Desai R, Durham J, Wassell RW, Preshaw PM. Does the mode of administration of the Oral Health Impact Profile-49 affect the outcome score? *Journal of Dentistry* 2014, 42(1), 84-89.

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DOI link to article:

<http://dx.doi.org/10.1016/j.jdent.2013.10.016>

Date deposited:

04/12/2015

Embargo release date:

29 October 2014

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Title: **Does the mode of administration of the Oral Health Impact Profile-49 affect the outcome score?**

Short Title: **Does the mode of administration impact on OHIP-49 scores?**

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Key words:

Periodontitis; Quality of life; Oral health impact profile; OHIP-49

Does the mode of administration of the Oral Health Impact Profile-49 affect the outcome score?

Abstract

Objective: To determine if there are differences in outcome scores if the Oral Health Impact Profile-49 (OHIP-49) is delivered by two different modes of administration (manual-self complete versus telephone interview).

Methods: Patients with chronic periodontitis (n=83, 54% females and 46% males, mean age 49.1 ± 9.5 years) completed the OHIP-49 using two modes of administration (manual self-complete and telephone interview) in a randomly assigned order, with a washout period of two weeks between modes, both episodes occurring prior to any periodontal treatment being provided. To assess convergent validity, after each mode of administration, the patients were additionally asked a global question about their oral health-related quality of life (OHRQoL).

Results: Median OHIP-49 scores recorded by manual self-complete (median 36 [IQR=20-70]) were significantly higher than those recorded by telephone interview (median 27 [IQR=11-61]) ($p<0.01$). The global question was well correlated to the OHIP domains, but did not reveal any evidence of an order effect such as was seen with OHIP-49 itself (which showed a higher impact on OHRQoL during the first administration in either mode).

Conclusions: The mode of administration (manual-self complete versus telephone interview) did substantially influence the OHIP-49 scores in patients with chronic periodontitis. The OHRQoL differed between the two modes of administration, with significantly higher scores (indicating poorer OHRQoL) when the questionnaire was manually self-completed.

CLINICAL SIGNIFICANCE

The mode of administration of quality of life questionnaires such as OHIP-49 could potentially affect the outcome scores derived. This study investigated whether there is a difference in outcome scores if OHIP-49 is delivered via manual self-complete or by telephone interview in patients with chronic periodontitis. We found that there was a significant difference between the two modes: manual self-completion by the patients yielded significantly higher scores than completion by telephone interview. It is therefore important to be consistent in the mode of completion of OHIP-49, as mixing modes could introduce additional error into clinical studies that utilise this instrument.

1. INTRODUCTION

Over recent years, a number of measures to assess oral health-related quality of life (OHRQoL) have been published which aim to assess the impact that various oral conditions have on an individual's well-being and their life quality. One of the most commonly used OHRQoL measures is the Oral Health Impact Profile (OHIP) (1). This measure has been used in a number of health surveys to assess the impact that chronic oral diseases have on an individual. The full version of OHIP (OHIP-49) contains 49 items (divided into 7 domains) that assess various impacts of oral health and disease on OHRQoL. The two main modes of administration of OHIP-49 that have been used are: (i) interview (in which a researcher asks the questions face-to-face with the respondent and records the responses) and (ii) self-administration (in which the respondent completes the questionnaire themselves) (2). The latter mode has been used most frequently, probably for reasons of convenience; this is despite the fact that OHIP was originally designed to be administered via an interview (1). An interview can either be conducted face-to-face or over the telephone, and the self-completion of the questionnaire can be performed either manually (i.e. hand-written on hard copies) or electronically (e.g. online). Both modes of administration (interview or respondent self-complete) have their advantages and disadvantages in terms of patient burden, response rates and costs, and these are related to the environment in which they are used (2).

Until recently, no study had examined if the scores derived from OHIP-49 are affected by the mode of administration. In a study of 42 prosthodontic patients, Reissman *et al.* examined the effect of three modes of administration (telephone interview, face-to-face interview, and self-complete) on the summary scores from OHIP-49 (2). These authors identified slightly, but significantly, lower OHIP summary scores when the questionnaire was administered via telephone interview versus the other two modes of administration ($p < 0.05$). However, as recognised by these authors, prosthodontic patients may not have been an ideal cohort for this study, because in such patients, the functional limitation and physical disability domains of OHIP-49 generally outweigh the psychosocial impacts and other impairments that are assessed by this instrument (2). This masking effect coupled with the

burden on respondents of having to complete three separate OHIP evaluations may mean that the true magnitude of any difference between modes of administration has not yet been fully described. This is an important issue, because if the mode of administration does influence OHIP scores, then this will need to be taken into account when designing future studies. Our previous work has shown that periodontal disease has significant psychosocial impacts on OHRQoL (3, 4). Durham *et al.* found that patients diagnosed with chronic periodontitis reported significantly poorer OHRQoL when compared with periodontally healthy patients, and reported significant functional, physical, social and psychological impacts on their QoL (4). Hence, patients with periodontal disease may provide a useful cohort in which to examine further the impact of mode of administration on OHIP scores.

The aim of this study was, therefore, to examine any differences between the summary scores derived from OHIP-49 between the two most commonly used modes of administration: manual self-complete and telephone interview, with the null hypothesis being that there would be no difference between manual self-complete or telephone delivered questionnaires ($\alpha=0.05$).

2. METHODS

2.1 Ethical approval

The study received ethical review and approval from the UK NHS National Research Ethics Service Committee North East, Northern and Yorkshire (Ref: 11/NE/0223).

2.2 Participants

For the study, a purposive sampling strategy was selected and participants were recruited from new patients attending for routine appointments at the periodontology clinic of Newcastle Dental Hospital (UK). All recruited participants provided written informed consent prior to enrolment into the study. The inclusion criteria were: participants should be dentate with a minimum of twenty natural teeth, with a diagnosis of chronic periodontitis, assessed using the Basic Periodontal Examination (BPE), with a BPE score of 4 in a minimum of three out of six sextants. Individuals were excluded if they had insufficient understanding of English to participate effectively in the reading, listening and speaking required for the study, or were suffering from any other dental/orofacial problems other than chronic periodontitis (as assessed by the global question “Do you have any current problems with your teeth, dentures, mouth, jaws or face other than the gum disease you are being seen on clinic for today?”).

2.3 Assessment of OHRQoL

The English language version of OHIP-49 was used in this study (1). It consists of 49 problem-based questions (items) and uses a reference period of the “last one month”. The items are grouped into seven domains consistent with Locker’s model of oral health (5) and are scored using an ordinal response scale: 0=never; 1=hardly ever; 2=occasionally; 3=fairly often; 4=very often. In this study OHIP ADD (i.e. a summed response code) was used as the outcome measure, as it is one of the methods of scoring of OHIP-49 that is most sensitive to change (2). A *higher* score indicates a *poorer* OHRQoL (6).

Each participant enrolled in the study completed the OHIP-49 using both modes of administration: (i) manual self-complete, and (ii) telephone interview. In order to minimise any influence of the administration sequence on the OHIP-49 scores, the sequence was randomised using a permuted squares randomisation procedure. Depending on whether it was the first or second mode of administration for manual self-complete of the questionnaire, the questionnaire was given to the patient to complete in the waiting room or to self-complete at home or was sent to the patient with a self-addressed envelope to be returned within a week. Telephone interviews were carried out with the patient at a prearranged appointment at a time convenient to them and the OHIP-49 was administered verbally over the telephone by a single researcher. The washout period between the first and the second modes of administration was a minimum of 2 weeks, during which time no periodontal treatment occurred. The same participant instructions were used for both modes of administration. Questions that were not relevant to the patient (e.g. questions about dentures in patients who did not wear dentures), were completed as “Never” responses. No explanations of questions were conducted in either mode of administration. In the telephone interview, patients did not have a copy of the questionnaire in front of them and at the beginning of the interview were simply given the five possible responses for each question and asked to write these down so they could verbally respond as appropriate.

After each completion of the OHIP-49, participants were *verbally* asked a single global question “How would you rate the present state of your oral health?” Answer options to this question were: ‘very good’, ‘good’, ‘moderate’, ‘poor’, ‘very poor’. The global question was asked either face-to-face or over the telephone, in order to provide a constant mode of OHRQoL assessment for comparison to the OHIP-49 scores derived from the two modes of OHIP-49 administration.

2.4 Data analysis

An *a priori* power calculation based on using paired inferential statistics such as Wilcoxon signed rank test indicated that a study powered at 80% in order to detect a type 1 error of 0.05 and a small to medium effect size of 0.3 (7) required 90 patients to complete the OHIP-49 using two different modes of administration: manual self-complete and telephone interview.

All analyses were performed using statistical software package STATA, Release 12 (Stata Statistical Software, College Station, TX, USA). The main aim of the analysis was to compare scores between modes of administration of OHIP-49 but additional statistical testing was used to compare responses between males and females in each method of delivery. Questionnaires with $\geq 10\%$ missing items (i.e. items without a response) were rejected. Those with missing data (but less than the 10% exclusion threshold) had missing responses imputed using the population mean score for the item (8, 9). This imputation then allowed the summary scores per domain to be calculated. The Wilcoxon signed rank test was used to test for significant differences between the two modes of administration (manual self-complete and telephone interview). The Intraclass correlation coefficient (ICC) (2,1) was calculated using a two way random effects model with absolute agreement according to the Shrout and Fleiss convention (10) and was used to assess all possible orderings of pairs of responses, and to provide an estimate of the correlation coefficient between all possible pairs of observations. The internal consistency of the OHIP-49 was calculated using Cronbach's alpha. The verbally delivered global question was used as a control to examine the consistency of responses to the OHIP-49, i.e. to identify whether OHRQoL varied spontaneously during the course of the study. The global question was also used to test convergent validity using Spearman's correlation against the relevant OHIP domain and/or overall summary OHIP score.

3. RESULTS

A total of 113 individuals were recruited to the study: 64 females and 49 males. Of these, 29 did not complete the study or were excluded for various reasons: (i) did not respond to telephone calls for telephone completion of questionnaire (n=9), (ii) failed to return the completed paper copy of the questionnaire (n=13), (iii) questionnaires lost in post (n=1), (iv) found to not meet periodontal inclusion criteria when BPE was performed (n=3), (v) commenced periodontal treatment prior to end of wash-out period (n=3). There was no significant difference between those who completed or did not complete the study on the basis of age or gender ($p>0.05$).

The mean ($\pm$ SD) number of teeth present was 27 ± 2.0 , and the mean number of sextants with a BPE score of 4 was 4.4 ± 0.9 . The mean age of the participants who completed the study was 49 ± 10 years (range 18-75 years). There were 14 current smokers (17%), 32 ex-smokers (38%) and 37 non-smokers (45%). The mean washout period between the first and the second administration modes was 24 ± 11 days.

With reference to missing data, one questionnaire (manual self-complete) had missing data in $\geq 10\%$ of items, and this patient was excluded, leaving a final sample size of 83 patients: 45 females (54%) and 38 males (46%). Two additional participants had a total of 3 items of missing data from the manual self-complete questionnaires (no data were missing from the telephone completed questionnaires).

With regard to the *chronological* order of administration (table 1, figure 1), we identified a small but statistically significantly higher median summary score of 8 OHIP units at the first mode of administration (median 35 [IQR = 20-65]), as compared to the second mode of administration (median 27 [IQR = 12-67]) ($p<0.01$). Significant differences were found individually, in the functional limitation, psychological discomfort and psychological disability domains between the first and second administration mode ($p<0.01$). However, there were no significant differences in the global assessment score between the first (median 2 [IQR = 2-3]) and second (median 2 [IQR = 1-3]) modes

of administration ($p>0.05$). Differences in domain scores between first and second modes of delivery are shown in table 1.

Table 2 demonstrates the OHIP mean scores by *mode of administration* irrespective of the chronology of administration. There were significant differences between the mode of administration in the overall summary scores (9 units difference, $p<0.001$), with significant differences identified in the functional limitation, physical pain, psychological discomfort and psychological disability domains ($p<0.01$). However, there was no significant difference between the global assessment of OHRQoL which was asked verbally at both modes of administration (telephone median 2 [IQR = 1-3]; manual self-complete median 2 [IQR = 2-3]) ($p>0.05$).

The ICC between modes of administration was 0.89, indicating “moderate to good” reliability and consistency of the measurement (11). The internal consistency for both modes of administration (Cronbach’s alpha) was identical at 0.97. The correlation coefficients for the OHIP summary score and the global assessment score did not differ significantly between the chronological order of administration (first mode $r=0.48$, $p>0.05$; second mode $r=0.36$; $p>0.05$). However, the correlations between the OHIP summary score and the respective global assessment score were statistically significant (telephone $r = 0.51$, $p<0.001$; self-complete $r = 0.48$, $p<0.001$).

A Bland and Altman ‘differences vs. means’ plot (12) identified that the maximum differences between manual self-complete and telephone interview OHIP summary scores for each patient compared to the means of their OHIP summary scores ranged from -37 to 22, and these wide limits of agreement illustrate the large individual variations that were observed between responses derived from the two modes of administration.

4. DISCUSSION

OHIP-49 is a large questionnaire, and this limits its use in all studies, due to the length of time to complete it, the increased possibility of missing data and potentially, increased cost (13). Clearly, if it could be shown that the OHIP summary scores were not influenced by the mode of administration, then it might then be possible to mix administration methods in order to achieve the best possible balance between respondent burden, cost, and minimising missing data. On the other hand, non-equivalence of the summary scores following different administration modes would mean that data from different studies could have limited comparability (2).

In our study, the OHIP summary scores for patients diagnosed with chronic periodontitis were statistically significantly different between the manual self-complete questionnaire and the questionnaire delivered over the telephone, with higher summary scores (indicating poorer OHRQoL) in the manual self-complete mode compared to the telephone administration. The OHIP summary scores varied both chronologically and also between the two modes of administration. We observed a median difference of 9 OHIP units between the two modes of administration.

The global oral health score did not vary significantly between modes of administration and was significantly, although moderately, correlated to the OHIP domain and summary scores. It was also not subject to any order effect which may be reflective of the fact that this was just one relatively blunt question to assess OHRQoL.

The significantly higher OHIP summary score recorded in the manual self-complete mode compared to the telephone interview mode is difficult to explain, and it is difficult to identify which method of completion was the most accurate in assessing OHRQoL. One could take the view that patients benefit perceptually by having more time with the self-complete questionnaire to reflect on each answer. On the other hand patients may respond more realistically to the question being asked verbally during the telephone interview. The important thing is to acknowledge that a significant difference exists between modes and to take this into account when designing OHRQoL studies.

The OHIP-49 summary scores also varied between the chronological first and second mode of administration, irrespective of the administration mode. This suggests that there is some change occurring in the washout period that affected the summary scores, the functional limitation, the psychological discomfort and disability scores. This occurred despite the fact that no treatment was performed during the washout period between modes of administration. Patients were referred into the dental hospital by their general dental practitioner for opinion or treatment of their periodontal condition. Some of the patients were unaware that they had periodontal disease, hence once they had received a diagnosis of chronic periodontitis, and the nature and prognosis of their condition had been explained, they may have become more anxious at that point in time. When subsequently approached by the researcher and asked to take part in the study, they may have recorded higher responses (indicating poorer OHRQoL) due to their sudden awareness of their periodontal health status on that day or shortly thereafter, hence reporting a poorer OHRQoL. The initial awareness of a poor OHRQoL might have settled over the washout period prior to the second administration mode, giving a lower score after the washout. This might lead one to question whether or not diagnosis of the problem, subsequent explanation of the disease, and reassurance, may be mitigating factors in the washout period that cause subtle changes in the individuals' OHRQoL as reported by the chronological changes in the OHIP scores. This phenomenon will need to be investigated further in future studies.

According to OHIP-49, periodontitis appeared to have the greatest impacts on the functional limitation, psychological discomfort and disability domains, irrespective of the mode of administration. These findings coincide with other work which suggested that periodontal disease has, in particular, psychosocial, physical functioning and pain impacts on OHRQoL (3, 4, 14).

Only one other study has compared modes of administration of the OHIP-49 (2); this study also showed significant differences between modes of administration, with higher scores recorded for self-complete than with interviews. However, unlike our study, although the difference was

statistically significant, it was smaller than the minimally important clinical difference in OHIP-49 scores that has been reported for prosthodontic patients (15). This is an important consideration, because if the minimally important clinical difference for periodontal patients is accepted to be broadly similar to that of prosthodontic patients, then our data suggest that it might be possible to falsely demonstrate a clinically significant change in status by simply mixing the modes of administration of the OHIP-49 in cohorts of patients with periodontal disease.

Our results are similar to those of other studies investigating the influence of modes of administration on generic health related quality of life (HRQoL) measures. Several studies have reported a larger impairment in HRQoL as recorded in questionnaires which were self-administered by the participants as opposed to those delivered by an interview-based process (16-19). One of these studies also examined the costs, response rates, and quality of data between mail self-complete (mailed to participants) and telephone interview using generic OHRQoL questionnaires. They concluded that mailed questionnaires for self-completion had lower costs, higher response rates, higher numbers of missing items, and produced more accurate data than interview-administered quality of life questionnaires. There are advantages and disadvantages to any mode of administration and it is important to select the mode most appropriate for the study type.

Our study has some limitations. Firstly, we slightly under-recruited, according to the *a priori* power calculation, but a post hoc power calculation based on the actual effect size of 0.31 between summary scores suggests we achieved a power of 79%. Secondly, the BPE diagnosis does not provide full details about extent or severity of disease as only the highest score is recorded in each sextant and also, the use of BPE alone limits the generalizability of the results (20). Thirdly, our global question that was used prior to inclusion into the study ("Do you have any current problems with your teeth, dentures, mouth, jaws or face other than the gum disease you are being seen on clinic for today?) may lack the sensitivity to identify all dental disease that may have been present (but should have identified any gross dental problems). Lastly, the disadvantage of recruiting a sample of

referred patients is that they are often at an extreme end of the disease spectrum and they may not be representative of the whole population. This group of patients with periodontitis was, however, selected purposively to study the impact of method of delivery of OHIP in light of Reissmann *et al.*'s comments regarding the relative lack of psychosocial impacts in prosthodontic patients (2).

5. CONCLUSION

The mode of administration (manual-self complete versus telephone interview) did substantially influence the OHIP-49 scores in patients with chronic periodontitis. The OHRQoL differed between the two modes of administration, with significantly higher scores (indicating poorer OHRQoL) when the questionnaire was manually self-completed, suggesting that mixing administration modes could introduce error into future studies. On the basis of our data, it would therefore appear to be inadvisable to mix administration modes of OHIP-49 in an attempt to, for example, reduce respondent attendance.

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Figure 1 Box plots presenting the differences in the summary scores between the first and second administration and the two administration modes: manual self-complete and telephone interview administration of the questionnaire.

The centre line is the median, the upper and lower limits of the box represent the upper and lower quartiles, and the whiskers indicate the range of values (excluding outliers, which are represented by the dots).

** : $p < 0.01$

*** : $p < 0.001$

Table 1 **Comparison of the OHIP-49 median scores between the first and second administration**

OHIP-49 Domains & Scores	First administration	Second administration	P value
	Median (IQR)	Median (IQR)	
Functional limitation	12 (6-16)	8 (4-15)	0.010
Physical pain	8 (4-13)	7 (2-13)	0.108
Psychological discomfort	8 (3-15)	7 (1-14)	0.002
Physical disability	3 (1-6)	2 (1-9)	0.894
Psychological disability	4 (1-10)	4 (0-8)	0.002
Social disability	0 (0-2)	0 (0-1)	0.102
Handicap	1 (0-4)	0 (0-4)	0.512
Summary score	35 (20-65)	27 (12-67)	0.004

Wilcoxon Signed Rank test

Table 2 **Comparison of the OHIP-49 median scores between the two administration modes: manual self-complete and telephone interview administration of the questionnaire**

OHIP-49 Domains & Scores	Manual self-complete	Telephone	P value
	Median (IQR)	Median (IQR)	
Functional limitation	12 (6-17)	8 (4-14)	0.001
Physical pain	9 (4-15)	7 (2-12)	0.001
Psychological discomfort	8 (3-15)	7 (1-14)	0.003
Physical disability	3 (1-9)	2 (1-7)	0.226
Psychological disability	5 (1-11)	3 (0-8)	0.000
Social disability	0 (0-2)	0 (0-1)	0.396
Handicap	1 (0-4)	0 (0-3)	0.142
Summary score	36 (20-70)	27 (11-61)	0.000

Wilcoxon Signed Rank test