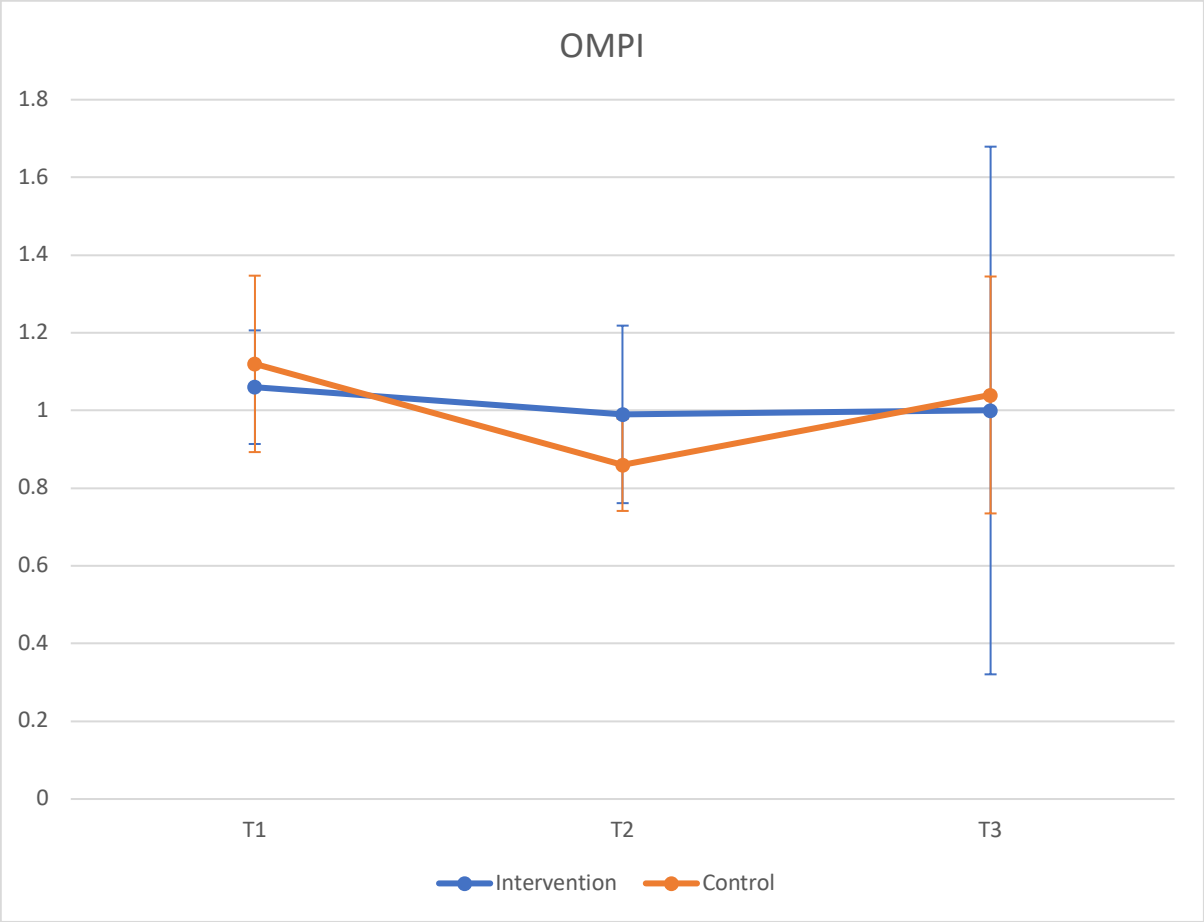

Figure 10: Plot of mean value of OMPI at T1, T2 and T3 for the Intervention and control groups.

The vertical error bars show the 95% CI.

14.6.2.1 Power Calculation Validation

The power calculation was based on an estimation of what the standard deviation of OMPI would be. It was estimated to be 0.3. The overall standard deviation for OMPI was 0.36.

14.6.2.2 Intra-Rater Reliability

Intra-rater reliability was assessed using intraclass correlation coefficient (ICC). The sets of clinical photographs taken of the patients disclosed were numbered and a random number generator was used to choose ten sets to measure the Photographic OMPI. At the point of the interim analysis, the Clinical OMPI had been recorded 53 times. Ten sets of photographs therefore represent 18.8% of the measurements of OMPI.

DT measured the OMPI from the selected photographs. Any surfaces which were not visible on the photographs were recorded as non-visible, and a Photographic OMPI was calculated with these surfaces excluded. The Clinical OMPI was re-calculated with all the non-visible surfaces excluded to give the Adjusted Clinical OMPI. The Adjusted Clinical OMPI was compared to the Photographic OMPI to give the ICC.

The ICC = 0.911 (95% CI 0.700, 0.977). Hence, there is good evidence for the repeatability of measurements of OMPI carried out by DT.

14.6.3 Gingival Index (GI)

For GI the estimated effect size was -0.06 (p = 0.45, 95% CI -0.21, 0.09), demonstrating that overall, there was no statistical difference between the Intervention and Control groups over time. The mean values at each time with 95% CI error bars is shown in Figure 10.

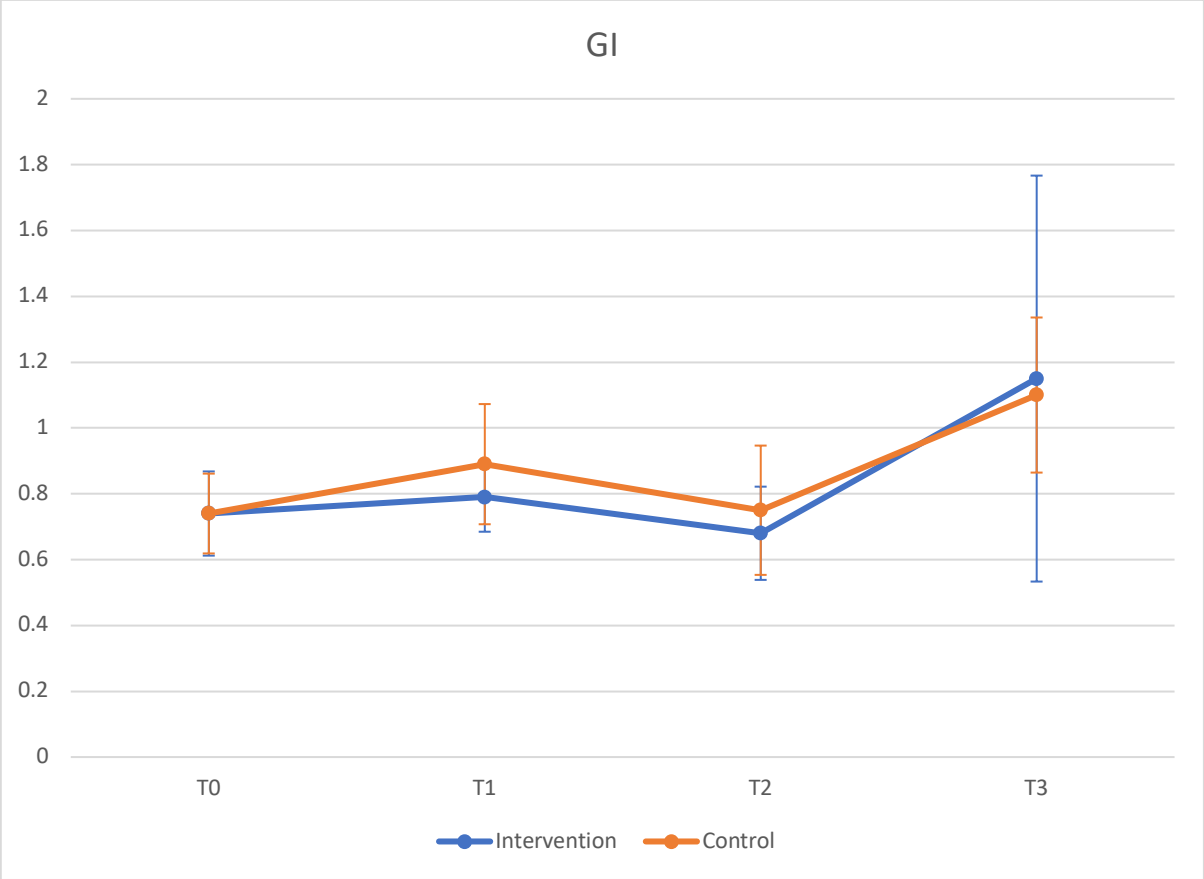

Figure 11: Plot of mean value of GI at T0, T1, T2 and T3 for the Intervention and control groups.

The vertical error bars show the 95% CI.

14.6.4 Interdental Bleeding Index (IBI)

For IBI the estimated effect size was -5.5 (p = 0.418, 95% CI -19.29, 8.21) demonstrating that overall, there was no statistical difference between the Intervention and Control groups over time. The mean values at each time with 95% CI error bars is shown in Figure 12.

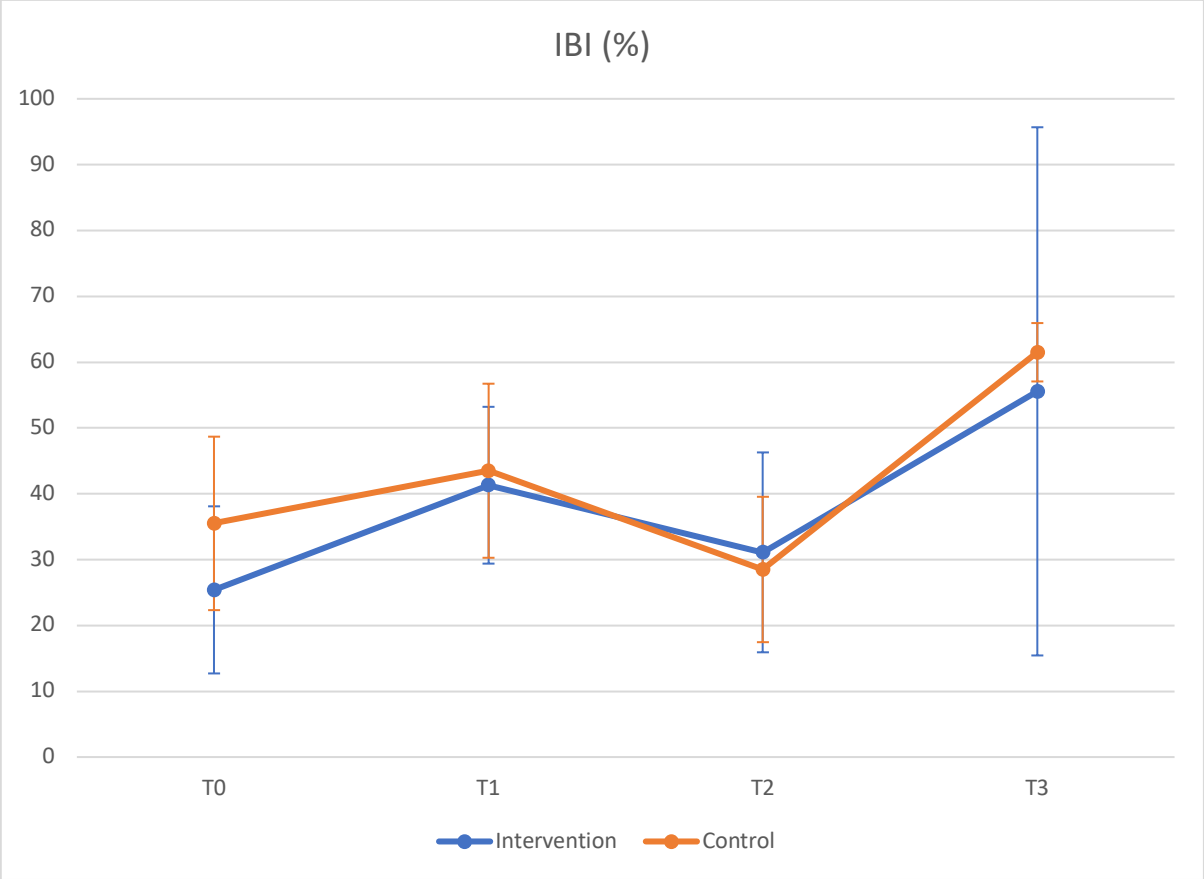

Figure 12: Plot of mean value of IBI at T0, T1, T2 and T3 for the Intervention and control groups. The vertical error bars show the 95% CI.

14.6.5 Soft tissue trauma

No soft tissue trauma secondary to oral hygiene regime was recorded in either group.

14.6.6 Adherence with oral hygiene regime

The return rates for the paper oral hygiene diaries were very poor, with many patients forgetting to bring them back to follow up appointments or admitting that they had never filled them in. For those who did return the diaries, a large proportion of the diaries had missing days and it was not clear whether these were days patients did not clean their teeth

or days when they had neglected to complete the diary. Many of the diaries had lists of oral hygiene events without any dates filled in. Furthermore, the diaries asked that patients estimated the time taken to brush or use the WP. Many patients returned the diaries with ticks or 'B' written when they had brushed instead.

Due to the poor response rate and poor quality of the data, the decision was made not to analyse the data at this point.

14.6.7 Satisfaction with oral hygiene regime

35 questionnaires were completed out of a potential 36 responses, with a single missing response at T3 due to the participant who dropped out. This is a response rate of 97.2%. 31 questionnaires at T1 and 4 questionnaires at T3 were completed. Due to the relatively low number of responses at T3 in this interim analysis of results, it is not possible to analyse the responses for changes over time at this point.

As previously discussed in 13.5.3.3, all participants answered 4 questions pertaining to general oral hygiene. The responses to these questions are shown in Table 9, Table 10, Table 11 and Table 12. Only the intervention group answered a further 3 questions pertaining to the WP. These results are shown in Table 13, Table 14 and Table 15.

14.6.7.1 How easy or difficult is it to clean your teeth with the manual toothbrush?

T1	Very easy	Easy	Neither easy nor Difficult	Difficult	Very difficult	Total
Intervention	6	7	3	1	0	17
Control	2	7	5	0	0	14
Total	8	14	8	1	0	31
T3						
Intervention	0	1	1	0	0	2
Control	0	1	1	0	0	2
Total	0	2	2	0	0	4

Table 9: Responses to the question 'How easy or difficult is it to clean your teeth with the manual toothbrush?'

14.6.7.2 How often do you clean your teeth in the way we have shown you?

T1	Every time	Most of the time	Sometimes	Rarely	Never	Total
Intervention	9	8	0	0	0	17
Control	7	7	0	0	0	14
Total	16	15	0	0	0	31
T3						
Intervention	1	1	0	0	0	2
Control	1	1	0	0	0	2
Total	2	2	0	0	0	4

Table 10: Responses to the question 'How often do you clean your teeth in the way we have shown you?'

14.6.7.3 How helpful or unhelpful were the instructions we gave you about cleaning your teeth?

T1	Very helpful	Helpful	Neither helpful nor unhelpful	Unhelpful	Very unhelpful	Total
Intervention	9	7	0	0	1	17
Control	5	9	0	0	0	14
Total	11	16	0	0	1	31
T3						
Intervention	0	2	0	0	0	2
Control	1	1	0	0	0	2
Total	1	3	0	0	0	4

Table 11: Responses to the question 'How helpful or unhelpful were the instructions we gave you about cleaning your teeth?'

14.6.7.4 If there is anything else you would like to tell us about brushing your teeth when you have braces, please write this below.

T1	
Intervention	'Hard to brush under wire and in between brackets with manual toothbrush' 'It is a bit awkward to get into the little nooks and crannies with a manual toothbrush'
Control	No responses
T3	
Intervention	'Difficult to brush in between brackets but other than that quite straightforward'
Control	No responses

Table 12: Free text responses to the question 'If there is anything else you would like to tell us about brushing your teeth when you have braces, please write this below'.

14.6.7.5 How easy or difficult is it to use the Waterpik®?

T1	Very easy	Easy	Neither easy nor Difficult	Difficult	Very difficult	Total
Intervention	8	8	1	0	0	17
T3						
Intervention	1	1	0	0	0	2

Table 13: Responses to the question 'How easy or difficult is it to use the Waterpik®?'

14.6.7.6 When you clean your teeth, how often do you use Waterpik®?

T1	Every evening	Most evenings	Some evenings	Rarely	Never	Total
Intervention	8	7	2	0	0	17
T3						
Intervention	0	2	0	0	0	2

Table 14: Responses to the question 'When you clean your teeth, how often do you use Waterpik®?'

The follow up to this question was 'If you rarely or never use the Waterpik® we gave you, please tell us why.' No participant chose 'Rarely' or 'Never', and none answered the follow up question.

14.6.7.7 How clean or unclean do your teeth feel when you have used the Waterpik®?

T1	Very clean	Clean	Neither clean nor unclean	Unclean	Very unclean	Total
Intervention	8	7	2	0	0	17
T3						
Intervention	0	2	0	0	0	2

Table 15: Responses to the question 'How clean or unclean do your teeth feel when you have used the Waterpik®?'

15 Discussion

15.1 Baseline Data

A thorough assessment of differences in baseline characteristics between the two study arms is essential to ensure that confounding variables can be identified. Significance tests of differences in baseline data were not performed. This is because significance tests assess the probability that differences between two groups have occurred by chance. By virtue of the type of data, we already know that any differences have occurred by chance, so these tests are generally not appropriate (Moher et al., 2012).

15.1.1 Age

The mean age of the patients was 14.79 in the intervention group and 14.55 in the control group with no outliers. The average age of the participants in both groups being so similar suggests that we can quite confidently expect there to be no difference in terms of outcome measures based on the age of the participants.

15.1.2 Gender

There was a higher proportion of females in the control group (62.5%) compared to the intervention group (50.0%). As previously stated, female patients have been shown to have lower levels of plaque and have a greater level of knowledge of oral health (Furuta et al., 2011). Female teenagers have also been shown to be more likely to clean their teeth twice a day, compared to males (Currie et al., 2011). Therefore, the presence of higher proportion of female participants in the control group compared to the intervention group could have masked the effects of the WP in the intervention group. However, the differences are relatively small.

15.1.3 Orthodontic appliances

Patients with a single arch bonded before T0 or an appliance attached to banded first molars had their baseline indices adjusted to eliminate these teeth. Therefore, if the patients with these appliances were unevenly distributed between the two groups, then their baseline indices may not have been necessarily comparable.

Furthermore, any banded molar teeth were not included in any of the subsequent indices. Research has demonstrated that PI and GI are higher in molar sites, compared to anterior teeth (Sreenivasan and Prasad, 2017). Therefore, if one group had significantly more banded and therefore eliminated molar teeth than the other, this could have artificially reduced their mean PI and GI scores.

There was one patient in each group with an arch already bonded and similar numbers of patients with appliances present between the groups. The presence of orthodontic appliances prior to T0 is therefore unlikely to have acted as a confounding variable.

15.1.4 Oral hygiene indices

Assessing the two groups for differences in baseline oral hygiene is important to ensure that any results are valid. If one group had a generally poorer standard of oral hygiene at baseline which is maintained throughout the trial period, then this could lead to erroneous conclusions being drawn. If a control group with comparatively poor oral hygiene at baseline was not noted, then this could lead to a Type I error in which the efficacy of the WP was overestimated. If an intervention group with comparatively poor oral hygiene at baseline was not noted, then this could lead to a Type II error in which it is underestimated.

The mean PI for the Intervention group of 0.927 is almost identical to that of the control group of 0.921. The mean GI for the intervention group of 0.747 is almost identical to that of the control group of 0.741. These values being so close demonstrate that there is no difference between the groups in terms of PI and GI. However, there is almost a 10% difference in IBI between the intervention group at 25.79 and the control group at 35.53. Although 10% does appear a relatively large difference at first glance, in a mouth which has had no extractions there are 22 interdental spaces. A difference of 10% IBI is just over 2 extra bleeding sites. In cases which have had extractions or teeth eliminated from the baseline indices for appliances, this could be as little as one bleeding site. Therefore, overall, it is sensible to conclude that there were no significant inter-group differences at baseline in terms of oral hygiene indices.

15.2 Outcomes

15.2.1 Duration between data collection points

As discussed in 14.6.1, there was a relatively large variation in the duration between data collection points between participants. This was partly due to delays in appointments due to the COVID-19 pandemic. Another contributing factor was the fact that patient's indices were performed at their regular appointments for the adjustment of their orthodontic appliances. The indices performed all have a degree of subjectivity, so to reduce the impact of inter-rater differences the study was designed so that all the indices would be performed by the same operator (DT). However, DT only had between two and three clinical sessions per week at the unit which the research was performed at. Longer appointments were required to have time to perform the indices as well as adjust the appliances, which made it challenging to find appointment slots for all participants at the appropriate time.

Throughout the trial there was a tendency to be seen 'late' which is seen in both groups. This makes it less likely to become a confounding variable, compared to if only one group were seen 'late'. The mean number of days between T0 and T1 in the Intervention and Control groups are within 7 days of each other, and for T0 and T2 within 9 days of each other. There is a larger difference between T0 and T3, however only four patients have progressed to this point in the trial, meaning outliers have a much bigger impact on the mean. This is likely to reduce as the trial progresses. It seems unlikely that a difference of 7 or 9 days over the trial period will have impacted the indices recorded in the trial. However, there is no published evidence base to support this. Based on visual inspection, participants who attended late or early do not appear to be outliers.

15.2.2 Orthodontic Modification of Plaque Index (OMPI)

The OMPI estimated effect size was 0.02 (p = 0.85, 95% CI -0.2, 0.2). This means that there was an overall difference of 0.02 in the mean OMPI between the intervention and control groups, which is both clinically and statistically insignificant. On average, the OMPI of the intervention group was 0.02 higher than the control group. Therefore, the null hypothesis 'There is no difference in plaque levels between patients using WP+MTB compared to using MTB alone', should be accepted based on this data.

Although the OMPI has been used in relatively few trials compared to the original Plaque Index (Silness and Loe, 1964), it has been shown to be sensitive (Williams et al., 1991). Published data on the reliability of the index is lacking, however the ICC of 0.911 (95% CI 0.700, 0.977) shows that the intra-rater reliability in this trial was high.

The descriptions given for grading 0 to 3 (shown in Table 1) have been taken from the PI and transferred to the OMPI. However, they are not a perfect fit for the methodology used. For example, the criteria for a grade 2 describe 'A film of plaque adhering to the free gingival margin and adjacent area of the tooth'. Only the gingival portion of the tooth below the bracket has a gingival margin, so it is not obvious how this description should be used for the other three surfaces scored. Although the descriptions provided aim to be as objective as possible, sometimes it was challenging to determine the subtle differences between whether a surface should be scored between a 1 and a 2 or a 2 and a 3. If a systematic error did indeed exist in the recording of the OMPI, this will likely have been applied to participants in both the intervention and control group. Therefore, it is unlikely to have affected the trial outcome.

Another issue with the OMPI is whether it is a valid surrogate measure for plaque control. It could be argued that the OMPI in this trial only represents the quality of plaque control prior to an orthodontic examination. The Hawthorne effect has also been shown to reduce tooth surface area covered with plaque in orthodontic patients (Feil et al., 2002). It is plausible that the participants were cleaning their teeth to a higher standard both as a result of taking part in a trial and because they knew that they had an orthodontic appointment that day. However, again, these factors apply to both the intervention and control groups.

There is only one published trial assessing orthodontic patients with or without a WP with an Orthodontic Tip. As discussed in 10.7.4, Sharma et al. (2008) found a statistically significant difference in terms of plaque score over 28 days. However, plaque was measured using a different index in this trial; the Turesky modification of the Quigley and Hein plaque index (Turesky et al., 1970). This index scores from zero to five, assessing the facial and lingual surfaces of all teeth apart from third molars. Only participants with a score of at least 3.0 at baseline met the inclusion criteria. This means that only patients with sub-optimal oral hygiene at baseline were included, whereas participants with poor oral hygiene at baseline

for this trial would have been excluded and unlikely to have been allowed to proceed with orthodontic treatment. The mean baseline plaque score was 3.73 out of a maximum score of 5 in Sharma's trial, compared to 0.92 out of a maximum of 3 in this trial. Although the scores cannot be statistically compared due to the different methodologies, it does appear that Sharma's participants had worse oral hygiene. This RCT had a selection bias for patients who already have good oral hygiene.

Patients were recruited for Sharma et al. (2008) once they were already wearing braces, rather than being recruited prior to bond up. Therefore, the participants in the two trials were quite different. This trial recruited patients with relatively good oral hygiene before commencing brace treatment, whereas Sharma et al. (2008) recruited patients already in braces struggling with oral hygiene. These differences could account for the differences in the results found. Another potential reason for the differences found is the different lengths of follow up. Sharma et al. (2008) followed up patients for a much shorter period. It may be that if the patients in this trial were seen after 28 days that a difference would have been seen due to the novelty value of the WP. It may be that over time as the novelty of the WP wears off, patients use them less or less effectively. The novelty effect of the WP has been acknowledged in other studies (Rosema et al., 2011)

15.2.2.1 Power calculation validation

Prior to commencement of the trial, a power calculation was completed by JK to inform the sample size. As detailed in 13.6, the sample size required for the trail was relatively small. This is due to the fact that the effect size required was relatively large (Jones et al., 2003). The power calculation was based on OMPI. The standard deviation for OMPI from a previous trial was used to estimate the standard deviation which would be found in this trial. The standard deviation was 0.3, taken from Clerehugh et al. (1998). The standard deviation for PI in this trial was 0.36. These standard deviations are very similar, suggesting that the estimated figures put into the calculation were robust.

15.2.3 Gingival Index (GI)

The GI estimated effect size was -0.06 (p = 0.45, 95% CI -0.21, 0.09). This means that there was an overall difference of 0.06 in the mean GI between the intervention and control groups, which is both clinically and statistically insignificant. Therefore, the null hypothesis 'There is no difference in overall gingival health between patients using WP+MTB compared to using MTB alone' should be accepted based on this data.

The GI is relatively subjective, and due to the requirement to probe the gingiva, photographs to assess intra-rater reliability were not feasible. The same patient could be re-assessed immediately after the first, but reliability studies have shown that there is a trend for scores to worsen, possibly because the first examination increases the tendency for the gingiva to bleed the second time around (Poulsen, 1981). The GI has been shown to be highly reproducible both between examiners and by the same examiner after 4-6 hours (Shaw and Murray, 1977). However, another study comparing the intra and inter-rater reliability of several oral health indices found a non-invasive modification of the GI to be one of the most variable indices tested (Marks et al., 1993)

The index is particularly challenging to differentiate between a score of 0; 'absence of inflammation' and 1; 'mild inflammation – slight change in colour and little change in texture'. By virtue of their oral hygiene and suitability for orthodontic treatment, the participants in the trial rarely scored above a 1, which perhaps made this an insensitive test for differences in gingival health between the two groups. Another issue for any index which has presence of bleeding as an outcome measure is the possibility of a false positive due to increased probing force, resulting in mechanical trauma of a healthy site (Panagakos, 2011). No other published literature comparing use of a WP with an orthodontic tip assessing GI exists.

15.2.4 Interdental Bleeding Index (IBI)

For IBI the estimated effect size was -5.5 (p = 0.418, 95% CI -19.29, 8.21). This means that there was an overall difference of 5.5% in the mean IBI between the intervention and control groups. This is clinically and statistically insignificant. Therefore, the null hypothesis 'There is no difference in interdental gingival bleeding between patients using WP+MTB compared to using MTB alone' should be accepted based on this data.

Like GI, photographs to assess the intra-rater reliability were not feasible. However, the intra-rater reliability of this index has been found to be 91.3 to 93.1% (Blieden et al., 1992). Research has shown it to be a more reliable clinical indicator of interdental gingival inflammation than other similar indices (Caton, J. et al., 1988). The index has also shown to be valid, with histological investigation showing that bleeding sites are associated with histological changes associated with gingivitis compared to those which do not bleed (Bouwsma et al., 1988). The IBI is a relatively objective index, however authors have suggested that although dichotomous indices are useful for patient education, for the purpose of research, quantitative measurements of bleeding are more appropriate (Panagakos, 2011). As with the GI, the possibility of false positives due to mechanical trauma also applies to the IBI, particularly due to the rigidity and shape of the wooden stick. However, it has been suggested that it may be more objective because there is less margin for variation in probe insertion depth, angulation or direction of movement (Hofer et al., 2011).

By virtue of only measuring interdental sites, relatively few sites are recorded throughout the mouth compared to the OMPI and GI. As alluded to in 15.1.4, in a non-extraction case with 22 interdental sites, just one extra bleeding site equates to a 4.5% increase in the IBI. In a case where a transpalatal arch has been placed and upper first premolars and lower second premolars have been extracted, interdental sites due to the extractions and because of the banded first molars are eliminated. This only leaves 12 interdental sites, meaning that just one extra bleeding site equates to an 8.3% increase in IBI. For the participants in this trial who have a good enough level of oral hygiene to access orthodontic treatment, the IBI is potentially not sensitive enough to demonstrate differences in oral hygiene.

In their 28-day randomised controlled trial using the WP with the Orthodontic tip, Sharma et al. (2008) recorded interdental bleeding using the Gingival Bleeding Index. This scores bleeding from 0 to 2 on four sites on each tooth. At four weeks there were no differences in terms of interproximal bleeding between the intervention and control groups. Although the methodology and follow-up time were different (as discussed in 15.2.2), the findings of this trial are similar.

15.2.5 Soft tissue trauma

There was no soft tissue trauma associated with oral hygiene practices detected in either group. Therefore, the null hypothesis 'There is no difference in experience of soft tissue trauma between patients using WP+MTB compared to using MTB alone' should be accepted based on these results. Contemporary trials using the WP have also consistently reported no adverse effects (Sharma et al., 2012b; Rosema et al., 2011; Magnuson et al., 2013; Goyal et al., 2018a) and therefore it can be concluded with relative certainty that the WP is safe to use.

15.2.6 Adherence with oral hygiene regime

Unfortunately, due to the poor response rate and poor quality of the responses, it was not possible to analyse the oral hygiene diaries. Therefore, it is not possible with the data available to reject the null hypothesis 'There is no difference in adherence to oral hygiene regime between patients using WP+MTB compared to using MTB alone'. As the trial continues, it may be that the response rate improves and that the responses could be evaluated for the final analysis of results. However, self-estimated brushing time has been shown to be much shorter than actual brushing time (Emling et al., 1981), and we are relying on the patients being honest regarding frequency, so any conclusions drawn from this secondary outcome may not be valid.

In a study such as this one, carried out over a long period of time, the inability to formally assess patient adherence with their oral hygiene regime is disappointing. This is because we are unable to assess whether patients are using the WP at home long term. It may be that some participants in the trial used the WP for a few weeks and then stopped and this is the reason that no differences in oral hygiene have been found. Although assessing patients using the 'intention-to-treat' principle over a 'per-protocol' analysis increases the external validity of RCTs (McCoy, 2017), knowing whether cooperation was an issue would have been useful data.

15.2.7 Satisfaction with oral hygiene regime

Satisfaction with the oral hygiene regime was assessed using unvalidated patient questionnaires which were adapted from a previous, similar study (Saini, 2016). The lack of validation of the questionnaires means that care must be taken when drawing any

conclusions from the data (Peter et al., 2017). As this is an interim analysis of results, much data is currently missing from the questionnaire results, again contributing to a lack of certainty when drawing conclusions.

Although results for the four participants who have reached T3 have been presented in 14.6.7, due to so few participants reaching this stage the results will not be analysed further.

15.2.7.1 How easy or difficult is it to clean your teeth with the manual toothbrush?

82% (n=13) of participants in the Intervention group and 64% (n=9) of participants in the Control group reported that using the MTB was 'Easy' or 'Very Easy'. All other participants bar one in the intervention group found using the MTB 'Neither easy nor difficult'. The remaining patient in the intervention group found it 'Difficult'. Based on these findings overall, it appears that patients generally did not find it difficult to use the MTB.

15.2.7.2 How often do you clean your teeth in the way we have shown you?

All participants reported cleaning their teeth in the way shown either 'Every time' or 'Most of the time'. The split between 'Every time' and 'Most of the time' are very similar between groups, demonstrating that self-reported adherence to the oral hygiene regime given was equal between the groups. Unfortunately, as discussed in 15.2.6, the oral hygiene diary data to cross reference this is not available.

15.2.7.3 How helpful or unhelpful were the instructions we gave you about cleaning your teeth?

All participants reported that the instructions given were either 'Helpful' or 'Very Helpful' apart from one. This participant was in the intervention group and reported that the instructions were 'Very Unhelpful'. Unfortunately, this participant did not write anything into the free text area to explain this decision. However, overall, it can be concluded that participants found the oral hygiene instruction provided useful.

15.2.7.4 If there is anything else you would like to tell us about brushing your teeth when you have braces, please write this below.

There was a low response rate of 6.5% for this question, with only two participants overall answering. Both participants were in the intervention group and mentioned the difficulties removing plaque around appliances with the MTB. It may be that these participants were commenting on the difficulty removing plaque with the MTB in comparison to removing it with the WP, however their answers are not detailed enough to conclude this.

15.2.7.5 How easy or difficult is it to use the Waterpik®?

94% (n=16) of participants in the intervention group stated that the WP was 'Easy' or 'Very easy' to use. The final participant stated that it was neither easy nor difficult. It can therefore be concluded that patients did not find it difficult to use the WP.

15.2.7.6 When you clean your teeth, how often do you use Waterpik®?

As per 13.4.2, participants in the intervention group were instructed to use the WP every evening. However, 8-weeks into the trial at T1, only 47% of patients in the intervention group (n=8) were doing so. The remaining 53% reported using the WP either 'Most Evenings' or 'Some Evenings'. With a question such as this, a degree of response bias is usually expected. This is where participants respond in order to appear socially desirable, or in the way they believe the investigator wants them to respond (van de Mortel, 2008). With the figures already showing that less than half of participants used the WP daily without adjusting for any response bias, it seems that the WP was not used by participants as instructed. As the WP was the independent variable in the trial, this is likely to have impacted the findings.

On reflection, the difference between 'Most Evenings' and 'Some Evenings' is ambiguous. In hindsight, the responses would have been better presented numerically, with the participant choosing how many times per week they use the WP.

15.2.7.7 How clean or unclean do your teeth feel when you have used the Waterpik®?

88.2% of participants in the Intervention group (n=15) described their teeth as feeling either 'Clean' or 'Very clean' after using the WP. The remaining 2 participants chose that their teeth

felt 'Neither clean nor unclean'. These responses demonstrate that most participants felt that using the WP made their teeth feel clean.

The questionnaire results overall appear not to show any major differences between the Intervention and Control groups in terms of self-reported satisfaction with oral hygiene measures. However, this has not been statistically tested. Based on the current data analysed for the interim analysis it is not possible to reject the null hypothesis 'There is no difference in patient reported satisfaction with oral hygiene regime between patients using WP+MTB compared to using MTB alone'. However, they have provided a useful insight into the potential lack of adherence to oral hygiene regime in the Intervention group which we have not been able to assess from the oral hygiene diaries.

15.3 Evaluation of research methods

At this stage of the trial, it is possible to reflect on areas of the research methodology which are satisfactory and those which are suboptimal. In areas which are suboptimal, it is useful to consider how they could be improved to inform possible future research.

15.3.1 Positive factors

15.3.1.1 Choice of trial design

This trial was an RCT. Hierarchical systems which rank levels of evidence consistently report that randomised controlled trials are the highest level of experimental evidence, just below systematic reviews and meta-analyses which collate the results of multiple studies (Burns et al., 2011). As demonstrated in the literature review (particularly 10.7.4) very little evidence exists for the use of the WP in patients with fixed orthodontic appliances. Therefore, a systematic review or meta-analysis would not have been possible to answer the research question. Due to this, an RCT was the highest level of evidence possible.

RCTs compare a novel intervention or treatment to the 'normal' or 'standard' treatment which the control group receive (Burns et al., 2011). The 'standard' treatment in this case was brushing with an MTB. However, a recent UK survey found that the majority (67%) of over 2,000 patients surveyed now use powered or electric toothbrushes (ETBs) (Oral Health Foundation, 2020). Furthermore, the most recent Cochrane review comparing MTBs and ETBs

concluded that the use of ETBs reduced PI and GI (Yaacob et al., 2014). It may, therefore, be argued that participants should have been provided with ETBs. However, in patients wearing fixed orthodontic appliances, the use of an ETB over an MTB has not been shown to impact PI or GI in a recent systematic review and meta-analysis (ElShehaby et al., 2020). Furthermore, providing all 40 participants with ETBs and replacement heads for the duration of the trial would have made the trial considerably more expensive to run. On balance, it can be concluded that the control group using an MTB was appropriate.

15.3.1.2 Homogeneity of groups

In an RCT with a relatively small sample size such as this one, it is important to assess for a covariate imbalance which can undermine the validity of the trial or alter the statistical method which should be employed to try and account for it if present. As discussed previously, the two groups in this trial were very similar in terms of age, gender, and oral health indices. This balance between the groups may suggest that confounders are less likely.

Although this may have occurred by chance, the use of stratified block randomisation (as discussed in 13.9) is likely to have contributed to this. As a result of changing the randomisation method to a single coin toss from participant 30 onwards, it is possible that by the end of recruitment there is more heterogeneity between the intervention and control groups which may introduce confounding variables. This will only be possible to assess once the trial is complete. An alternative randomisation method which aims to ensure balance between groups is the minimisation method (Pocock and Simon, 1975). Using this method, participants are sequentially allocated into the intervention or control group depending on the prognostic factors of the patients already randomised to maintain balance between the groups. Specialist software exists to do this automatically (Altman and Bland, 2005).

Using the minimisation method would have prevented the need to change to single coin toss randomisation and maintained balance between the groups, but would have made the randomisation more complicated and the first appointment more laborious. On balance, minimisation would have been a better choice.

15.3.1.3 Blinding

As described in 13.10, due to the nature of the trial, it was not possible to blind the participants. However, the investigator carrying out the indices (DT) was blinded to allocation. This reduced the chance of introducing observer bias. As DT was also responsible for recruitment of patients and carrying out their orthodontic treatment, the trial had to be carefully set up to ensure the blinding was not broken. As previously described, allocation was carried out by DNs, and participants were regularly reminded not to discuss their allocation with DT. In the most part this was successful and observer bias was prevented.

However, the blinding was inadvertently broken at T1 for two participants in the intervention group. One participant broke the blinding just before the indices were completed by commenting to DT that they were having difficulties using the WP. The second participant told the DN that their WP charger had stopped working. The DN inadvertently mentioned this to DT. This participant was given a new WP unit and kept in the trial.

After discussion with the trial statistician JK, the decision was made for both participants to continue taking part in the trial with their results included in the analysis, as per the intention-to-treat principle. Sensitivity analysis was carried out by removing the cases and repeating the statistical analyses. This showed very little change to the p values, demonstrating that observation bias was limited.

15.3.1.4 Observation period

This trial followed up patients for considerably longer than previous similar trials such as Sharma et al. (2008) who only followed up patients for 28 days. This extended follow up period overcomes the novelty effect of the WP (Rosema et al., 2011) and it might be assumed that any Hawthorne effect would reduce over such a long follow up period. Furthermore, the external validity is increased because patients wear orthodontic appliances for much longer than 28 days.

However, it could be argued that a 56 week follow up is excessive. RCTs are expensive and time consuming, and this is of particular importance when they are undertaken in the setting of the NHS by an investigator in a training role such as DT. As discussed in 13.6, the trial

requires seven participants in each group to satisfy the power calculation. Once satisfied, it could be suggested that if there are still no differences shown, then there would be an argument for ending the trial early 'for futility' (Moher et al., 2012). The power calculation would suggest that it is unlikely that a difference between the groups would be seen by continuing to recruit, despite the group numbers being small. In hindsight, *a priori* stopping rules for the trial may have been a beneficial addition to the methods.

15.3.2 Negative factors

15.3.2.1 Assessment of adherence with oral hygiene regime

The primary method through which the study had planned to assess adherence with the oral hygiene regime was through the use of oral hygiene diaries (as described in 13.5.3.2). However, as discussed in 15.2.6, due to such a poor response rate it was not possible to analyse the data at this point. Participants were asked to indicate the time spent in minutes brushing their teeth for each of three time periods (morning, afternoon, and tea/evening), as well as indicating if they used the WP in the evening. A patient fully completing their diaries three times a day over a 56-week trial period would have to write in it 1,176 times. This provides scope for patients to forget, for their compliance to burn out, or for them to simply make up results to have something to return. Furthermore, estimated time brushing is likely to be overestimated (Emling et al., 1981), and with any spaces in the diary it was not clear whether the participant had not cleaned or not completed the diary. Overall, any data which was collected was of poor quality.

As well as the data being of such poor quality, due to the participants completing them on paper, to input this data into a computer would have been extremely time consuming. If all 40 participants filled out the diaries properly then this would have generated 47,040 pieces of data to be input. Lastly, it may be possible that those patients who adhere well with their oral hygiene regime may also be the patients who adhere well with completing their oral hygiene diaries. If this were true and only the returned diaries were assessed, an artificially high level of adherence may have been found. On reflection, this was not a robust method to assess adherence with the oral hygiene regime.

The second method of assessing adherence which was possible was using the questionnaires. As discussed in 15.2.7.6, the responses to the question 'When you clean your teeth, how often do you use Waterpik®?' could be analysed to assess how often intervention patients used the WP. However, there was no similar question which the control group answered to assess adherence with the MTB. Therefore, no differences between groups could be assessed.

Assessing adherence with oral hygiene regimes is challenging. To assess adherence with use of the WP, other researchers have placed timers into the WP without notifying the participants (Flemmig et al., 1995). However, doing this would have increased the cost of the trial, required the patient to return the unit at the end of the trial, and participants could not have been fully consented for this, complicating the ethical approval process. This would also not have provided any information on whether the control group were adhering. A similar RCT asked patients to return their used toothbrushes and inter-dental brushes to assess their wear to assess adherence (Saini, 2016). However, this trial had issues with participants failing to return them.

15.3.2.2 Duration between data collection points

As discussed in 15.2.1, there was a tendency for patients to be seen 'late' for their indices because of a lack of appointment availability at the correct time.

One strategy to tackle this would have been for another clinician such as a dental hygienist to record all the indices. Having a hygienist complete the indices would also have made blinding less likely to be broken, as they would only see the patient on the four occasions required for indices, rather than every orthodontic appointment. However, this would have incurred financial costs and made the trial more expensive to run. Furthermore, it would have been logistically challenging to coordinate a hygienist appointment immediately after the orthodontic appointment and would have been inconvenient for participants to come at a separate time, incurring time costs for accompanying parents and missing school.

On reflection, considering the impact of the COVID-19 pandemic and the fact that DT was only available for three clinical sessions per week, there was little more that could be done to ensure patients were seen 'on time'.

15.3.2.3 Consistency of oral hygiene instruction

At the beginning of the trial, a single trial DN was responsible for providing oral hygiene instruction to all participants. The DN was trained in how to provide the information to participants depending on group allocation. However, once around ten participants had been recruited, this nurse went on long term leave, and two new trial DNs were allocated to the trial. Although a thorough handover process was arranged, including the new trial DNs shadowing the previous whilst she gave oral hygiene instruction as well as them providing oral hygiene instruction to a mock participant, the possibility of this should have been considered at the start of the trial. The trial DN may have been absent for sickness, meaning that a handover was not possible, or could have been sick or on leave when a patient was recruited.

On reflection, a more effective way to ensure consistency between oral hygiene instruction for all participants would have been to produce two oral hygiene instruction videos. One could have provided instructions for the control group, whilst the other was for the intervention group, and the participants could have been shown the appropriate video following allocation. If the trial were to be repeated, such videos would be a useful addition.

15.3.2.4 Trial registration issues

Prospective registration of clinical trials is important in order to ensure transparency of planned outcome measures and to attempt to reduce publication bias (Aslam et al., 2013). Although this is widely accepted, research has found that in orthodontics as many as 76% of clinical trials are registered retrospectively (Papageorgiou et al., 2017a). Unfortunately, due to an administrative error in the York Teaching Hospital Research and Development Department, this trial was not registered until 10/2020, whereas the first patient was recruited in 01/2020. As soon as this error was noted the trial was registered. Were the trial to find positive outcomes, it may be open to the accusations that the outcome measures were changed to find these outcomes.

Furthermore, due to an error in the protocol, the trial was registered stating that a repeated measures ANOVA test would be used to analyse the results. Repeated measures ANOVA tests can only be applied to data from repeated measures methods, which this trial did not employ.

Again, were the trial to find positive outcomes, there could be accusations that the statistical test was changed to find these outcomes.

15.3.2.5 Trial setting and patient cohort

The trial was carried out in an NHS district general hospital. Patients in this setting do not pay for their treatment as it is funded by the health service. It has been demonstrated that patients who self-pay for orthodontic treatment have higher levels of compliance than those who receive state supported treatment (Wilson and Harris, 2015). Compliance was an important contributing factor to the outcomes of this study, and if the trial was carried out in a different setting different conclusions may have been drawn. Furthermore, the malocclusions which are treated in secondary care settings are likely to be more complex than those treated in primary care (Jawad et al., 2015). Therefore, caution must be taken when generalising the results of this study to primary care or self-paying orthodontic patients.

15.3.2.6 Quality of questionnaire

The questionnaire was not validated and in hindsight the possible responses were ambiguous. They were designed without an intended plan as to how the data would be analysed. For qualitative data regarding how patients in the intervention group felt about the WP, structured interviews are likely to have been more fruitful. However, this would likely require a separate trial as it would be outside the scope of this RCT.

16 Conclusions

Any conclusions drawn from an interim analysis of results must be assessed with caution, as on completion of the trial the outcomes may change. Around 50% of the data in this RCT has yet to be collected, however conclusions can be drawn based on what has been analysed. The power calculation has been satisfied at T1 and T2, but not T3. Therefore, it is unwise to make any conclusions beyond 32 weeks. On the other hand, there is no evidence that we would expect oral hygiene to change dramatically between 36 and 52 weeks.

Assuming the continuation of the observed trends in the data, the following may be concluded:

1. There is no difference in plaque levels between patients using WP+MTB compared to using MTB alone.
2. There is no difference in overall gingival health between patients using WP+MTB compared to using MTB alone.
3. There is no difference in interdental gingival bleeding between patients using WP+MTB compared to using MTB alone.
4. There is no difference in experience of soft tissue trauma between patients using WP+MTB compared to using MTB alone.

Due to a poor response rate with the oral hygiene diaries and a lack of data to compare patient satisfaction, it is not possible to draw conclusions based on this data at this moment in time.

Following completion of the trial, it may of benefit for the trial to be repeated in a different setting or with patients who are struggling with oral hygiene.

Based on the findings of this research, there are no benefits to providing a WP to patients wearing fixed orthodontic appliances, although final results should be analysed before this is confirmed.

17 Bibliography

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18 Appendices

Appendix 1: Patient suitability checklist.

WaterPik Selection Checklist Participant Number:

Patient	Yes
10-20 years old?	☐
No conditions/meds which alter tissue response to appliance treatment?	☐
Clear of medications which alter plaque accumulation?	☐
Clear of decreased manual dexterity?	☐
Willing and able to comply with trial regime?	☐
Baseline OH	
Dental history includes brushing at least twice a day?	☐
Acceptable initial periodontal health?	☐
Treatment Plan	
Brackets as opposed to bands except permanent molar teeth?	☐
Full upper and lower arch treatment?	☐
Bonded using Transbond XT?	☐
Pre adjusted edgewise braces with MBT prescription brackets?	☐

Appendix 2: Standard script for OHE used for the control group.

Oral Hygiene Instructions for Standard Toothbrush Group

"Thank you for taking part in this study, it is important you follow our instructions carefully to ensure your teeth and gums stay healthy.

You have been allocated to the group to only our normal toothbrush.

To use the brushes correctly you should brush like this..."

1. Demonstrate tooth brushing technique on models –
    a. *"Brushing above and below the brackets*
    b. *Forcing toothbrush bristles between the brackets*
    c. *Do this twice a day for 2 minutes*
    d. *Use a pea sized amount (if you use too much the froth will stop you seeing where you need to clean)*
    e. *Use only the toothbrush we provide."*

"You should use 10ml (half a capful of mouthwash)

1. *At a different time to brushing.*
2. *Rinse for 30 seconds*

"The following pack contains all the equipment you need for the first 8 weeks and beyond, if you require more ask one of us (not Danny):

1. *One toothbrush should last 2-3 months*
2. *One mouthwash bottle should last 7 weeks*
3. *One toothpaste tube should last 8 weeks*
4. *Do not show your pack to Danny.*
5. *We will give you more when required"*

Remember to complete your diary every time you clean your teeth.

Appendix 3: Standard script for OHE used for the intervention group.

Oral Hygiene Instructions for Waterpik Group

"Thank you for taking part in this study, it is important you follow our instructions carefully to ensure your teeth and gums stay healthy.

You have been allocated to the group to use both the Waterpik and a normal toothbrush.

To use the brushes correctly you should brush like this…"

1. Demonstrate tooth brushing technique on models –
    a. "*Brushing above and below the brackets*
    b. *Forcing toothbrush bristles between the brackets*
    c. *Do this twice a day for 2 minutes*
    d. *Use a pea sized amount (if you use too much the froth will stop you seeing where you need to clean)*
    e. *Use only the toothbrush we provide."*

2. Explain and demonstrate use of Waterpik brush on models
    a. *Fill the reservoir with warm water.*
    b. *Insert the orthodontic tip. Only use this tip. We will give you 4 spares which you need to change every 3 months. Keep them in the box so that you do not lose them.*
    c. *Adjust the pressure control (start at low pressure)*
    d. *Lean over the sink, put in your mouth and then switch it on and water will start coming out. Keep your mouth open slightly to allow the water to drip into the sink.*
    e. *Starting at the back on one side, glide the tip along the gumline, around the bracket and between the teeth. You can increase the pressure if you wish,*
    f. *Move onto the next tooth*
    g. *Do this once at night*
    h. *It should take an extra minute or so. You will need to re-fill the reservoir during cleaning, particularly if you use at a higher pressure. Do not stop just because the water runs out, continue until you have cleaned around all of the brackets.*
    i. *Clean it after use as you would the toothbrush."*

"You should use 10ml (half a capful of mouthwash)
1. *At a different time to brushing.*
2. *Rinse for 30 seconds*

"The following pack contains all the equipment you need for the first 8 weeks and beyond:
1. *One toothbrush should last 2-3 months*
2. *One Waterpik tip should last 3 months*
3. *One mouthwash bottle should last 7 weeks*
4. *One toothpaste tube should last 8 weeks*
5. *Do not show your pack to Danny.*
6. *We will give you more when required"*

Remember to complete your diary every time you clean your teeth.

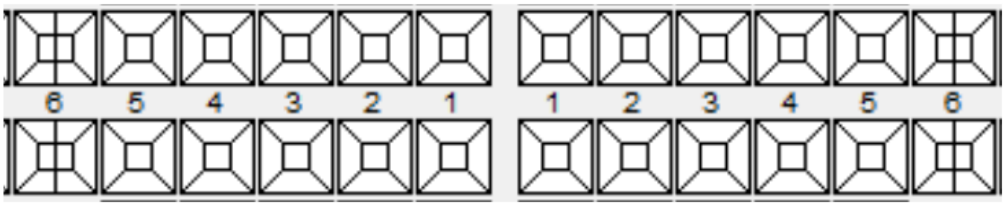
Appendix 4: Data collection form for baseline indices.

Baseline Indices
Date: Affix patient label here

Gingival Index:

Record scores for mesial, distal, buccal, lingual gingival surfaces only.
Need CPITN periodontal probe.

Score	Gingival Index
0	Normal gingivae
1	Slight change in colour and slight oedema. No bleeding on probing.
2	Redness, oedema and glazing. Bleeding on probing
3	Marked redness and oedema. Ulceration with tendency to spontaneous bleeding.

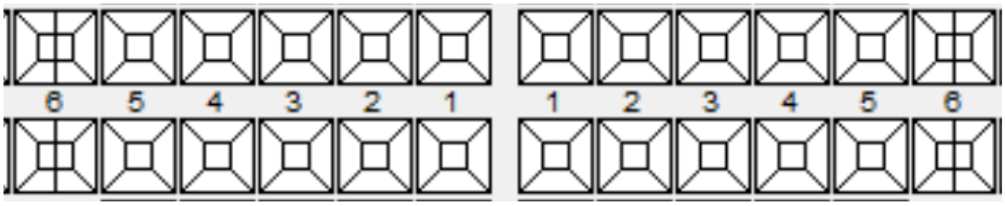


Gingival Index (Ratio) = Total of all scores / Number of sites : _____

Eastman Interdental Bleeding Index

Record presence of bleeding at interproximal sites only
Need interdental wood-sticks.

Score	Eastman Interdental Bleeding Index
0	Not bleeding
1	Bleeding



Bleeding score (%) =

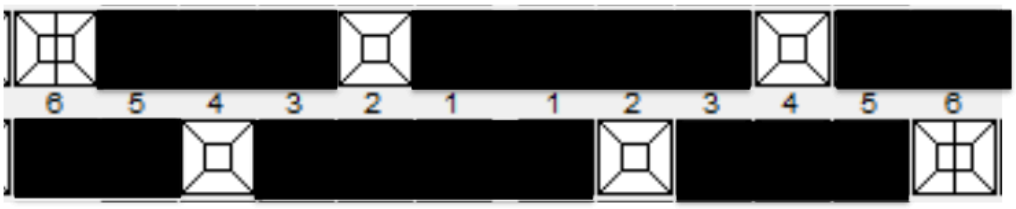
Number of bleeding sites / Total number of sites x100 :

Baseline Indices
Date: Affix patient label here

Silness and Loe Plaque Score

Plaque mesial, distal, buccal and lingual on index teeth.
Need disclosing solution.

Score	Criteria
0	No plaque
1	A film of plaque adhering to the orthodontic bracket and adjacent area of the tooth. The plaque may be seen ONLY after application of disclosing solution
2	Moderate accumulation of soft deposits within the gingival pocket or tooth and gingival margin. Visible to naked eye.
3	Abundance of soft matter within the gingival pocket and or the tooth and gingival margin



Plaque score (Ratio) = Total of all scores / Number of sites : _____ =

Appendix 5: Data collection form for recall indices.

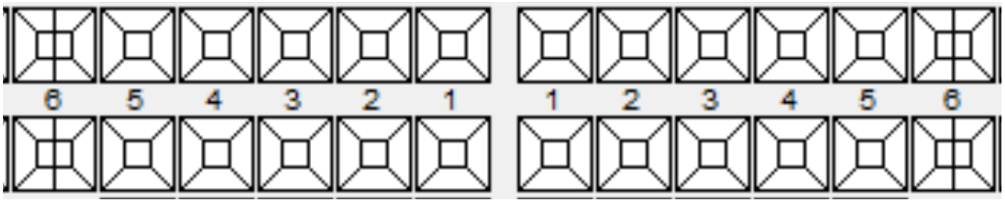
Recall Indices
Date:

Affix patient label here

Gingival Index:

Record scores for mesial, distal, buccal, lingual gingival surfaces only.
Need CPITN periodontal probe.

Score	Gingival Index
0	Normal gingivae
1	Slight change in colour and slight oedema. No bleeding on probing.
2	Redness, oedema and glazing. Bleeding on probing
3	Marked redness and oedema. Ulceration with tendency to spontaneous bleeding.

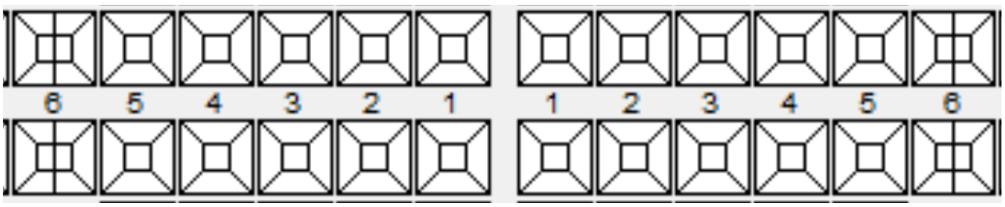


Gingival Index (Ratio) = Total of all scores : _____ =
Number of sites

Eastman Interdental Bleeding Index

Record presence of bleeding at interproximal sites only
Need interdental wood-sticks.

Score	Eastman Interdental Bleeding Index
0	Not bleeding
1	Bleeding



Bleeding score (%):
Number of bleeding sites x100 : _____ x100 =
Total number of sites

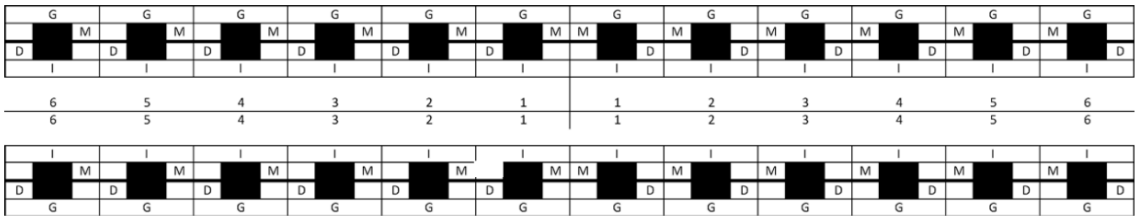
Recall Indices
Date:

Affix patient label here

Orthodontic Modification of Plaque Index

Record plaque around mesial, distal, gingival and incisal (MDGI) of edge of bracket (black square on chart)
Need disclosing solution and camera.

Score	Criteria
0	No plaque
1	A film of plaque adhering to the orthodontic bracket and adjacent area of the tooth. The plaque may be seen ONLY after application of disclosing solution
2	Moderate accumulation of soft deposits within the gingival pocket or tooth and gingival margin. Visible to naked eye.
3	Abundance of soft matter within the gingival pocket and or the tooth and gingival margin



Plaque score (Ratio) = Total of all scores : _____ =
Number of sites

Appendix 6: Oral Hygiene Diary.

IRAS Project ID number is 266235

York Teaching Hospital NHS Foundation Trust

Identification Number for this study: ☐☐☐

Diary for oral hygiene for Waterpik ® Trial

Please indicate time spent in minutes in brushing teeth for each period. If Waterpik ® is used in the evening, please indicate by writing "W" next to the time. Thank you.

Date:	Morning	Afternoon	Tea/Evening

Diary for oral hygiene for Waterpik ® Trial V1.0. 01/08/2019

Appendix 7: Control group patient satisfaction questionnaire.

IRAS Project ID number: 266235

York Teaching Hospital NHS
NHS Foundation Trust

PATIENT SURVEY B

Participant Identification Number for this Trial:_____

Week of completion: Week 8 ☐ Week 56 ☐

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Thank you for agreeing to take part in this study. It will help us understand the best way for people to brush their teeth when they have fixed braces. In order to help us further, we would like to know what you think about the equipment and procedures we have given you to clean your teeth.

1. How easy or difficult is it to clean your teeth with the normal toothbrush? Please tick one answer

a. Very easy	☐
b. Easy	☐
c. Neither easy nor difficult	☐
d. Difficult	☐
e. Very difficult	☐

2. How often do you clean your teeth in the way we have shown you? Please tick one answer

a. Every time	☐
b. Most of the time	☐
c. Sometimes	☐
d. Rarely	☐
e. Never	☐

3. How helpful or unhelpful were the instructions we gave you about cleaning your teeth? Please tick one answer

a. Very helpful	☐
b. Helpful	☐
c. Neither helpful nor unhelpful	☐
d. Unhelpful	☐
e. Very unhelpful	☐

If there is anything else you would like to tell us about brushing your teeth when you have braces, please write this below:

Version 3.0 (21/05/2019)

Appendix 8: Intervention group patient satisfaction questionnaire

IRAS Project ID number: 266235

York Teaching Hospital NHS
NHS Foundation Trust

PATIENT SURVEY A

Participant Identification Number for this Trial:_____

Week of completion: Week 8 ☐ Week 56 ☐

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Thank you for agreeing to take part in this study. It will help us understand the best way for people to brush their teeth when they have fixed braces. In order to help us further, we would like to know what you think about the equipment and procedures we have given you to clean your teeth.

1. How easy or difficult is it to use the Waterpik®? Please tick one answer

a. Very easy	☐
b. Easy	☐
c. Neither easy nor difficult	☐
d. Difficult	☐
e. Very difficult	☐

2. When you clean your teeth, how often do you use Waterpik®? Please tick one answer

a. Every evening	☐
b. Most evenings	☐
c. Some evenings	☐
d. Rarely	☐
e. Never	☐

If you rarely or never use the Waterpik® we gave you, please tell us why

_____

_____

_____

3. How clean or unclean do your teeth feel when you have used the Waterpik®? Please tick one answer

a. Very clean	☐
b. Clean	☐
c. Neither clean nor unclean	☐
d. Unclean	☐
e. Very unclean	☐

Version 3.0 (21/05/2019)

IRAS Project ID number: 266235

York Teaching Hospital NHS
NHS Foundation Trust

4. How easy or difficult is it to clean your teeth with the manual toothbrush? Please tick one answer

a. Very easy	☐
b. Easy	☐
c. Neither easy nor difficult	☐
d. Difficult	☐
e. Very difficult	☐

5. How often do you clean your teeth in the way we have shown you? Please tick one answer

a. Every time	☐
b. Most of the time	☐
c. Sometimes	☐
d. Rarely	☐
e. Never	☐

6. How helpful or unhelpful were the instructions we gave you about cleaning your teeth? Please tick one answer

a. Very helpful	☐
b. Helpful	☐
c. Neither helpful nor unhelpful	☐
d. Unhelpful	☐
e. Very unhelpful	☐

If there is anything else you would like to tell us about brushing your teeth when you have braces, please write this below:

_____

_____

_____

_____

_____

_____

Version 3.0 (21/05/2019)

IRAS ID: 266235

York Teaching Hospital NHS
NHS Foundation Trust

Participant Information Leaflet

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Invitation

We would like to invite you to take part in our research study. Joining the study is entirely up to you, but before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We think this will take about 15 minutes. Please feel free to talk to others about the study if you wish

Part 1 of the information sheet tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information.

Part 1

What is the purpose of the study?

You are going to be fitted with fixed braces or train-track braces to straighten your teeth. This can make cleaning your teeth with a normal toothbrush more difficult. There is some research which shows that using the Waterpik® helps but these trials are really short lasting less than one month. In this study we want to see if the Waterpik® really does help to keep your teeth cleaner than just using a normal toothbrush for the entire treatment.

A normal manual toothbrush

A Waterpik ® dental water jet

Version 4.0 01/08/2019

Why have I been invited to take part in this study?

We are asking you to take part in this study because you are going to have fixed braces or train track braces.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

When we do not know the best way of doing something, we need to make comparisons. In this study we are looking at the best way for people with braces to keep their teeth clean. We are comparing whether using a normal manual toothbrush with Waterpik® is better at keeping teeth clean than just using a normal manual toothbrush.

In this study we will be comparing two groups of patients. One group will just use a manual toothbrush (group 1). The other group will use a manual toothbrush AND a Waterpik® (group 2). A computer programme will decide by chance which group you go into. You will have an equal chance of being in group 1 or group 2.

- Once you have had your braces fitted we will show you how to clean your teeth properly.

- We will give everyone in both groups manual toothbrushes, toothpaste and mouth rinse to use during the study. This is to make sure that everyone is using the same toothbrushes, toothpaste and fluoride mouth rinse. We are giving everyone fluoride mouth rinse because we know this helps to keep teeth healthy.

- If you are in the group not using Waterpik® for the study (also known as control group), you will get the Waterpik® when the study ends. Waterpik® is useful for use by everyone to keep their gums healthy and there is evidence to support this.

- After you have had your braces fitted we will ask you to come to the hospital 3 times in the first year (at 8, 32 and 56 weeks). At these visits we will check your mouth for plaque, gum infection and bleeding. These visits will coincide with your usual adjustment appointments at the hospital. You will not need any extra appointments. None of the examinations are invasive or involve the use of drugs. They are all visual examinations using standard dental instruments:

    - We will press softly on your gums with a dental stick to see if your gums bleed. We also use a special probe which we also press softly on your gums.

    - We will give you a tablet to chew that colours any plaque on your teeth. This tablet colours the plaque either purple or pink. The discolouration goes away after you brush your teeth.

- We will take a picture of your teeth to make sure we have checked everything properly. The pictures will let us compare what your teeth look like from visit to visit.

- At two of the visits (weeks 8 and 32) we will ask you to fill out a questionnaire asking for your views about cleaning your teeth and the brushes you have used. Your views will help us give better advice to other people who have fixed braces in the future.

What are the alternatives for treatment?

An alternative treatment is to use an electric or battery operated toothbrush but this has already been tested and does not seem to be more effective than using a normal toothbrush.

What are the possible disadvantages and risks of taking part?

We do not think there are any disadvantages or risks involved in taking part in this study, however there may be some inconvenience. It may take longer to clean your teeth and when you come to the hospital your appointments may last a little longer than usual.

There are some important safety instructions in the manual that you should read before using the Waterpik device.

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

READ ALL INSTRUCTIONS BEFORE USING.

DANGER:
To reduce the risk of an electric shock:
• Do not handle charger with wet hands.
• Do not put charger in or drop charger into water or other liquid.
• Check the charger cord/wiring for damage before the first use and regularly.

WARNING
To reduce the risk of burns, electrocution, fire, or injury to persons:
• Do not plug this device into an electrical socket if you are unsure, get an adult to do it for you.
• If product is opened/disassembled for ANY reason, warranty is not valid.
• Do not use this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into any liquid. Contact Waterpik International, Inc. UK Service Centre on +44 (0) 333 123 5677.
• Do not direct water under the tongue, into the ear, nose or other delicate areas. This product is capable of producing pressures that may cause serious damage in these areas.

What are the possible benefits of taking part?

There may be no direct personal benefit to you. However if you take part you may help us to find out if using the Waterpik® along with the normal manual toothbrush is better than just using a normal manual toothbrush in keeping people's teeth clean when they have fixed braces.

What if there is a problem?

Any complaints about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details of how we will do this are given in Part 2 of this information sheet.

If the information in Part 1 of this sheet has interested you and you are considering taking part, please read the additional information in Part 2, before making any decision.

IRAS ID: 266235

Part 2

What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive.

Will my taking part in the study be kept confidential?

Information we collect from you as part of the study will be recorded on paper and/or on a computer database. The research team will each have unique passwords to access the database. You will be given a numeric code, unique to this study, and this code will be used on the paper questionnaires and the database rather than your name so you cannot be immediately recognised from the information. The code linking your name with the information we collect during the study will be kept in separate locations.

The way we manage information will comply with The General Data Protection Regulation 2016/679 as described below.

York Teaching Hospital will make sure that relevant information about the study is recorded for your care, and will oversee the quality of the study. Individuals from York Teaching Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in York Teaching Hospital who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

York Teaching Hospital is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. York Teaching Hospital will keep identifiable information about you for 2 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.research.yorkhospitals.nhs.uk/about-us1/patient-information-amp-health-and-care-research/.

With your permission, we would like to tell your dentist that you are taking part in this study. It is important to keep your dentist involved as they may be in touch with you during the period of this study and we would like to avoid you receiving advice which conflicts with the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their telephone number is 01904 725614.

If you are unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service at the hospital by writing to them at

PALS,
York Teaching Hospital NHS Foundation Trust,
Freepost, NEA 11112,
York, YO30 7ZZ.

by phoning them on (01904) 726262 or by emailing them at pals@york.nhs.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the Parliamentary and Health Service Ombudsman, who is independent of the NHS and government, at 0345 015 4033.

You may also find helpful information online at:
http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/pages/nhscomplaints.aspx

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against York Teaching Hospital (who is sponsoring the study and where the study is being carried out) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to the results of the research study?

We will look at the results to see if using a normal toothbrush and the Waterpik® is better at keeping teeth clean than just a normal toothbrush when people have braces. We hope to publish the results in journals which dentists and orthodontists read. If we do this, no one reading the article would know you had taken part in the study.

Who is organising the research?

The study has been designed and will be run by Mr Goh, Consultant Orthodontist at York Teaching Hospital. Mr Goh also works at the Dental Institute at the University of Leeds.

The study is being sponsored by the York Teaching Hospital. This means that York Teaching Hospital is taking overall responsibility for the way the research has been designed and is conducted.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a

Research Ethics Committee. This is to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by the NHS Health Research Authority. This project has been registered and the IRAS Project ID number is 266235.

Further information and contact details

If you would like further information about this study, please contact:

Mr. H. H. Goh
Department of Orthodontics
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York
YO31 8HE
Tel No: 01904 725614

If you would like general information and advice about taking part in a research project, you can contact:

Dr. Deborah Phillips
Research and Development Unit
01904 725123

There is also general information about research on the NHS Choices website at http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx

IRAS ID: 266235

York Teaching Hospital NHS
NHS Foundation Trust

Young Person's Information Leaflet

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Invitation

We are asking if you would take part in a research project. Before you decide if you want to join in, it is important that you understand why the research is being done and what it will mean for you.

What is the purpose of the study?

You are going to be fitted with fixed braces or train-track braces to straighten your teeth. This can make cleaning your teeth with a normal toothbrush more difficult. Research has been carried out a while ago which shows that the dental water jet can help keep teeth cleaner but the research was done only over a 4 week period. In this study we want to see if the Waterpik really does help for the whole treatment.

A normal manual toothbrush

A Waterpik ® dental water jet

What is the Waterjet® dental water jet?

A dental water jet (also called an oral irrigator, dental water flosser, dental water toothpick or water pick) is a home dental care device. It uses a stream of pulsating water to remove plaque and food debris between teeth as well as below the gum line. Waterpik® is made by the people who invented this device.

Why have I been invited to take part in this study?

We are asking you to take part in this study because you are going to have fixed braces or train track braces.

IRAS ID: 266235

Do I have to take part?

You do not have to take part, it is up to you. If you do take part, the dentist at the hospital will ask you and your parents, to sign a form. We will give you a copy of that form and this information leaflet to keep. If you don't take part we will still give you the treatment you need to straighten your teeth.

What will happen to me if I take part?

This research is to find out if the Waterpik® is better at keeping your teeth clean than just using a normal toothbrush. We will have two groups of patients. One group will just use a normal toothbrush. The other group will use a normal toothbrush AND the Waterpik®. A computer programme will decide by chance which group you go into. You will have an equal chance of being in Group 1 or Group 2.

Group 1 Group 2

- We will give everyone in both groups normal toothbrushes, toothpaste and mouth rinse to use during the study. This is to make sure that everyone is using the same toothbrushes, toothpaste and a fluoride mouth rinse. We are giving everyone fluoride mouth rinse because we know this helps your teeth.

- If you are in the group using the Waterpik®, we will also give you those brushes to take home. If you are in the other group, you will get the Waterpik® when the study ends.

- After you have had your braces fitted we will ask you to come to the hospital 3 times in the first year. At these visits we will check your gums and teeth to see how healthy they are. These visits will be at the same time as when you have your braces adjusted.

    - We will press softly on your gums to see if they bleed. We also use a special probe which we also press softly on your gums.

    - We will give you a tablet to chew that colours any food that is stuck to your teeth (we call the food that is stuck to your teeth 'plaque'). This tablets colours the plaque either purple or pink. The colour goes away after you brush your teeth.

    - We will take a picture of your teeth to make sure we have checked everything properly. The picture will let us compare what your teeth looked like at each visit.

- At two of the visits we will ask you fill out a form telling us how easy or difficult it is to use the Waterpik®. Your views will help us give better advice to other people who have fixed braces in the future.

Is there anything to be worried about if I take part?

We do not think there is anything to be worried about if you take part. However there are some important safety instructions in the manual that you should read before using the Waterpik device.

> *When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:*
>
> *READ ALL INSTRUCTIONS BEFORE USING.*
>
> *DANGER:*
> *To reduce the risk of an electric shock:*
> *• Do not handle charger with wet hands.*
> *• Do not put charger in or drop charger into water or other liquid.*
> *• Check the charger cord/wiring for damage before the first use and regularly.*
>
> *WARNING*
> *To reduce the risk of burns, electrocution, fire, or injury to persons:*
> *• Do not plug this device into an electrical socket if you are unsure, get an adult to do it for you.*
> *• If product is opened/disassembled for ANY reason, warranty is not valid.*
> *• Do not use this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into any liquid. Contact Waterpik International, Inc. UK Service Centre on +44 (0) 333 123 5677.*
> *• Do not direct water under the tongue, into the ear, nose or other delicate areas. This product is capable of producing pressures that may cause serious damage in these areas.*

Will anyone else know I'm doing this?

If you decide to take part in this research, we would like to tell your dentist.

The way we manage your information will comply with The General Data Protection Regulation 2016/679, this is explained at the end of this information sheet.

What happens when the research study stops?

We will look at the results to see if a normal toothbrush and Waterpik® together are better at keeping teeth clean than just a normal toothbrush when people have braces. We will write up the results in magazines which dentists read. If we do this, no one reading the article would know you had taken part in the study. If you wish to know we can tell you what we have found out at the end of the study.

Who has reviewed the study?

IRAS ID: 266235

Before any research goes ahead it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research is fair. This project has been checked and approved by the NHS Health Research Authority.
This project has been registered and the IRAS Project ID number is 266235

More Information

Please ask me if you have any questions, or if you would like to see a more grown-up version of this information. My contact details are:
Mr. H. H. Goh
Department of Orthodontics
York Teaching Hospitals NHS Foundation Trust
Wigginton Road, York, YO31 8HE
Tel No: 01904 725614

If you would like to know more about research you can go to the NHS Choices website at http:www.nhs.uk/conditions/clinical-trials/pages/introduction.aspx

Thank you for reading this information.

General Protection Data Regulations

York Teaching Hospital will make sure that relevant information about the study is recorded for your care, and will oversee the quality of the study. Individuals from York Teaching Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in York Teaching Hospital who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

York Teaching Hospital is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. York Teaching Hospital will keep identifiable information about you for 2 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at https://www.research.yorkhospitals.nhs.uk/about-us1/patient-information-amp-health-and-care-research/.

IRAS ID: 266235

York Teaching Hospital NHS
NHS Foundation Trust

Parent Information Leaflet

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Invitation

We would like to invite your child to take part in our research study. Joining the study is entirely up to you and your child, but before you decide we would like you to understand why the research is being done and what it would involve. One of our team will go through this information sheet with you and your child, to help you decide whether or not you would like to take part and answer any questions you may have. We think this will take about 15 minutes. Please feel free to talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of the study and what will happen if your child takes part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information.

Part 1

What is the purpose of the study?

Your child is going to be fitted with fixed braces or train-track braces to straighten his/her teeth. This can make cleaning the teeth with a normal toothbrush more difficult. There is some research which shows that using the Waterpik® helps but these trials are really short lasting less than one month. In this study we want to see if the Waterpik® really does help to keep teeth cleaner than just using a normal toothbrush for the entire treatment.

A normal manual toothbrush

A Waterpik ® dental water jet

Version 1.0 01/08/2019

IRAS ID: 266235

Why has my child been invited to take part in this study?

We are asking your child to take part in this study because he/she is going to have fixed braces or train track braces fitted.

Does my child have to take part?

No, it is up to you and your child to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to.

If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care your child receives.

What will happen if my child takes part?

When we do not know the best way of doing something, we need to make comparisons. In this study we are looking at the best way for people with braces to keep their teeth clean. We are comparing whether using a normal manual toothbrush with Waterpik® is better at keeping teeth clean than just using a normal manual toothbrush.

In this study we will be comparing two groups of patients. One group will just use a manual toothbrush (group 1). The other group will use a manual toothbrush AND a Waterpik® (group 2). A computer programme will decide by chance which group patients go into. There will be an equal chance of being in group 1 or group 2.

- Once the braces are fitted we will show your child how to clean their teeth properly.
- We will give everyone in both groups manual toothbrushes, toothpaste and mouth rinse to use during the study. This is to make sure that everyone is using the same toothbrushes, toothpaste and fluoride mouth rinse. We are giving everyone fluoride mouth rinse because we know this helps to keep teeth healthy.
- If your child is not in the group using Waterpik® for the study (also known as control group), you will get the Waterpik® when the study ends. Waterpik® is useful for use by everyone to keep their gums healthy and there is evidence to support this.
- After the braces have been fitted we will ask your child to come to the hospital 3 times in the first year (at 8, 32 and 56 weeks) to have these adjusted. At these visits we will check the mouth for plaque, gum infection and bleeding. These visits will coincide with the usual adjustment appointments at the hospital so no extra appointments will be needed. None of the examinations are invasive or involve the use of drugs. They are all visual examinations using standard dental instruments:
    - We will press softly on the gums with a dental stick to see if the gums bleed. We also use a special probe which we also press softly on the gums.
    - We will give your child a tablet to chew that colours any plaque on the teeth either purple or pink. The discolouration goes away after brushing the teeth.

- We will take a picture of your child's teeth to make sure we have checked everything properly. The pictures will let us compare what the teeth look like from visit to visit.

- At two of the visits (weeks 8 and 32) we will ask your child to fill out a questionnaire asking for their views about cleaning their teeth and the brushes they have used. These views will help us give better advice to other people who have fixed braces in the future.

What are the alternatives for treatment?

An alternative treatment is to use an electric or battery operated toothbrush but this has already been tested and does not seem to be more effective than using a normal toothbrush.

What are the possible disadvantages and risks of taking part?

We do not think there are any disadvantages or risks involved in taking part in this study, however there may be some inconvenience. It may take longer to clean the teeth and when you come to the hospital the appointments may last a little longer than usual.

There are some important safety instructions in the manual that you should read before using the Waterpik device.

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

READ ALL INSTRUCTIONS BEFORE USING.

DANGER:
To reduce the risk of an electric shock:
• Do not handle charger with wet hands.
• Do not put charger in or drop charger into water or other liquid.
• Check the charger cord/wiring for damage before the first use and regularly.

WARNING
To reduce the risk of burns, electrocution, fire, or injury to persons:
• Do not plug this device into an electrical socket if you are unsure, get an adult to do it for you.
• If product is opened/disassembled for ANY reason, warranty is not valid.
• Do not use this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into any liquid. Contact Waterpik International, Inc. UK Service Centre on +44 (0) 333 123 5677.
• Do not direct water under the tongue, into the ear, nose or other delicate areas. This product is capable of producing pressures that may cause serious damage in these areas.

What are the possible benefits of taking part?

There may be no direct personal benefit to your child. However, taking part may help us to find out if using the Waterpik® along with the normal manual toothbrush is better than just using a normal manual toothbrush in keeping people's teeth clean when they have fixed braces.

What if there is a problem?

Any complaints about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my child's taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details of how we will do this are given in Part 2 of this information sheet.

If the information in Part 1 of this sheet has interested you please read the additional information in Part 2, before making any decision.

IRAS ID: 266235

Part 2

What will happen if we do not want to carry on with the study?

You are free to withdraw your child from the study at any time, without giving a reason. This would not affect the standard of care your child receives.

Will my child's taking part in the study be kept confidential?

Information we collect as part of the study will be recorded on paper and/or on a computer database. The research team will each have unique passwords to access the database. Your child will be given a numeric code, unique to this study, and this code will be used on the paper questionnaires and the database rather than a name so they cannot be immediately recognised from the information. The code linking your child's name with the information we collect during the study will be kept in separate locations.

The way we manage information will comply with The General Data Protection Regulation 2016/679 as described below.

York Teaching Hospital will make sure that relevant information about the study is recorded for your child's care, and will oversee the quality of the study. Individuals from York Teaching Hospital and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study. The only people in York Teaching Hospital who will have access to information that identifies your child will be people who need to contact them/you or audit the data collection process. The people who analyse the information will not be able to identify your child and will not be able to find out their name or contact details.

York Teaching Hospital is the sponsor for this study based in the United Kingdom. We will be using information from your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your child's information and using it properly. York Teaching Hospital will keep identifiable information about your child for 2 years after the study has finished.

You or your child's rights to access, change or move their information are limited, as we need to manage information in specific ways in order for the research to be reliable and accurate. If your child withdraws from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use information at https://www.research.yorkhospitals.nhs.uk/about-us1/patient-information-amp-health-and-care-research/.

With your permission, we would like to tell your child's dentist that they are taking part in this study. It is important to keep their dentist involved as they may be in touch with you during the period of this study and we would like to avoid you receiving advice which conflicts with the study.

IRAS ID: 266235

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their telephone number is 01904 725614.

If you are unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service at the hospital by writing to them at

PALS,
York Teaching Hospital NHS Foundation Trust,
Freepost, NEA 11112,
York, YO30 7ZZ.

by phoning them on (01904) 726262 or by emailing them at pals@york.nhs.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the Parliamentary and Health Service Ombudsman, who is independent of the NHS and government, at 0345 015 4033.

You may also find helpful information online at:
http://www.nhs.uk/choiceinthenhs/rightsandpledges/complaints/pages/nhscomplaints.aspx

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against York Teaching Hospital (who is sponsoring the study and where the study is being carried out) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to the results of the research study?

We will look at the results to see if using a normal toothbrush and the Waterpik® is better at keeping teeth clean than just a normal toothbrush when people have braces. We hope to publish the results in journals which dentists and orthodontists read. If we do this, no one reading the article would know you had taken part in the study.

Who is organising the research?

The study has been designed and will be run by Mr Goh, Consultant Orthodontist at York Teaching Hospital. Mr Goh also works at the Dental Institute at the University of Leeds.

The study is being sponsored by the York Teaching Hospital. This means that York Teaching Hospital is taking overall responsibility for the way the research has been designed and is conducted.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This is to protect patients' safety, rights, well-being and

dignity. This study has been reviewed and approved by the NHS Health Research Authority.

This project has been registered and the IRAS Project ID number is 266235.

Further information and contact details

If you would like further information about this study, please contact:

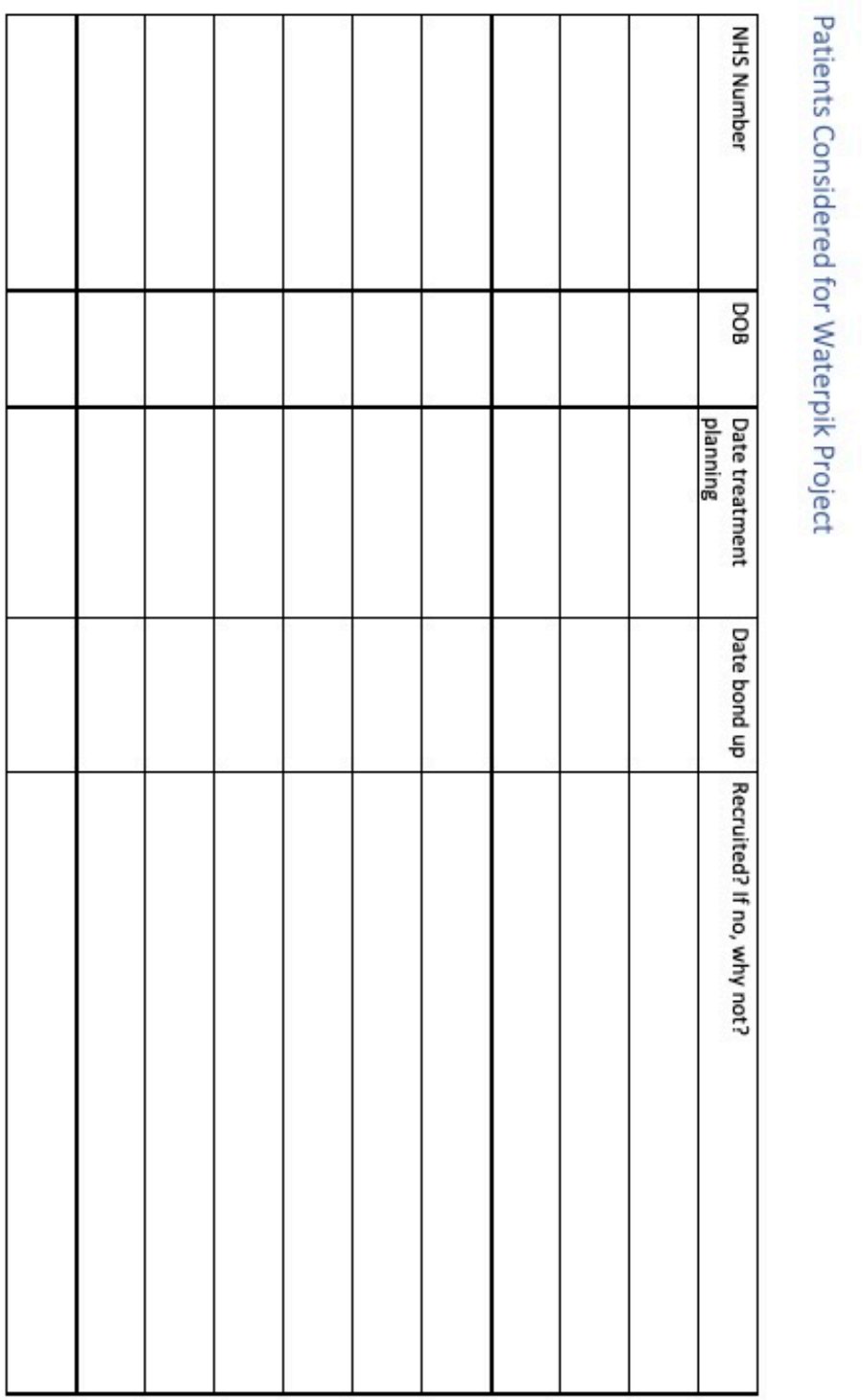
Mr. H. H. Goh
Department of Orthodontics
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York
YO31 8HE
Tel No: 01904 725614

If you would like general information and advice about taking part in a research project, you can contact:

Dr. Deborah Phillips
Research and Development Unit
01904 725123

There is also general information about research on the NHS Choices website at http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx

Appendix 12: Patients considering participation table.



Patients Considered for Waterpik Project

NHS Number	DOB	Date treatment planning	Date bond up	Recruited? If no, why not?

Appendix 13: Adult consent form.

York Teaching Hospital NHS
NHS Foundation Trust

IRAS Project ID number: 266235

Participant Identification Number for this Trial:_____

CONSENT FORM

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Name of Researcher: Mr Hock Hoe Goh

		Please initial box
1.	I confirm that I have read and understand the information sheet dated 03/10/2019 (Version 4.1) for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3.	I understand that selections of any of my medical notes may be looked at by responsible individuals from York Teaching Hospitals NHS Foundation Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	☐
4.	I also understand that my doctor and/or my dentist will be informed that I am taking part in this study.	☐
5.	I agree to take part in the above study.	☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

1 for Participant, 1 for researcher site file, 1 to be kept with hospital notes

Version 3.0 (21/05/2019)

Appendix 14: Young people consent form.

York Teaching Hospital NHS
NHS Foundation Trust

IRAS Project ID number: 266235

Participant Identification Number for this Trial:_____

ASSENT FOR FOR CHILDREN / YOUNG PEOPLE

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Name of Researcher: Mr Hock Hoe Goh

Child (or if unable, parent / guardian on their behalf) / young person to circle all they agree with:

1.	Have you read (or has somebody read to you) the information about this project?	YES / NO
2.	Has somebody explained this project to you?	YES / NO
3.	Do you understand what this project is about?	YES / NO
4.	Have you asked all the questions you want to ask?	YES / NO
5.	Do you understand the answers you had to your questions?	YES / NO
6.	Do you understand that it is okay to stop taking part in the study at any time?	YES / NO
7.	Are you happy to take part in the study?	YES / NO
If you say '**No**' to any of these questions, please don't sign your name!		

If you do want to take part, please write your name down below

Your name _____ Date _____

The dentist who explained this project to you needs to write their name too:

Name _____ Signature _____ Date _____

Thank you for your help

When completed, 1 copy for child/parent/guardian; 1 copy for medical notes (if applicable), 1 for researcher site file

Version 3.1 (03/10/2019)

Appendix 15: Parent consent form.

York Teaching Hospital NHS
NHS Foundation Trust

IRAS Project ID number: 266235

Participant Identification Number for this Trial:_____

PARENT CONSENT FORM

Is the use of the Waterpik® in addition to a manual toothbrush necessary to maintain clean teeth in patients with fixed braces?

Name of Researcher: Mr Hock Hoe Goh

		Please initial box
1.	I confirm that I have read and understand the information sheet dated 03/10/2019 (Version 1.1) for the above study and that I and my child have had the opportunity to ask questions.	☐
2.	I understand that my child's participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected.	☐
3.	I understand that sections of my child's medical notes may be looked at by responsible individuals from York Teaching Hospitals NHS Foundation Trust or from regulatory authorities where it is relevant to their taking part in this research. I give permission for these individuals to have access to my child's medical records.	☐
4.	I also understand that my child's dentist will be informed that he/she is taking part in this study.	☐
5.	I agree for my child to take part in the above study.	☐

_____	_____	_____
Name of Child	Date (optional)	Signature (optional)
_____	_____	_____
Name of Parent	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

1 for Participant, 1 for researcher site file, 1 to be kept with hospital notes

Version 1.0 (01/08/2019)

Appendix 16: Letter sent to GDPs of participants.

IRAS Project ID number is 266235

York Teaching Hospital
NHS Foundation Trust

GDP
[insert address]

Dear *[GDP],*

Re: *[insert patient name] [insert patient DoB]*
[insert patient address]

We are about to start *[insert patient name]*'s orthodontic fixed brace treatment.

She/he and her/his family have kindly consented and subsequently been enrolled in the Waterpik trial whilst undergoing treatment in our department. I enclose a Patient Information Sheet for your information.

There is no long term evidence to show that the use of Waterpik® is effective for orthodontic patients with fixed braces. The aim of this study is to find out if the use of Waterpik® in addition to the manual toothbrush is better to maintain clean teeth in patients with fixed braces. This will be a 56-week single blind, stratified; parallel group randomised controlled clinical trial. This will be a pseudo-longitudinal trial where observations are recorded at certain fixed intervals. Examinations will be conducted at baseline, 8, 32 and 56 weeks with 56 weeks classified as the completion of treatment. Your patient will be seen by us at these time-points but you need not do anything special/extra. They will also be issued with a standardised toothpaste and fluoride mouthwash. If you need to supplement these with either high fluoride toothpaste or chlorohexidine mouthwash then please advise us as this may alter the outcome measures.

I trust this information is helpful. If you require more information or the study protocol please don't hesitate to contact me.

Thank you.
Kind regards

Mr. H. H. Goh
Department of Orthodontics
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York, YO31 8HE
Tel No: 01904 725614

Dentist letter version 1.0 01-AUG-2019

Appendix 17: Intervention or control table.

Waterpik Intervention/Control

#	NHS Number	DOB	Date of bond up	Intervention (given waterpik) or control (no waterpik)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Appendix 18: Appointment checklist.

Waterpik Appointment Checklist – Shaded tasks to be completed by DN

Patient Label

Appointment 1 (Treatment planning)	
Discussion with patient and parent to ascertain interest and get verbal consent	
Suitability checklist completed	
Has patient been through oral care? To book before bond up if not	
Appropriate patient information sheet given for age (child's and adult's <16, just adult's >16)	
Added to 'patients considered' table	
Appointment 2 (Bond up)	
Check whether patient wants to proceed, update 'considering patients' table	
Baseline indices and photographs recorded	
Patient allocated into group according to baseline indices	
Consent form signed	
Parent consent form signed	
Patient allocated to control or intervention with envelope	
OHI +/- Waterpik given, +4 replacement tips.	
Toothbrush, toothpaste and mouthwash given	
Patient diaries given	
Patient and group recorded on control or intervention table	
Patient label put on back of allocation slip and put in folder	
Letter sent to patient's dentist	
Baseline indices transferred to data collection form	

Appointment 3 (8 weeks)	
Indices recorded including trauma checklist and photos	
Record if further OHI given	
Toothbrush, toothpaste and mouthwash given. Remind to change ortho tip at 3 months.	
Patient questionnaire completed and put in folder	
More patient diaries given	
Indices transferred to data collection form	
Appointment 4 (32 weeks)	
Indices recorded including trauma checklist and photos	
Record if further OHI given	
Toothbrush, toothpaste and mouthwash given. Remind to change ortho tip every 3 months.	
More patient diaries given	
Appointment 5 (56 weeks)	
Indices recorded including trauma checklist and photos	
Record if further OHI given	
Patient questionnaire completed and put in folder	
If patient in control group, Waterpik given	

Appendix 19: HRA & HCRW ethical approval letter.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Goh
Department of Orthodontics
Leeds Dental Institute
Clarendon Way
LS2 9LUMr Hock Hoe Goh
Department of Orthodontics
York Teaching Hospital NHS Foundation Trust,
Wigginton Road
York
YO31 8HE

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

23 August 2019

Dear Dr Goh

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**A randomised controlled clinical trial to determine if the use of the Waterpik® in addition to the standard toothbrush maintains cleaner teeth in patients with fixed braces**
IRAS project ID:	**266235**
Protocol number:	**0000**
REC reference:	**19/YH/0206**
Sponsor	**York Teaching Hospital Foundation NHS Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **266235**. Please quote this on all correspondence.

Yours sincerely,
Alex Thorpe

Approvals Manager

Email: hra.approval@nhs.net

Copy to: *Dr Deborah Phillips, York Teaching Hospitals Foundation NHS Trust*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
GP/consultant information sheets or letters [Letter to Dentist]	1.0	01 August 2019
IRAS Application Form [IRAS_Form_04062019]		04 June 2019
IRAS Application Form XML file [IRAS_Form_04062019]		04 June 2019
IRAS Checklist XML [Checklist_06082019]		06 August 2019
Letter from funder		20 June 2019
Non-validated questionnaire	3.0	21 May 2019
Other [Appendix C]	2.0	10 November 2018
Other [Comments in response to provisional opinion]		01 August 2019
Other [Patient Diary]	1.0	01 August 2019
Participant consent form [Parent Consent Form]	1.0	01 August 2019
Participant consent form [Consent Form adult]	3.0	21 May 2019
Participant consent form [Consent Form Young Person]	3.0	21 May 2019
Participant information sheet (PIS) [PIS adults]	4.0	01 August 2019
Participant information sheet (PIS) [PIS Young person]	4.0	01 August 2019
Participant information sheet (PIS) [PIS adults]	1.0	01 August 2019
Participant information sheet (PIS) [PIS adults - tracked]	4.0	01 August 2019
Participant information sheet (PIS) [PIS Young person - tracked]	4.0	01 August 2019
Research protocol or project proposal [Protocol]	4.0	21 May 2019
Summary CV for Chief Investigator (CI) [CV of CI]		31 May 2019
Summary CV for supervisor (student research) [Supervisor CV]		
Summary CV for supervisor (student research) [Supervisor CV]		

IRAS project ID	266235

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
This is a single site study sponsored by the participating NHS organisation.	This is a single site study sponsored by the participating NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study sponsored by the participating NHS organisation. No agreement is required.	Funding provided by the company that manufactures the Waterpik device. No funding letter provided.	A Principal Investigator should be appointed at study sites.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement

					checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. The student is not named in the IRAS application.

Appendix 20: Risk assessment.

York Foundation Trust R&D Unit
Form
R&D/F15

Risk Assessment Form

This form is to be used in conjunction with SOP R&D/S18 Risk Assessment

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS FORM TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

Form Reference:	R&D/F15
Version Number:	4.0
Author:	Deborah Phillips
Implementation date of current version:	5th August 2019

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019

This Form will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	23rd August 2010	Document previously issued as guidance
2.0	14th June 2013	Change of SOP Controller. Removal of North and East Yorkshire R&D Alliance references.
3.0	21st August 2017	Routine review. No changes
4.0	5th August 2019	Change of link to R&D website.

RISK ASSESSMENT FORM

CHIEF INVESTIGATOR:	Mr Hock Hoe Goh	**PROJECT TITLE:**	Effectiveness of Waterpik in patients with fixed braces
R&D REFERENCE NUMBER	266235Y	**SPONSOR:**	York Teaching Hospital NHS Foundation Trust
EUDRACT NUMBER:	*N/A*	**CTIMP STUDY:**	NO

STUDY RELATED ACTIVITIES DELEGATED TO TRUST:	MONITORING	YES
	PHARMACOVIGILANCE	NO
	OTHER	

HAZARD CATEGORY **REFER TO R&D/S18**	**HAZARD DESCRIPTION** **ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT*** If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	**LIKELIHOOD OF HAZARD OCCURING** 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	**IMPACT IF HAZARD OCCURS** 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	**RISK** Impact x Likelihood	**Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.**
RISKS TO PARTICIPANTS' RIGHTS					
Entry into study without fully informed consent	**1. Participants under 16 years old** **2. Understanding of information and time to process**	**1**	**2**	**2**	**1. Consent from parent/guardian and assent from participant will be sought. Young person PIS created to go alongside parent/guardian PIS.** **2. Information will be provided by the Investigator both verbally and written in the form of information sheets. Participants will be given time to consider the information and consent/assent will be sought at their next visit – usually a minimum period of 4 to 6 weeks. Participants will always be given at least 24 hours to decide whether to take part.**
Failure to act on a participant's request to withdraw from a study	**1. A participants right to withdraw is not highlighted, acted upon or documented correctly**	**1**	**2**	**2**	**1. Participants will be advised during the consent process that they are allowed to withdraw freely at any point during the study This is documented on the PIS and consent form.** **In the event of a participant choosing to withdraw**

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
					all the data pertaining to them will be destroyed and not used in the final outcome report.
Failure to protect participants' privacy	**1. Confidential, sensitive participant data is stored incorrectly, or misplaced**	**1**	**2**	**2**	**1. The trust policy on Confidentiality of Data and the NHS guidelines on Data protection will be in use. All records will be kept confidential and the patient's name will not be released at any time. Data sets for each patient will be identified by the patient enrolment number and initials only.** **Study reference code held on personal protected files in a separate personal lockable cabinet.** **Data collected will not possess any patient identifying data with the exception of hospital number. This data is kept within the folder of the Principal Investigator which will remain protected by username and password access to computers on site.** **Patient name and hospital numbers will be required to identify their records for measurements. Thereafter data will be stored purely as a number identifier. This data will be tabulated and stored both in electronic and paper formats.** **Data will ultimately be stored using secure NHS servers or University of Leeds secure servers accessed remotely using the University desktop anywhere service. All patient identifiers will be retained at York Teaching Hospital NHS Foundation Trust. No personal identifiable information will be transferred to (or accessible from) the University of Leeds.** **The data will then be kept until all necessary analysis has been completed then destroyed. This is anticipated not to take more than 12 months after the last data has been collected.**
Other – give details	**N/A**				

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
RISKS TO PARTICIPANTS' SAFETY					
Hazards of the intervention	**1. Incorrect use of the Waterpik device**	**1**	**3**	**3**	**1. Participants will be provided training on the use of the Waterpik device and shown how to use it by a dental nurse. Participants advised that they should read the important safety instructions in the Waterpik manual provided prior to use. The main safety considerations from the manual are also highlighted in the PIS.**
Hazards of the study assessment methods	**N/A**	**1**	**1**	**1**	**All procedures are non-invasive and involve assessment of gum health only. The only clinical part of the study will involve assessing for gum health using standardised indices. These are non-invasive procedures and are often carried out routinely.**
Indemnity arrangements	**Indemnity arrangements within the NHS address only negligent harm. The NHS cannot provide non-negligent cover**	**1**	**1**	**1**	**NHS indemnity scheme will apply** **All staff will have standard NHS contracts or be in possession of an honorary contract as required.**
Other – give details	**N/A**				
RISKS TO RESEARCHERS					
Lack of experience to carry out responsibilities delegated within study	**Postgraduate student will be PI carrying out the investigations**	**1**	**2**	**2**	**The postgraduate student was appointed as part of national recruitment for Specialty Registrars for Orthodontics. 3 x academic supervisors, including the CI who is an experience researched, will be overseeing this as a masters by research science project. Statistical analysis will be carried out under supervision from the Statistics Supervisor.**
Inadequate/outdated or lack of training	**Inadequate training provided to teams**	**1**	**2**	**2**	**All involved individuals take responsibility for ensuring that their training is adequate for the tasks delegated to them for this study.**

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
					A representative from Waterpik will demonstrate the device to the research team prior to recruitment starting. All dental nurses demonstrating the use of the Waterpik device to participants should be comfortable with **Clinical examinations will be carried out by the investigator and/or trained student, assessments are non-invasive and are often carried out routinely.**
Contact with abusive individuals	**N/A**	**1**	**2**	**2**	**This is very unlikely to occur during this study but in the event an issue occurs Trust policy will be followed at all times.**
Study proceeding without necessary regulations	**N/A**	**1**	**1**	**1**	**York R&D Unit checked and confirmed that all necessary regulations had been applied for and received prior to confirming capacity and capability for the study to proceed.**
Researcher time	**Insufficient research time to complete the study**	**1**	**2**	**2**	**A Postgraduate student has been appointed as PI for the study to conduct the study as part of their Masters project and is expected to have adequate protected time to complete the study.** **The planned research project, including timings, recruitment required and costings have all been carefully considered by a group of senior clinicians who are experienced in research prior to initiating the research.**
Other – give details					
RISKS TO COMPLETION OF THE STUDY					
Recruitment and follow-up	**1. Insufficient recruitment into the study** **2. Length of Follow-up**	**1**	**2**	**2**	**1. The sample size of 40 is seen as achievable. The Chief Investigator will be having monthly meetings to monitor progress, recruitment rates will be reported to the Sponsor.** **2. The final follow-up is at 56 weeks. Most**

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
					Orthodontic treatments last more than 12 months so participants would still be seeing the PI who will be their clinician till the end of the study.
Competency of partner organisations	**N/A**				**This is a single site study Sponsored and based at York Teaching Hospital NHS Trust. The course is being undertaken at Leeds University however this is under the supervision of the Chief Investigator who is employed by York Teaching Hospital NHS Foundation Trust**
Adequacy of study management	**Inadequate managing of the study leading to errors in data collection, management or deviation from the protocol**	**1**	**2**	**2**	**Within the research group there are both experienced clinicians and researchers. The research group itself is small, and all members will be well briefed regarding the protocol and have access to it at all times.** **All members of the research team are encouraged to seek clarification from the CI/PI should they have any concerns or questions throughout the project.**
Other – give details					
RISKS TO RELIABILITY OF RESULTS					
Lack of study power	**1. Insufficient recruitment of participants to the study, resulting in insufficient study power.** **2. Drop out of participants resulting in insufficient study power**	**1.**	**3.**	**3**	**1. Consideration has been given to achieving recruitment targets in this study, please see above section for details.** **2. The departmental average loss of patients or discontinuation of treatment for any reason is 15%. Patients lost to follow-up will not be included in the final statistical analysis. In order that the power of the study is not lost, the power calculation has been made to accommodate this.**
Setting the wrong eligibility criteria	**1. Unduly restrictive/prescriptive eligibility criteria** **2. Appropriate access to clinical trials**	**1**	**3**	**3**	**1. Inclusion/exclusion criteria have been written to encompass as large a population as possible whilst reducing potential confounding variables and participants who would be unable to comply with**

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	to patients of both sexes, all ages, ethnic backgrounds, etc.				**the study interventions. All criteria are appropriately justified in the Protocol and are not expected to be unduly restrictive so as to prevent recruitment.** **2. Participants will be recruited from all patients aged 10-20 years old starting fixed appliance treatment.**
Major violation of Eligibility criteria	**Recruiting participants outside of the eligibility criteria in error**	**1**	**1**	**1**	**As the selection criteria are quite complicated, a checklist will be used to ensure conformity and completed prior to consent.**
Fraud	**Very limited risk of fraud**	**1**	**1**	**1**	**There is very little potential or incentive for fraud. Investigators undertaking assessments are blinded to patient treatment groups. Funding is limited to the supply of Waterpik for the 40 participants. No investigators have any conflict of interest.** **Any occurrence of fraud will be highlighted to the Sponsor.**
Randomisation procedure	**Potential for loss of blinding, as the study is a single blind participants could inadvertently unblind the Investigator**	**2**	**1**	**2**	**Investigators will not discuss Waterpik with participants during the course of the study. In the event that an Investigator were to become unblinded if possible another qualified individual, blinded to allocation, would be asked to perform the assessment as the assessments are often carried out in standard care. Photographs of the mouth during the plaque assessments are to be taken to allow for re-score and to check the validity of the clinical score, this will be done by a blinded investigator.**
Outcome assessment	**Study outcome assessments are routine clinical assessments**	**1**	**1**	**1**	**Routine assessments so no risk above standard care expected. Photos taken to allow re-score of plaque assessments.**
Data being incomplete and inaccurate	**1. Assessment data**	**1**	**3**	**3**	**1. Data Collection Form has been checked and validated by a statistician.** **Participant surveys will be collected and checked**

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
	2. Participant Diary not fully completed	**4**	**1**	**4**	**for completeness by one of the dental nurses to avoid unblinding.** **2. It's accepted that over the 56 weeks there's a high chance of missing or inaccurate data in the participant diary. To reduce this new diary's will be given our at 8 week appointments along with reminders to complete these. Any information gained from these will be useful for assessing compliance but if it is missing it won't be detrimental to the primary outcomes looking at gingival health.**
Non-adherence to the protocol, GCP or SOPs	**1. Potential for lack of adherence to protocol by participants** **2. Non-adherence by Investigators (likelihood considered remote)**	**3**	**1**	**3**	**1. Participants may not be fully compliant with the Protocol. Only participants who show good compliance at initial discussion and instruction will be eligible. During the study if compliance is lost to the point that a participant needs additional oral hygiene instructions they won't be withdrawn but this will be accounted for in the analysis.** **2. Investigators will be appropriately trained on the Protocol requirement. Assessment procedures are often carried out routinely. CI is an experienced research supervisor with good understanding of Trust SOPS having undertaken multiple research projects within the Trust.**
Other – give details					
RISKS TO ORGANISATION					
Research project inaccurately costed	**N/A**	**1**	**1**	**1**	**Research as part of Masters project. Waterpiks provided for the study, only potential overheads toothpaste, toothbrushes and mouth wash. The post graduate student will use their bench fee to pay for these if Sponsorship can't be found.**

HAZARD CATEGORY REFER TO R&D/S18	HAZARD DESCRIPTION ASSIGN EACH HAZARD A SCORE FOR *LIKELIHOOD* AND *IMPACT* If a particular hazard is: (i) not applicable, state N/A (ii) not listed, enter details under 'other'	LIKELIHOOD OF HAZARD OCCURING 1 – Remote 2 – Unlikely 3 – Possible 4 – Likely 5 - Certain	IMPACT IF HAZARD OCCURS 1 – Low 2 – Moderate 3 – Significant 4 – Severe 5 – Catastrophic	RISK Impact x Likelihood	Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level.
Routine clinical services affected	**Minimal impact on routine clinical services**	**1**	**1**	**1**	**Visits timed to coincide with usual adjustment appointments at the Hospital. Research assessments are often carried out routinely and will be performed by the Investigator or trained student. Questionnaire**
Other – give details					

DECLARATION OF Chief Investigator (CI) / Principle Investigator (PI)			
As the CI/PI of the above study, I declare that the above Risk Assessment is true and complete to the best of my knowledge			
Name:		Signature:	
CI/PI:		Date (dd/mm/yyyy):	

RISK ASSESSMENT MATRIX

IMPACT	LIKELIHOOD				
	1 Remote	**2 Unlikely**	**3 Possible**	**4 Likely**	**5 Certain**
1 Low	1	2	3	4	5
2 Moderate	2	4	6	8	10
3 Significant	3	6	9	12	15
4 Severe	4	8	12	16	20
5 Catastrophic	5	10	15	20	25

RISK MANAGEMENT KEY

Action and time scales
Immediate action must be taken to manage the risk. Control measures should be put in place which will have the effect of reducing the impact of an event or the likelihood of an event occurring. A number of control measures may be required.
Significant resources may have to be allocated to reduce the risk. Where the risk involves work in progress urgent action should be taken.
Effort should be made to reduce the risk, but the costs of prevention should be carefully measured and weighed against the impact of the event. Establish more precisely the likelihood of harm as a basis for determining the need for improved control measures.
On or below this level a risk is acceptable. Existing controls should be monitored and adjusted. No further action or additional costs are required. Consideration may be given to a more cost-effective solution or improvement that imposes no additional cost burden.
Acceptable risk. No further action or additional controls are required. Risks at this level should be monitored, and reassessed at appropriate intervals.

Appendix 21: Trust confirmation of capacity and capability to act as the trial sponsor.

From: Phillips, Deborah <Deborah.Phillips@York.nhs.uk>
Sent: 01 October 2019 16:02
To: Tyler, Danny
Cc: GOH, Hock (YORK TEACHING HOSPITAL NHS FOUNDATION TRUST)
Subject: Waterpick Trial - confirmation of capacity and capability

Dear Danny and Goh,

Study title: A randomised controlled clinical trial to determine if the use of the Waterpik® in addition to the standard toothbrush maintains cleaner teeth in patients with fixed braces
IRAS project ID: 26623
Sponsor: York Teaching Hospital NHS Foundation Trust

This email confirms that **York Teaching Hospital NHS Foundation Trust** has the capacity and capability to deliver the above referenced study.

This is a Trust sponsored study and as outlined in the HRA approval letter no Agreement between parties is required.

You have permission to commence the study once training has been received and the equipment is in place but please note that only staff with an existing York Teaching Hospital contract may access data for the purposes of this study. Any additional and/or external staff need to apply for a letter of access or honorary contract. This may be obtained by contacting Sarah Sheath.

Please retain a copy of this email in your study file.

Additionally, please familiarise yourself with the Trust's SOPs for Research which can be found here: http://www.northyorksresearch.nhs.uk/sops_and_guidance_/sops/
If anything is not clear at any stage then please do not hesitate to ask but please do note that ANY change to your study should be discussed with the R&D Unit prior to being implemented in order that the correct amendment process is followed. Refer to R&D/S74 for information.

I wish you every success with your research and please do share a copy of any outputs from your study with us as this is always of interest.

Kind regards
Deborah

Please find attached a copy of the finally approved documents for the Waterpik trial.

Dr Deborah Phillips
Research Adviser
York Teaching Hospital NHS Foundation Trust
Usual working days are Tuesday - Thursday

Appendix 22: Trial registration receipt.

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 9, 2020

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	266235
Brief Title:	A Randomised Controlled Clinical Trial to Determine if the Use of the Waterpik in Addition to the Manual Toothbrush Maintains Cleaner Teeth in Patients With Fixed Braces
Official Title:	A Randomised Controlled Clinical Trial to Determine if the Use of the Waterpik in Addition to the Manual Toothbrush Maintains Cleaner Teeth in Patients With Fixed Braces
Secondary IDs:	

Study Status

Record Verification:	October 2020
Overall Status:	Recruiting
Study Start:	September 1, 2019 [Actual]
Primary Completion:	August 31, 2021 [Anticipated]
Study Completion:	August 31, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	York Teaching Hospitals NHS Foundation Trust
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Exempt
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary: There is no long term evidence to show that the use of Waterpik® is effective for orthodontic patients with fixed braces. A Cochrane Systematic Review confirms this. The aims of this study is to find out if the use of Waterpik® in addition to the manual toothbrush is better to maintain clean teeth in patients with fixed braces. The null hypothesis is that there is no difference between patients using either Waterpik® in addition to the manual toothbrush (treatment group) when compared with patients using just the manual toothbrush (control group).

Detailed Description: This will be a 56-week single blind, stratified; parallel group randomised controlled clinical trial. This will be a pseudo-longitudinal trial where observations are recorded at certain fixed intervals. The CONSORT guidelines for reporting randomised control trials will be followed. Examinations will be conducted at baseline, 8, 32 and 56 weeks with 56 weeks classified as the completion of treatment.

These are patients undergoing active orthodontic treatment involving full upper and lower arch fixed appliance therapy. As the selection criteria are quite complicated, a checklist will be used to ensure conformity.

Selection criteria:

1. All patients will have a dental history that included brushing at least twice a day and be willing and able to comply with the trial regime. They will also be between 10 and 20 years of age and in good general health. Any patients with medical conditions and those necessitating chemotherapy which may alter the oral tissue's response to fixed appliance treatment will be excluded. Examples include heart conditions requiring antibiotic cover, diabetes mellitus, immunosuppressant drugs, antibiotics, steroids and hormonal therapy.
2. Patients with decreased manual dexterity either due to mental or physical disabilities and poor compliance will be excluded. Patients with poor initial periodontal health will also be excluded.
3. All medications which may alter plaque accumulation should be avoided during the trial period, but if required on professional advice should report this to the clinical investigator.
4. All patients will have brackets as opposed to bands except permanent molar teeth which may be banded.
5. The patients will have full upper and lower arch treatment as oppose to sectional arch treatment. This is so that the difficulties involved in cleaning all the teeth are similar.
6. They should be bonded using one single type of cement, as we are unsure if different types of cement would influence the accumulation of plaque. This may be true with glass ionomer cement, as it has been shown to inhibit growth of some bacteria. The cement chosen for this purpose is Transbond XT® by 3M Unitek as this the cement most familiar to the operator. Furthermore any breakages from the appliances will be repaired using this cement. This will also ensure that consistent cement will be used.
7. The fixed braces will be of the pre-adjusted Edgewise type as auxiliaries used in other appliance type may pose to be confounding factor. As this unit uses the AO Orthodontics, MBT prescription brackets, this will be the brackets used for this trial.
8. Patients who already use any other supplements to the manual toothbrush for their oral hygiene will be excluded so as not to disadvantage their oral hygiene during their trial

The gold standard The Gold Standard for orthodontic patients is the use of manual toothbrushes to clean in the inter-bracket areas of the fixed braces after each meal or snack. However, for practical purposes, it may not be possible to

do so. Some schools do not provide facilities for their pupils to clean their teeth except for the sinks in the toilet. Therefore, patients will be asked to clean their teeth after breakfast, tea and last thing at night. They will be asked to do so for two minutes each time. They will be asked to time themselves and to keep a diary. They will not be given a timer as this is not in keeping with a “real world” situation.

They will also be shown how to clean around the orthodontic brackets using a manual toothbrush by the dental nurse/hygienist using a model. To ensure conformity, this advice will be given by the same two/three dental nurse on each occasion. The dental nurse would be a qualified dental health educator and would be familiar with providing oral hygiene instruction to patients with fixed appliance therapy. However, no further oral hygiene instructions will be given throughout the duration of the trial.

Additionally, if they live in a non-fluoridated area, a 10 mls 2% Fluoride mouthwash would be advised. They would be advised to do this last thing at night by holding the mouthwash for one full minute and spitting out. They would be asked not to rinse thereafter and to go to bed. Since the North Yorkshire area is non-fluoridated, this advice would follow.

Each subject should be issued with a standard fluoride containing toothpaste, a manual toothbrush and those requiring, a Waterpik®. At each visit, they will be issued with replacement brushes or as recommended by the toothbrush manufacturers. As part of the agreement for the patient to take part, they will be given the fluoride mouth rinse to be used last thing at night. The use of any other oral hygiene implements will not be permitted throughout the duration of the trial. No other members of the family will be allowed to use the implements supplied for the purposes of this trial.

All subjects will be issued with a diary of their cleansing habits to encourage motivation and compliance. Only patients who showed good compliance at the preliminary discussion and instruction will be allowed to participate in the trial.

All the instructions will be reinforced by a printed handout.

Conditions

Conditions:	Orthodontic Appliance Complication
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Supportive Care
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment This will be a 56-week single blind, stratified; parallel group randomised controlled clinical trial. This will be a pseudo-longitudinal trial where observations are recorded at certain fixed intervals.
Number of Arms:	2
Masking:	Single (Outcomes Assessor) Independent outcome assessors
Allocation:	Randomized
Enrollment:	40 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Treatment Group Waterpik® in addition to the manual toothbrush	Device: Waterpik Waterpik dental water jet
No Intervention: Control Manual toothbrush	

Outcome Measures

Primary Outcome Measure:

1. Plaque
   The patient will be disclosed by the clinical investigator who will be blind to the toothbrush group allocation. The disclosed mouth will be photographed and plaque scored at the same time. The photograph will allow for a re-score and to check the validity of the clinical score.

   Plaque will be assessed on the buccal surfaces of the teeth on which orthodontic brackets has been placed using the orthodontic modification of the Silness and Loe plaque index. This index has been shown to be sensitive in detecting differences in plaque levels in orthodontic patients with fixed braces. This index divides the tooth surface into four zones in relation to the orthodontic bracket: incisal, distal, mesial and cervical and codes 0-3 were assigned.

   [Time Frame: 8, 32, 56 weeks]
2. Gingivitis
   Gingivitis will be measured on the buccal surfaces of the teeth with the gingival index using a CPITN probe.

   [Time Frame: 8, 32, 56 weeks]
3. Gingival bleeding
   Gingival bleeding will be determined using the Eastman interdental bleeding index. This will involve inserting a wooden interdental cleaner (Interdental woodsticks, Oral-B Laboratories, Aylesbury, UK) between the teeth from the buccal aspect and depressing the interdental papilla by 1-2 mm. The presence or absence of marginal interdental bleeding from the papilla within 15 seconds will be recorded. The Eastman interdental bleeding index is the number of bleeding sites as expressed as a percentage of the total sites evaluated.

   [Time Frame: 8, 32, 56 weeks]

Eligibility

Minimum Age: 8 Years

Maximum Age: 60 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria:

1. All patients will have a dental history that included brushing at least twice a day and be willing and able to comply with the trial regime. They will also be between 10 and 20 years of age and in good general health. Any patients with medical conditions and those necessitating chemotherapy which may alter the oral tissue's response to fixed appliance treatment will be excluded. Examples include heart conditions requiring antibiotic cover, diabetes mellitus, immunosuppressant drugs, antibiotics, steroids and hormonal therapy.
2. Patients with decreased manual dexterity either due to mental or physical disabilities and poor compliance will be excluded. Patients with poor initial periodontal health will also be excluded.

3. All medications which may alter plaque accumulation should be avoided during the trial period, but if required on professional advice should report this to the clinical investigator.
4. All patients will have brackets as opposed to bands except permanent molar teeth which may be banded.
5. The patients will have full upper and lower arch treatment as oppose to sectional arch treatment. This is so that the difficulties involved in cleaning all the teeth are similar.
6. They should be bonded using one single type of cement, as we are unsure if different types of cement would influence the accumulation of plaque. This may be true with glass ionomer cement, as it has been shown to inhibit growth of some bacteria. The cement chosen for this purpose is Transbond XT® by 3M Unitek as this the cement most familiar to the operator. Furthermore any breakages from the appliances will be repaired using this cement. This will also ensure that consistent cement will be used.
7. The fixed braces will be of the pre-adjusted Edgewise type as auxiliaries used in other appliance type may pose to be confounding factor. As this unit uses the AO Orthodontics, MBT prescription brackets, this will be the brackets used for this trial.
8. Patients who already use any other supplements to the manual toothbrush for their oral hygiene will be excluded so as not to disadvantage their oral hygiene during their trial

Contacts/Locations

Central Contact Person:

Central Contact Backup:

Study Officials:

Locations: **United Kingdom**
York Teaching Hospital NHS Foundation Trust
[Recruiting]
York, North Yorkshire, United Kingdom, YO31 8HE
Contact: Deborah Phillips 01904 725123 deborah.phillips@york.nhs.uk
Principal Investigator: Hock Goh, Dr

IPDSharing

Plan to Share IPD: Undecided

References

Citations:

Links:

Available IPD/Information:

Appendix 23: Letter sent to participants during the COVID-19 closure.

NHS
York Teaching Hospital
NHS Foundation Trust

14 April 2020

York Hospital
Wigginton Road
York
YO31 8HE

Personal & Confidential
x
x
x
x

WaterPik Research Project During COVID-19

Dear x

We recently contacted you to let you know that your orthodontic appointment had been cancelled, and with information on your orthodontic treatment during and after the COVID-19 pandemic.

As you will now be aware, all orthodontic treatment has been postponed until the pandemic is over and we are sincerely sorry that your care has been interrupted.

In terms of the WaterPik research project, the outbreak will also disrupt the study. As you will remember, we planned to assess your gum health and cleaning at 8 weeks, 32 weeks and 56 weeks after fitting your orthodontic appliance. Unfortunately, due to appointment cancellations, it is likely that at least 1 of these appointments will be missed.

However, we will still be able to use the data from appointments after the restrictions on appointments have been lifted to investigate our study outcomes. Therefore, **please continue to use your Waterpik (if provided with one) and the toothpaste, toothbrushes and mouthwash we have provided you with as instructed.**

Please also continue to complete your oral hygiene diaries.

We will be posting all trial participants more toothbrushes, toothpaste and mouthwash. **Please also remember to change your Waterpik tip at 3, 6, 9 and 12 months from having your brace fitted.**

If you have concerns which you need to discuss with a clinician, please do not hesitate to contact our dental nurses on 01904 726408 or email daniel.tyler@nhs.net. We will answer your queries as quickly as possible.

Thank you for continuing to support the clinical trial, and please do not hesitate to get in contact if you have any questions.

With best wishes,

Yours sincerely

Mr D Tyler (Speciality Registrar in Orthodontics)
Mr H Goh (Consultant Orthodontist)