KEY WORDS
Hawthorne effect, Spoon-feeding effect, Oral hygiene, Preventive dentistry, Randomized controlled trial, Tooth brushing.

Randomized controlled trial

USE OF HAWTHORNE AND SPOON-FEEDING EFFECTS TO MODIFY ORAL HYGIENE HABITS. A TWO-FACTORIAL RANDOMIZED CONTROLLED TRIAL

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PURPOSE The aim of the study was to estimate the Hawthorne effect through the patients' awareness of being observed regarding the detection of bacterial plaque with the use of a periodontal chart or the awareness of being observed in toothbrushing manoeuvres.

MATERIALS AND METHODS A randomized factorial trial with two-week follow-up was conducted. The factors investigated were: awareness of being observed in the detection of bacterial plaque accumulation and bleeding on probing (Factor Chart, FC), and awareness of being observed in toothbrushing manoeuvres (Factor Toothbrush, FT). Forty adult patients from a private dental practice were recruited, and divided into 4 groups of 10 patients each, which were randomly assigned to one, both or none of the study factors. Two weeks later, full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) were evaluated by a blinded examiner. The randomization list was computer generated, and allocation was concealed by using opaque sealed numbered envelopes.

RESULTS Regarding FMPS, there was a positive Hawthorne effect in the case of FC, but it was not statistically significant [difference in FMPS: -4.5 95%CI from -14.5 to 5.4, P-value = 0.359], while a statistically significant negative Hawthorne effect was recorded in the case of FT [difference in FMPS: +10.0 95%CI from 0.1 to 19.9, P-value = 0.048].
Regarding FMBS, there was a positive, but not statistically significant, Hawthorne effect in the case of FC [difference in FMBS: -3.7 95%CI from -8.1 to 0.8, P-value = 0.103], while a statistically significant negative Hawthorne effect was recorded for FT [difference in FMBS: +5.2 95%CI from 0.8 to 14.8, P-value = 0.023].

CONCLUSIONS The Hawthorne effect can take on a positive or negative value, depending on the indications given to the patient. The negative effect could be due to the expectation that others will tell us what to do (spoon-feeding effect). The intentional use of the Hawthorne effect to improve home oral hygiene habits is not supported by the results of this study.

CONFLICT OF INTEREST STATEMENT The authors declare that they have completely self-funded the study, and that there are no conflicts of interest.

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INTRODUCTION

When performing and analysing a trial, researchers should take into account the possibility that the participants' behavioural changes may affect the results of the trial[1]. The Hawthorne, or "observer effect" describes a change in normal behaviour when individuals are aware that they are being observed[2]. The type of bias caused by this phenomenon is a false-positive bias that may lead to over-optimistic results[1].

The original studies into the Hawthorne effect were undertaken at a Western Electric telephone manufacturing factory at Hawthorne, near Chicago, between 1924 and 1933[3]. Increases in productivity were observed among a selected group of workers who were supervised intensively by managers under the auspices of a research programme[3].

Recently, a systematic review has been conducted to elucidate whether the Hawthorne effect exists, explore under what conditions, and estimate the size of any such effect[4]. The conclusions of the authors were that little can be confidently inferred about the size of these effects, the conditions under which they operate, or their mechanisms. There is a clear need to rectify the limited development of research into the issues raised by the Hawthorne effect, as they indicate the potential for profound biases[4].

The "Hawthorne effect" has frequently been used to account for gains made by placebo control groups when none were expected[5]. In the context of oral health, this suggests that the frequency, duration, and effectiveness of home care regimens (all behavioural in nature) might be improved if the Hawthorne effect could be intentionally induced[5]. A controlled non-randomized study showed that, when used intentionally, the Hawthorne effect can alter subjects' oral health behaviour, reducing the percentage of dental plaque[5].

Therefore, knowing whether or not the presence of bacterial plaque will be examined via a periodontal chart, or knowing that toothbrushing will be supervised, could play a role in the reduction of plaque and gingival bleeding. The aim of this factorial randomized controlled trial was precisely to estimate whether the awareness of being examined using a periodontal chart and/or being supervised in toothbrushing could reduce the percentage of dental plaque and bleeding.

MATERIALS AND METHODS

Trial design

This study was written in accordance with the Consort 2010 explanation and elaboration guidelines for reporting parallel-group randomized controlled trials[6], and with the design, analysis and presentation of factorial randomized controlled trials[7].

This was a monocentric, examiner-blind randomized clinical trial, with balanced randomization and two-factorial design. All of the patients underwent debridement using dedicated ultrasonic scalers at baseline.

The two factors at two levels each were the following.

1. Factor Chart (FC): Patients were told that after two weeks, bacterial plaque and gingival bleeding would be measured and recorded on a periodontal chart.
2. Factor Toothbrush (FT): Patients were told to return with their toothbrush after two weeks to check their brushing technique.

Eligibility criteria for participants

This investigation was carried out from June to October 2013. During this period, 40 subjects presenting for oral hygiene procedures were consecutively recruited for the study, conducted in a private clinic located in Campi Bisenzio, Florence, Italy.

The inclusion criteria used for selection were:

- Age older than 18 years;
- Presence of at least 10 teeth or dental implants.

The following individuals were excluded:
- Subjects with manual inability to perform dental care;
- Patients with neurological disorders;
- Pregnant women.

The presence of dental caries and periodontal diseases did not represent exclusion criteria. Both patients already treated in the practice and new patients attending for the first time were included in the study.
Written consent was obtained from all subjects to be enrolled in the study.

Interventions

At baseline, a graduate expert hygienist (MG) performed the various procedures, which consisted of an oral hygiene session, and delivered any communications. The envelope with the randomization code was opened after professional oral hygiene.
The four groups resulting from the combination of the two factors were as follows.

1. Control group (N): the patients belonging to this group were merely told after scaling to return two weeks later for prophylaxis.
2. Chart group (C): after scaling, patients were told to return two weeks later for bacterial plaque and gingival bleeding measurement and recording on a periodontal chart. A prophylaxis procedure would also be performed.
3. Toothbrush group (T): after scaling, patients were told to return with their toothbrush after two weeks to check their brushing technique. A prophylaxis procedure would also be performed.
4. Chart-Toothbrush group (CT): after scaling, patients were told that after two weeks bacterial plaque and gingival bleeding would be measured and recorded on a periodontal chart. Patients were also told to return with their toothbrush to have their brushing technique checked. A prophylaxis procedure would also be performed.

Outcome measures

The primary outcome of the study was plaque index, measured in dichotomous manner[8] on six sites per tooth (buccal, lingual, mesial-buccal, mesial-lingual, distal-buccal, distal-lingual) after staining solution for dental plaque (GC Tri Plaque ID Gel™, Tokyo, Japan). Full-mouth plaque score (FMPS) was calculated as the percentage of sites with bacterial plaque.
Bleeding on probing (BoP) was measured in dichotomous manner[9] on six sites per tooth (buccal, lingual, mesial-buccal, mesial-lingual, distal-buccal, distal-lingual) using a PCP-UNC 15 periodontal probe. Full-mouth bleeding score (FMBS) was calculated as the percentage of sites with bleeding.
The examiner (DM) recorded the plaque index and bleeding on probing two weeks after professional oral hygiene. The examiner was blinded to the treatment assignment. The examiner was subjected to three calibration plaque assessment sessions on 9 patients before the start of the study. The intra-rater agreement was good (the k-statistic on plaque assessment resulted 0.74). After examination, prophylaxis was performed.

Sample size

To detect a difference between treatments of 15 points in the FMPS, standard deviation of 14[10], with a two-side 5% significance level and power of 80%, a sample size of 40 patients was necessary, given an anticipated drop-out rate of 25%. This sample size determination followed

the common procedure in factorial trials based on target effect size for each of the factors with their respective controls[7]. The sample size is based on the assumption that there would be no interaction between the factors[7].

Random sequence

To allocate the participants to the respective groups, two computer-generated lists of random numbers were used-one for the factor "Chart" and one for the factor "Toothbrush". Blocked randomization was applied to include 20 patients in each level of each factor, resulting in 10 participants allocated to each intervention (N, C, T, CT).

Allocation concealment and blinding

The allocation sequence was concealed from the researcher (MN) enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes. The envelopes were opened by the operator (MG) only after professional oral hygiene. Outcome assessors were kept blinded to the allocation.

Statistical methods

Descriptive statistics were performed (MN) using mean and standard deviation for quantitative data, and frequency and percentage for qualitative data. The statistical unit of the analysis was the participant.

Two general linear models using the two-factorial model were performed for FMPS and FMBS. A secondary analysis was performed to test the interaction term, which was added to the model only if significant[7]. If the interaction term was significant, the Tukey HSD post-hoc test was used to confirm where the difference between interventions occurred.

The significant level was set at 0.05. The statistical software was JMP v. 13 (SAS Institute Inc, Cary, NC).

RESULTS

Participant flow and recruitment

Forty patients were consecutively enrolled in the trial and randomized in a factorial two-factor two-level non-surgical study: 20 patients were randomized to Chart (FC) and 20 patients were randomized to the Toothbrush (FT) so that 10 patients each would receive a combination of four interventions (N, C, T, CT). For explicative reasons, the descriptive results are reported considering the factors and their combinations in the four cells of the study. Nevertheless, the inferential analysis considered only the main factors (factor Chart and factor Toothbrush), while the interaction was investigated as a secondary analysis.

Two participants from the N group, one from the T group, and one from the CT group dropped out after debridement (4 dropouts in total); all declined to return for the follow-up visit. In addition, one participant from the T group agreed to participate in the FMPS assessment, but refused the FMBS evaluation.

Baseline data

The main baseline patient characteristics are shown in **TABLES 1–3**. There were no apparent baseline imbalances between the four interventions or the two factors.

Outcomes and estimation

FMPS two weeks after professional scaling are shown in **TABLE 4** and **TABLE 5**. No significant difference was observed regarding the factor Chart (estimated difference in FMPS -4.5,

TABLE 1 PATIENT CHARACTERISTICS IN EACH GROUP; AGE: MEAN (STANDARD DEVIATION)

Age years	FT yes	FT no	Total
FC yes	Group CT 43.7 (11.7) n = 10	Group C 48.7 (15.8) n = 10	FC yes 46.2 (13.8) n = 20
FC no	Group T 38.7 (8.8) n = 10	Group N 44.5 (14.0) n = 10	FC no 41.6 (11.8) n = 20
Total	FT yes 41.2 (10.4) n = 20	FT no 46.6 (14.7) n = 20	Total 43.9 (12.9) n = 40

FC: Factor Chart; FT: Factor Toothbrush; Group CT: Chart-Toothbrush group; Group C: Chart group; Group T: Toothbrush group; Group N: Control group

TABLE 2 PATIENT CHARACTERISTICS IN EACH GROUP; GENDER: FEMALE (PERCENTAGE)

Gender: female	FT yes	FT no	Total
FC yes	Group CT 6 (60) n = 10	Group C 8 (80) n = 10	FC yes 14 (70) n = 20
FC no	Group T 4 (40) n = 10	Group N 7 (70) n = 10	FC no 11 (55) n = 20
Total	FT yes 10 (50) n = 20	FT no 15 (75) n = 20	Total 25 (62) n = 40

FC: Factor Chart; FT: Factor Toothbrush; Group CT: Chart-Toothbrush group; Group C: Chart group; Group T: Toothbrush group; Group N: Control group

TABLE 3 PATIENT CHARACTERISTICS IN EACH GROUP; SMOKING HABITS (PERCENTAGE)

Smoking habits	FT yes	FT no	Total
FC yes	Group CT 4 (40) n = 10	Group C 4 (40) n = 10	FC yes 8 (40) n = 20
FC no	Group T 3 (30) n = 10	Group N 5 (50) n = 10	FC no 8 (40) n = 20
Total	FT yes 7 (35) n = 20	FT no 9 (45) n = 20	Total 16 (40) n = 40

FC: Factor Chart; FT: Factor Toothbrush; Group CT: Chart-Toothbrush group; Group C: Chart group; Group T: Toothbrush group; Group N: Control group

favouring the use of the factor Chart; 95% CI from -14.5 to 5.4; P = 0.359). This indicates that knowledge of upcoming plaque assessment had no effect on oral hygiene. However, a significant difference was observed for the factor Toothbrush, at the expense of the participants who were told to return with their toothbrush after two weeks to check their tooth brushing technique (estimated difference in FMPS of 10.0, against the use of the factor Toothbrush; 95% CI from 0.1 to 19.9; P = 0.048). In other words, contrary to expectations, knowledge of upcoming brushing assessment appeared to worsen plaque score.

FMBS two weeks after professional scaling are shown in **TABLE 6** and **TABLE 7**. No difference was observed regarding the factor Chart (estimated difference in FMBS of -3.7, favouring the

TABLE 4 FMPS AFTER 2 WEEKS OF FOLLOW-UP; MEAN (STANDARD DEVIATION)

FMPS	FT yes	FT no	Total	
FC yes	Group CT 35.3 (15.6) n = 9	Group C 25.1 (8.3) n = 10	FC yes 29.9 (13.0) n = 19	Difference -4.5 P = 0.359
FC no	Group T 39.6 (18.3) n = 9	Group N 29.8 (16.0) n = 8	FC no 35.0 (17.5) n = 17	
Total	FT yes 37.5 (16.6) n = 18	FT no 27.2 (12.1) n = 18	Total 32.3 (15.3) n = 36	
	Difference 10.0; P = 0.048			

FMPS: Full-Mouth Plaque Score. FC: Factor Chart; FT: Factor Toothbrush; Group CT: Chart-Toothbrush group; Group C: Chart group; Group T: Toothbrush group; Group N: Control group

TABLE 5 FACTORIAL MODEL OF FMPS (R^2=0.14)

Term	Estimate	Standard Error	95% CI	P-value
Intercept	29.7	4.4		
FC (yes)	-4.5	4.9	-14.5; 5.4	0.359
FT (yes)	10.0	4.9	0.1; 19.9	0.048

FMPS: Full-Mouth Plaque Score. FC: Factor Chart; FT: Factor Toothbrush

TABLE 6 FMBS AFTER 2 WEEKS OF FOLLOW-UP; MEAN (STANDARD DEVIATION)

FMBS	FT yes	FT no	Total	
FC yes	Group CT 13.0 (3.8) n = 9	Group C 7.7 (4.3) n = 10	FC yes 10.2 (4.8) n = 19	Difference -3.7 P = 0.103
FC no	Group T 16.6 (10.3) n = 8	Group N 11.5 (6.6) n = 8	FC no 14.0 (8.8) n = 16	
Total	FT yes 14.7 (7.5) n = 17	FT no 9.4 (5.6) n = 18	Total 12.0 (7.1) n = 35	
	Difference 5.2; P = 0.023			

FMPS: Full-Mouth Plaque Score. FC: Factor Chart; FT: Factor Toothbrush; Group CT: Chart-Toothbrush group; Group C: Chart group; Group T: Toothbrush group; Group N: Control group

TABLE 7 FACTORIAL MODEL OF FMBS (R^2=0.14)

Term	Estimate	Standard Error	95% CI	P-value
Intercept	11.5	1.9		
FC (yes)	-3.7	2.2	-8.1; 0.8	0.103
FT (yes)	5.2	2.2	0.8; 9.6	0.023

FMBS: Full-Mouth Bleeding Score. FC: Factor Chart; FT: Factor Toothbrush

use of the factor Chart; 95% CI from -8.1 to 0.8; P = 0.103). This too indicates that knowledge of upcoming plaque assessment had no effect on oral hygiene. However, a significant difference was observed for the factor Toothbrush, at the expense of the participants who were told to return with their toothbrush after two weeks to check their tooth brushing technique (estimated difference in FMBS of 5.2, against the use of the factor Toothbrush; 95% CI from 0.8 to 9.6; P = 0.023). In other words, contrary to expectations, knowledge of upcoming brushing assessment appeared to be linked to more bleeding on probing.
No significant interaction was detected.

DISCUSSION

The objective of this study was to estimate whether the awareness of being subsequently examined using a periodontal chart or supervised in toothbrushing could reduce the percentage of dental plaque and bleeding. However, neither factor led to a significant improvement in bacterial plaque scores. Surprisingly, the awareness of being observed in toothbrushing in fact caused a significant *increase* in bacterial plaque and gingival bleeding on probing.
Several motivation methods have been proposed to improve compliance with oral hygiene[11-14]. Furthermore, it has recently been observed that an apparent improvement in oral hygiene can be achieved even without any therapy or motivation method[15]. The Hawthorne effect, although often invoked to explain improvements in oral hygiene in the control group from randomized controlled studies, has been little investigated in practice. To our knowledge, only one non-randomized study has shown its effects in reducing bacterial plaque[5]. In our randomized study, telling patients that they would be assessed for the presence of bacterial plaque and gingival bleeding led to a modest, but not significant, reduction in plaque and bleeding. Perhaps, the power of this study was not adequate to highlight such a small difference in FMPS and FMBS. It may also be that a Hawthorne effect of another type may give more noticeable results. For example, patients could be told that they are participating in a very important clinical trial, or that they would only be considered eligible for one if they could significantly reduce the presence of bacterial plaque, etc. It may be worth studying these aspects more in depth.
An interesting result of this study was that, surprisingly, participants who were told their toothbrushing technique would be observed displayed a significant *increase* in FMPS and FMBS. This negative Hawthorne effect was the opposite of what could be expected, and in the past a negative Hawthorne effect has been linked to multiple factors, including the wish to receive greater consideration or priority management status, concern about failing to meet criteria for receiving a new treatment or being included in a therapeutic trial, or conformism related to cultural factors or to circumstance[16]. In our specific study, a possible explanation for the negative Hawthorne effect could be participants performing less careful cleaning due to their awareness of upcoming supervision in their toothbrushing technique and that they would be given direct coaching by the dental hygienist at their next visit. This could be a general behaviour, when nothing is done waiting for others to tell us what to do. This negative Hawthorne effect could be renamed the “spoon-feeding effect”.
Negative effects have also been highlighted for other famous effects, for example the well-known nocebo versus placebo effect[17,18]. Another famous example in education research is the Pygmalion effect[19]. The Pygmalion, or Rosenthal, effect, is a psychological phenomenon wherein high expectations lead to improved performance in a given area[19]. The Golem effect, on the other hand, is essentially the negative version of Pygmalion: behaviour reflecting low or negative supervisory expectations generates poorer performance[20,21].

In any event, very little is known about the negative Hawthorne effect (in fact, this could be the first randomized controlled trial to study it), and it is therefore difficult to advance any theories as to its significance.

A sequence of a strong negative Hawthorne effect before treatment prescription followed by a strong positive Hawthorne effect after treatment initiation may make a greater contribution than the placebo effect to the improvements produced by treatments[16]. From these observations derives the assumption that to establish the efficacy of a therapy is necessary to use a control group, possibly in a randomized controlled study. Only in this way, by comparing the difference in efficacy between two or more therapies, we can have results unbundled from the positive or negative Hawthorne effect. Indeed, these effects, which are unpredictable, can be produced in the same way in the different arms of a randomized controlled study and, consequently, they are deleted considering the outcome differences between the arms.

The results of this study were obtained in adult patients undergoing normal oral hygiene procedures, and it is difficult to generalize the results to other patients or conditions.

CONCLUSIONS

The intentional use of the Hawthorne effect to improve home oral hygiene habits is not supported by the results of this study. A negative Hawthorne effect was highlighted when patients were aware that their toothbrushing technique would be supervised.

A possible explanation could lie in the fact that the patients cleaned their teeth with less attention while awaiting the instructions that the hygienist would give them ("spoon-feeding effect").

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