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A randomised controlled trial to determine patient experience of a magnetostrictive stack scaler as compared to a piezoelectric scaler, in supportive periodontal therapy.

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Short title: Patient preference for piezoelectric scaler compared to magnetostrictive scaler

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Abstract

Objectives: To compare the pain/discomfort experienced by patients in supportive periodontal therapy, following treatment with a piezoelectric ultrasonic scaler, designed for use with warmed water irrigation, and a magnetostrictive ultrasonic scaler.

Methods: This was a single-centre, randomised, split mouth study with regard to side, and crossover with regard to treatment order. Patients attending general dental practice for supportive periodontal therapy were randomised to receive treatment from one scaler on the left and the other scaler on the right-hand side of the mouth, the left side of the mouth always being treated first. The piezo scaler (Tigon+®) was used with room temperature irrigation for half of the participants (approx 20°C) and warmed water irrigation (approx 36°C) for the other half. The magnetostrictive scaler (Cavitron Select SPS 30K®) was used with room temperature irrigation (approx 20°C) only. Participants rated their pain/discomfort, noise and vibration by VAS scale.

Results: 140 participants completed the study. Mean VAS scores for all measures were significantly better for the piezo scaler used with warm irrigation as compared to the magnetostrictive scaler $p<0.001$. When both scalers were used with room temperature irrigant, there were no significant differences in the VAS scores between scalers (pain/discomfort, $p=0.68$; noise $p=0.2$; vibration $p=0.85$).

Conclusions: Participants indicated to statistical significance, less pain/discomfort, noise and vibration when the piezo scaler (Tigon+®) device was used with warmed irrigant, compared to the magnetostrictive scaler (Cavitron Select SPS 30K®). There were no significant differences between the instruments when room temperature irrigant was used.

Clinical Significance:

Regular scaling in supportive periodontal therapy, is essential for maintenance of susceptible patients, however it can be painful due to dentine hypersensitivity deterring patients from attending. Using a piezo scaler with warm water improves patient quality of life and subsequent oral health. This may have positive effects on patient attendance

ISRCTN registered

INTRODUCTION

Accumulation of dental plaque biofilm leads to gingival inflammation [1], which in turn is associated with the progression to periodontal destruction [2-4]. Periodontitis being characterized by non-reversible tissue destruction resulting in progressive attachment loss, eventually leading to tooth loss [5]. The treatment of gingivitis centres on the disruption of bacterial plaque biofilm and elimination of plaque retentive factors such as calculus [6,7]. For many individuals professional cleaning to remove plaque and calculus on a regular basis, in association with twice daily toothbrushing, is a pre-requisite for the maintenance of oral health, with the reduction of gingival inflammation and plaque scores demonstrated by systematic review [7].

Professional cleaning is achieved using hand or powered scalers, and while evidence supports the use of both methods in the maintenance of a periodontally susceptible individual, it has been shown *in vitro* that hand scalers take longer to achieve the same results [8], and may cause more damage to the root surface than powered scalers [9]. With regards to quality of life outcomes, both powered and hand scalers have been shown to induce dentine hypersensitivity (DH) [10], an arresting, but transient oral pain condition arising from stimulation of exposed dentine [11]. Powered scalers contain a generator in the scaler which converts electrical energy into ultrasonic waves that cause the scaler tip to vibrate [12]. The mechanical action of the vibrating tip is the primary mode of plaque/calculus removal, but this is aided by the interaction of a water irrigant [13]. There are 2 categories of ultrasonic scaler, magnetostrictive and piezoelectric which create vibration using different mechanisms. In magnetostrictive devices a resonating stack of metal strips attached to a scaling tip generates tip vibration at a frequency of 18 kHz to 45 kHz while in piezoelectric scaler devices vibrations are produced by oscillations of a quartz crystal in the handpiece at a frequency of 25kHz to 50kHz [12]. Scanning laser vibrometry has demonstrated that the probes of both scalers oscillate in an elliptical pattern, with the pattern of motion dependent on the power used as well as the physical size and shape of the probe [14].

All ultrasonic scalers operate with an irrigant where the primary benefit is to reduce the frictional heat generated by its use [15]. This includes cooling of the generator stack within the handpiece and cooling of the treatment site where friction occurs between the scaler tip and the tooth surface [15,16]. A secondary benefit of an irrigant is that it clears the treatment site of debris and disperses blood, which significantly improves operator vision [15]. Further documented benefits of the presence of an irrigant are the 'biophysical' forces [15] of microscopic bubble cavitation and acoustic streaming forces in the water flowing over the vibrating tip which release energy and together may boost deposit removal. The potential effects of the biophysical forces are recognized *in vitro* [17,18] but contributions to clinical outcome are few. Magnetostrictive scalers generate considerably more heat than piezo scalers and require approximately

twice as much water for cooling [19], than the piezo scalers. Piezo scalers therefore have the ability to be used with warmed irrigant.

An unfortunate common consequence of periodontal diseases, the management of these diseases and overzealous toothbrushing, is gingival recession with subsequent exposure of root dentine [20-22]. Recession is highly prevalent amongst the population, indeed 100% of individuals were affected in a recent paper by Seong et al [23]. During supportive periodontal therapy using ultrasonic devices in order to effectively clean areas of pocketing the device is applied in areas where there is recession. When exposed dentine is stimulated, and if sufficient numbers of the dentine tubules are patent from the tooth surface to the pulp, dentine hypersensitivity (DH) can occur [24]. Absi et al [25] demonstrated that sensitive dentine shows an eight fold increase of patent tubules than in non-sensitive dentine. DH is a transient short sharp pain that occurs following stimulation of exposed dentine by thermal, evaporative, tactile or osmotic triggers [26]. The cold stimulus is the most potent stimulus to induce DH, with most sensitive teeth responding to this stimulus [27], however any or all of the DH stimuli may evoke the pain of DH for the patient whilst undergoing periodontal maintenance with ultrasonic treatment with exposed dentine. Further, during the disruption of the biofilm and removal of oral debris and calculus, occluded dentine tubules may become patent, again leading to potential oral pain and discomfort during the maintenance procedure [28].

The rationale for this study is to compare patient experience of a commercially available piezo ultrasonic scaler (Tigon+®) with that of a commercially available magnetostrictive ultrasonic scaler (Cavitron Select SPS 30K®) for treating periodontally susceptible individuals in supportive periodontal therapy, the maintenance phase of periodontal treatment. The piezo scaler has a reservoir of water that can be pre-heated to deliver irrigation at body temperature that is warm compared to standard scalers. It has also been developed to produce the minimum noise and vibration without compromising efficacy. Specifically, this study will compare patient reported assessment of pain/discomfort, noise and vibration following treatment with a piezo and a magnetostrictive scaler when both are used with room temperature irrigation and when the piezo scaler is used with warmed irrigation.

MATERIALS AND METHODS

This was a single centre, blind (with respect to the patient although difference in irrigation temperature could not be masked), randomised controlled trial in periodontally susceptible patients in maintenance phase undergoing supportive periodontal therapy. The study was split mouth, with regard to side, and simultaneously crossover with regard to treatment order. Eligible participants were randomly allocated to one of four groups within the 2 arms of the study, according to a predetermined randomisation schedule.

The study was conducted at a private dental practice according to GCP guidelines, and permission for the study was granted by the University Faculty Research Ethics Committee ref: 59162.

Patient recruitment, screening and randomisation

Patients attending their general dental practice were asked if they would be interested in taking part in the study during routine dental appointment visits. Interested potential participants were provided with a participant information sheet and invited to attend a screening appointment. Participants who gave informed consent were enrolled onto the study which was undertaken in the dental practice. Eligibility was then determined by the study dentist according to the inclusion and exclusion criteria. Eligible patients were adults in good general health who had no significant or relevant abnormality in their medical history or oral exam, with susceptibility to periodontal disease but currently stable on examination (in supportive periodontal phase of treatment). Patients with current or recurrent disease/dental pathology that could affect the assessments or with current or previous history of serious severe or unstable physical or medical disorder that could have made them unlikely to fully complete the study, or any condition that presented undue risk for study products or procedures including allergy to any study products were excluded.

Participants who fulfilled all the necessary criteria were randomised to receive supportive periodontal therapy to one of 4 groups (Table 1), according to the randomisation schedule provided by the study statistician. Randomisation was undertaken by study staff who initially allocated potential participants a screening number in sequential order as the participant arrived at the screening appointment. As participants who fulfilled eligibility criteria and were happy to take part were enrolled in the study, they were allocated the next available treatment regime as indicated on the randomisation schedule.

Table 1. Treatment groups

Treatment Regimen	Left side (treated first)	Right side (treated second)
A1	[a]Cavitron room temperature water (C-RT)	[b]Tigon+ room temperature water (T-RT)
A2	Tigon+ room temperature water (T-RT)	Cavitron room temperature water (C-RT)
B1	Cavitron room temperature water (C-RT)	Tigon+ warm water (T-W)
B2	Tigon+ warm water (T-W)	Cavitron room temperature water (C-RT)

[a]Magnetostrictive scaling unit Cavitron® Select SPS Ultrasonic Scaler with Reservoir Pump, THINsert, FSI SlimLINE 10 left and FSI SlimLINE 10 right tips (Dentsply Sirona, Weybridge, UK). [b]Piezo scaling unit Tigon+® with 1P,3PI, 3Pr tips (W&H St Albans, UK).

Treatment Phase

At the start of the treatment visit, the participant was trained in the use of a Visual Analogue Scale (VAS) by the study dental nurse. The study dentist then recorded periodontal pocketing and removed any plaque or tartar present. Ultrasonic irrigation (scaling) was then carried out on both sides of the mouth (left side first), with one of the two scalers according to the manufacturer's instructions and using room temperature (~20^{o}C) or warm water (~36^{o}C) as indicated by the treatment allocation. The tip inserts used were appropriate for each device and comparable, and the flow of water was standardized (37ml/minute for the Cavitron and setting 7 for the Tigon+). Both devices were set on constant power settings and a standard low volume aspirator was used.

Immediately following treatment of each side of the mouth participants were asked to rate pain/discomfort, noise and vibration on 100mm VAS scales from zero to the worst imaginable. All participants were asked to rate the treatment undertaken on the left side of their mouth first, and after rating the second treatment (right side) they were asked which treatment they preferred. At the end of the study the clinician also rated the two scalers by VAS for ease of use, vibration and noise and indicated their preference.

Statistical analysis

Each study arm (Tigon room temperature vs. Cavitron room temperature and Tigon warm vs. Cavitron room temperature) yields within-participants comparisons. For each arm, the mean differences adjusted for treatment order effects [29] with 95% confidence intervals were calculated for each of the 3 VAS scores representing pain/discomfort, noise and vibration. Patient preferences were likewise adjusted for treatment order effects: preferences within each group were summarised including the no-preference responses [30], then compared between the two groups [31].

RESULTS

The study was undertaken in July-August 2018. Participant recruitment and flow through the study is shown in figure 1, almost a third of participants were female (64%) and the majority were Caucasian (96%). The mean age was 40.5 years (range 18.0 to 81.2). There were no AEs reported.

The mean VAS scores (mm) for all measures and all treatments are shown in Table 2 and varied widely, from a minimum of 0 (all measures/ all treatments) to a maximum of between 48 and 92.

Table 2. Mean VAS scores (mm) for pain, noise and vibration in study arms A and B

	Pain/discomfort		Noise		Vibration	
	Tigon	Cavitron	Tigon	Cavitron	Tigon	Cavitron
Groups A1 & A2: Both at room temperature						
Mean (SD)	14.3 (15.2)	15.3 (17.4)	22.5 (16.4)	25.2 (18.4)	17.0 (16.0)	17.5 (16.5)
Range	0-56	0-88	0-68	0-78	0-68	0-76
Groups B1 & B2: Tigon+ warm, Cavitron at room temperature						
Mean (SD)	9.2 (10.9)	16.6 (17.8)	20.0 (16.8)	26.3 (20.9)	13.5 (12.1)	19.0 (19.6)
Range	0-49	0-81	0-74	0-87	0-48	0-92

When scalers were compared following the use of both instruments with unwarmed water (T-RT vs C-RT) differences in all measures favoured the Tigon+ but did not approach significance (Table 3). Participant preference for the scaler also showed no significant differences between scalers, the net preference for the Tigon+ being 50% (95% CI 39-60).

Table 3. Mean differences in VAS score (mm) between the two scalers when both were used with room temperature water

	Mean difference (Cavitron minus - Tigon)	95% confidence limits	p-value
Pain/discomfort	+1.0	-3.9 to +5.9	0.68
Noise	+2.7	-1.4 to +6.8	0.20
Vibration	+0.4	-4.0 to +4.8	0.85

By contrast, comparing T-W and C-RT, VAS scores statistically significantly favoured the Tigon+ for all measures, especially for pain/discomfort (Table 4). Participants were also shown to prefer the Tigon+ when used with warm water, with a net preference of 72% (95% CI 62 – 79%), p<0.001.

Table 4. Mean differences in VAS score (mm) between the two scalers using warm water in the Tigon+

	Mean difference (Cavitron minus Tigon)	95% confidence limits	P-value
Pain/discomfort	+7.5	+4.2 to +10.9	<0.001
Noise	+6.2	+1.9 to +10.6	0.006
Vibration	+5.5	+1.4 to +9.7	0.010

Comparing VAS scores for the Tigon+ RT v W (Table 5), it was shown that for all measures scores for T-W were more favourable than scores for T-RT, but that this was only significant for pain/discomfort. A similar

analysis of participant preferences relative to Cavitron showed a significant preference for T-W as compared to T-RT ($\chi^2 = 8.4$, $p = 0.004$).

Table 5. Mean VAS scores (mm), and differences in the means for the Tigon+ used with water that was warm vs water at RT

	Difference of means (T-RT minus T-W)	95% confidence limits	p-value
Pain/discomfort	+5.1	+0.7 to +9.5	0.024
Noise	+2.5	-3.0 to +8.1	0.373
Vibration	+3.5	-1.2 to +8.3	0.145

The data also demonstrated that participants preferred the first treatment to the left side of the mouth more often than the second treatment to the right side. This preference for the first treatment to the left side of the mouth was highly statistically significant by the McNemar test, $X^2 = (73 – 44)^2 / (73 + 44) = 7.19$, $p = 0.007$.

DISCUSSION

This study demonstrated that there were no differences in patient acceptance between the Magnetostrictive and piezoelectric ultrasonic scalers when these were used at room temperature. However, patients preferred the piezoelectric scaler used with warm water for all measures, pain/discomfort, noise and vibration, as compared to either scaler used with room temperature water. It is well recognised that periodontal patients may suffer from DH as a result of the exposure of root dentine, with prevalence figures as high as 98% reported [32]. The mechanical management of periodontal diseases inevitably causes further exposure of dentine and patency of dentine tubules [33] and although the discomfort of periodontal maintenance with an ultrasonic scaler is usually short lived [28], these findings indicate that the development of devices that may be used with warmer water to reduce sensitivity, is warranted.

DH pain is found particularly as a result of stimulation from cold and evaporative stimuli, and less frequently tactile stimuli [26]. Supportive periodontal therapy using ultrasonic devices with a cold water irrigant could trigger DH by all three of these stimuli. Mechanical stimulation, although over a small area, can lead to the very short, sharp pain of DH for the individual due to compression of dentine with patent tubules [34]. The cool irrigant in scalers can reach a wide area of exposed dentine which could contribute to a more intense pain [35] due to the vast number of patent tubules affected. Thus, essential periodontal maintenance therapy may be accompanied by DH pain as an unpleasant side effect.

The significantly lower VAS score for discomfort/pain and subsequent preference observed for the piezo scaler when used with warm water compared to room temperature water is likely due to a reduced experience of dentine hypersensitivity during treatment. The most common stimuli to cause DH are cold and evaporative, 70% of stimuli, compared to tactile [36,37]. Hot and warm temperature stimuli rarely cause DH and indeed pain following a hot stimuli tends to be indicative of pulpal pathology not DH [38]. However, while the VAS scores for noise and vibration favoured the piezo with warm water compared to room temperature water, these differences were not significant. Given that vibration and noise should have been unchanged by the water temperature it is perhaps surprising to note the difference scores, but it suggests that the sensation of pain/discomfort is dominant over noise and vibration and that these scores were influenced by temperature indirectly through its beneficial effect on sensitivity. The piezo scaler assessed here, was designed to minimise noise and vibration, as noise in particular, has been shown produce anxiety in periodontal patients undergoing treatment [39].

VAS was chosen as the measure of patient reported experience as it is a simple, robust means of deriving a numerical measure [40]. The provision of a line without intermediate descriptors as included in other similar scales such as the verbal rating scale avoids clustering of responses around specific descriptors [41]. However, individuals may vary markedly in their perception of their pain/discomfort [42] and large variations in scores were recorded in the present study even though participants were trained in the use of the scale prior to the start of their treatment. VAS is a well-established measure of pain perception [43] that is used frequently in dentine hypersensitivity studies [44] and despite the variation encountered, was able to discriminate between the piezo used with warm water and the other treatments in this study.

The finding that patients tended to prefer the treatment used first (always applied to the left side of the mouth) was unexpected. One plausible explanation is that as treatment progresses, the participants become less comfortable in general. Taken together, the findings of the present study demonstrate that patient experience was significantly better following treatment using the piezo scaler with warmed water compared to either scaler used with room temperature water and that pain/discomfort was significantly improved with the use of warm water. This finding is particularly important given that the actual pain and expectation of pain are two major causes of anxiety in periodontal patients attending for periodontal therapy (78 and 67%, respectively) [39]. Reducing this anxiety improves the patient experience and, as a consequence, may improve attendance rates for treatment. If this difference had been seen only for the pain/discomfort VAS, it may be perceived that some participants were scoring the second treatment relative to the first treatment and not in absolute terms. This would lead to scores of around 50 if they judged the second treatment similar to the first. However, this was not the case and cannot be the explanation. A study with this design cannot tell us whether the apparent preference for the first treatment

is related to the order of use of the two scalers or to some anatomical left-right difference. The former seems much more plausible than the latter explanation. Nevertheless, in future studies using such a design, it would be prudent to enhance the design so that half the participants get treated on the left side of the mouth then the right side, the others right then left.

CONCLUSION

Supportive periodontal therapy is the gold standard for maintaining the stability of a patient susceptible to periodontal disease, and is routinely performed using an ultrasonic device. Due to the frictional forces between the tooth surface and the ultrasonic scaler tip, heat is generated and water irrigation is imperative to avoid tissue damage [43]. Dentine hypersensitivity is known to be induced by cold and evaporative stimuli [44] and warming the irrigant using the piezo scaler (Tigon+®) in this study demonstrated a reduction in the patients' perception of pain compared to using either scaler at room temperature during supportive periodontal therapy. This study suggests that manufacturers should work to enable the delivery of warm water by their scalers at the operating site which would improve patient acceptance of ultrasonic scaling.

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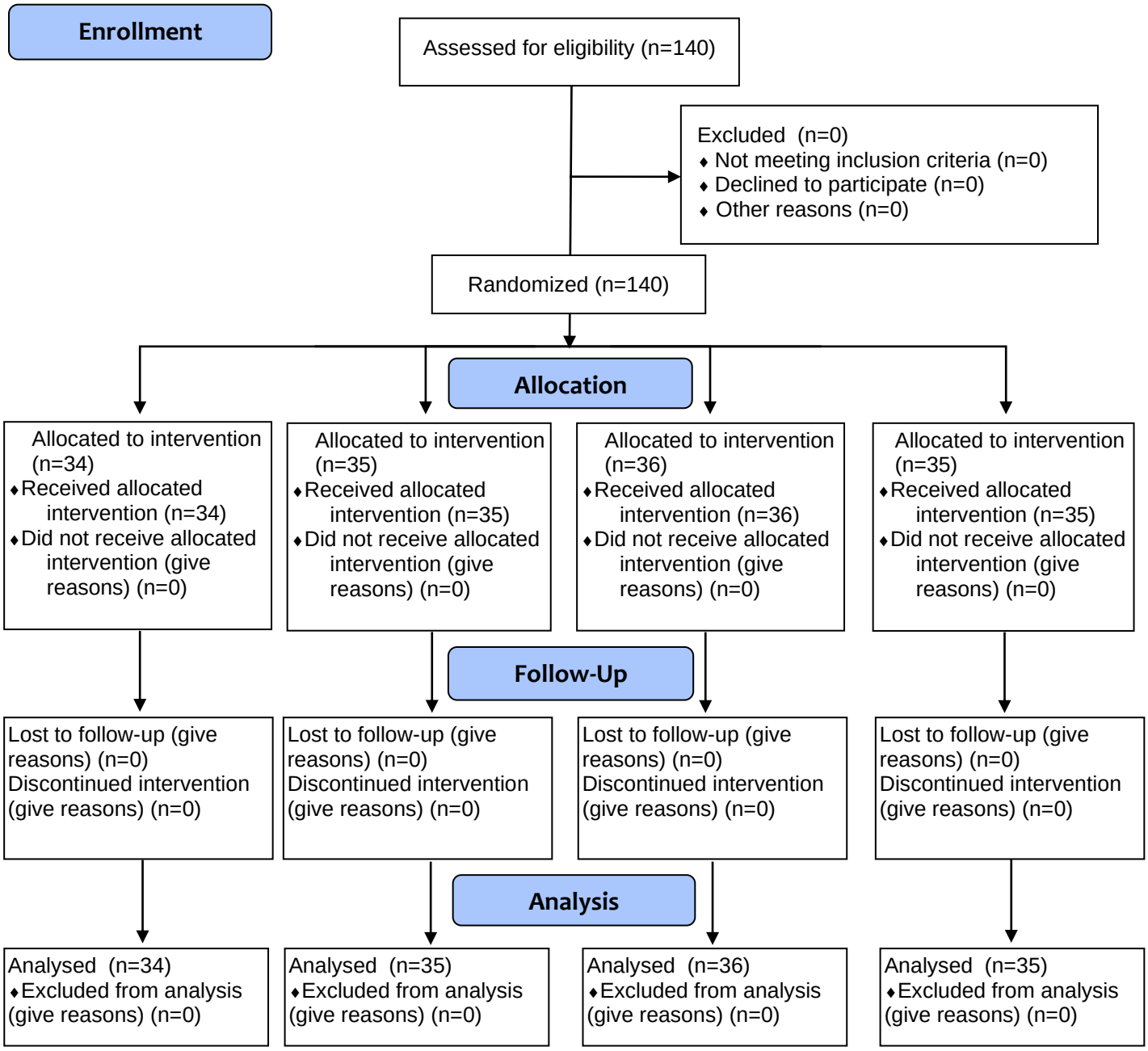

Figure 1. Patient flow through the study