

IN BRIEF

- A well-designed information leaflet has the potential to raise immediate knowledge levels of oral cancer in patients attending primary care facilities.
- Anxiety about an oral health screen appears not to be raised by such written material.
- Patients may be more willing to receive an oral health screen following access to the leaflet.
- Patient information leaflets are inoffensive for the patient, and inexpensive and time neutral for the practice

The immediate effect on knowledge, attitudes and intentions in primary care attenders of a patient information leaflet: a randomized control trial replication and extension

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Aim To determine whether the influence of a leaflet on mouth cancer improves knowledge, related attitudes and intention to accept a mouth screen.

Design Randomized controlled trial.

Setting Dental and medical waiting rooms in the North West of England.

Sample Nine hundred and forty nine patients from 16 practices were invited to participate.

Measures Standardized multi-item scales of six outcome measures including knowledge, beliefs and intention to accept an oral cancer screen.

Procedure A patient information leaflet was given to a randomized intervention group of patients. A single sheet questionnaire was completed by both groups of patients (immediately following leaflet administration in the intervention arm of study).

Statistical analysis *t* tests were used to compare outcome variables between patients with and without access to the leaflet with Bonferroni correction.

Results Participation rate was high (91%). Knowledge ($P < 0.001$) and intentions ($P = 0.003$) benefited from patient access to leaflet. Anxiety was not raised with leaflet exposure. Some beliefs about the screening procedure appeared to be slightly improved by reading the leaflet ($P < 0.05$).

Conclusion This study supports previous findings of an immediate positive effect of an information leaflet on patients' knowledge of oral cancer and willingness to accept an oral cancer screen.

The most significant delay in referral of patients with oral cancer to a district maxillofacial unit appears to be due to patients' non-recognition of the seriousness of their condition.¹ This would not be surprising as the public possess little knowledge about signs of oral cancer and its major risk factors. For example, over 80% were unaware that high alcohol consumption was associated with oral cancer.² Calls have been made in the UK³ and the USA⁴ for dental teams to improve patient awareness of oral cancer itself and associated risk factors. Previous work has demonstrated that a significant benefit can be obtained from the introduction of a patient information leaflet on 'mouth cancer' developed by the authors in hospital and primary care settings.⁵⁻⁷ Measurable improvements in knowledge of oral cancer were shown with patients who have access to the leaflet in the waiting room. Patients reported correctly on questions about signs and risk factors associated with oral cancer.⁶ Not only were relevant points of information drawn from the leaflet but also some evidence suggested that patients would be more amenable to accept an oral cancer screen.⁷ Concern about raising anxiety with patients accessing information about this cancer appeared to be exaggerated.⁷ In fact, the finding suggested the reverse; that is, patients with written information tended to be reassured rather than frightened, a result similar to that found in a different field (bowel cancer) where information and prevention is an important issue.⁸ Interestingly, these findings were not influenced by the age, gender or self-reported dental attendance of patients. Some questions were generated by our initial investigation. First, each self-report measure used previously was based on a single Likert question and their measurement qualities were uncertain, with the exception of the knowledge scale which was based upon the sum of 36 true/false questions. Further development of the assessment of attitudes and beliefs towards the preventive action of having an oral cancer screen was indicated.

Second, would an improvement in the measurement process in the same type of study result in similar findings to our previous work?^{6,7} Third, does the introduction of a leaflet that recommends

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a dental visit for checking for oral cancer have some influence on beliefs associated with having a screen?

AIM

To determine whether the influence of a leaflet on mouth cancer improves knowledge, related attitudes and intention to accept a mouth screen.

METHOD

Design of study

Patients were randomized into leaflet or no leaflet groups. Randomisation was achieved by assigning the session (defined as the typical period when the practice was open for a series of patients) as either: experimental or control, rather than individual patient assignment. The advantage of this approach was to prevent 'contamination' of patients who had not received a leaflet having access, unwittingly, to the written information when both experimental and control patients were sitting in the same waiting room area. The total sample required was a minimum of 530 to test for an expected difference of 5 on the primary outcome variable: knowledge of oral cancer, with a standard deviation of 4.3 (derived from previous study),⁶ adopting an alpha of 0.05 at 90% power assuming 15 observations per session and an intra-class correlation coefficient of 0.75.⁹

The leaflet described previously,⁵ has been improved by changes to layout and presentation, and was produced by Zila Europe™. It contained pictorial, diagnostic and textual information, presented under headings designed in a question and answer format on a multicoloured, double-sided, glossy A4 sheet, folded to provide six sections. Information was included on signs, risk factors, incidence, death rate, and behavioural approaches for the prevention and early detection of 'mouth' cancer in accessible language (Flesch formula = 78, classed as 'fairly easy'). The leaflet scores highly (11 out of a possible maximum of 13) on the new evaluation system for patient information sheets (MIDAS).¹⁰

Sample

A maximum variation-sampling frame for practice was adopted. Sixteen practices (9 dental, 7 medical) were selected within

Merseyside from a wide ranging set of localities. Deprivation has been highlighted as a key variable in predicting various aspects of oral health^{11,12} and is often expressed as a summary measure known as the Townsend index.¹³ The Townsend indices associated with the locality from which the practice resided at ward level were comparable (mean = 4.35; SD = 4.73) to the values for Merseyside (mean = 3.68; SD = 4.56).

Each interviewer collected a minimum of 50 patients. The number of sessions attended ranged from 3 to 8 (mean = 4). The interviewers were trained to ask for consent and to note all refusals. Inclusion criteria were to invite all consecutively attending patients who spoke English, and were 16 years of age or above. Visitors to the practice or relatives of patients were excluded. Gender and age group was determined to assess for a possible difference in response to questions (eg patients refusing to enter study may diminish generalisation of the findings as displayed). Randomisation into leaflet (experimental) and non-leaflet (control) groups was conducted by designating whole sessions to either experimental or control group.

Measures

Knowledge of oral cancer was assessed by the scale comprising 36 statements which respondents reply individually with either 'yes'-'no' or 'true'-'false' answers. The measure possesses reasonable reliability (KR-20 = 0.76) and criterion validity when tested in its development phase.⁵ Further psychometric details of the scale and other measures used in this study were collected from a sample of 140 undergraduate health science students who completed the questionnaire and retested 1 week later. This test-retest sample comprised predominantly of women (84%), aged 18 to 43 years (mean = 21, SD = 5). The majority claimed to visit the dentist every 6 months (81%) and drank alcohol (88%). Only 13% reported smoking tobacco. The reliability results are presented in Table 1. The Kuder Richardson-20 formula was applied to the knowledge scale as it comprised dichotomous items.¹⁴ The value obtained was 0.84 and gave a test-retest coefficient using the intra-class correlation coefficient (ICC) of 0.68.¹⁴

Five additional attitudinal scales were tested for reliability and their corresponding internal and test-retest coefficients are listed together with the number of items, range of scores and

Table 1 Description of questionnaire measures including number of items, possible range and direction of meaning, internal consistency (Cronbach's alpha) and test-retest (ICC) and example wording. (Reliability data obtained from undergraduate student sample, n = 140)

Scale	No. of items	Possible range	Internal consistency	Test-retest	Example
Knowledge of cancer scale	36	0-36 [†]	0.84*	0.68	You are more likely to get mouth cancer if you drink alcohol heavily.
Attitudes about negative consequences	2	2-14 [‡]	0.57	0.62	The dentist checking my mouth for oral cancer will give me discomfort.
Attitudes about lack of control	4	4-20 [‡]	0.69	0.55	I feel I am able to decide whether to allow the dentist to examine my mouth for cancer.
Normative beliefs ^α	6	3-48 [‡]	0.80	0.81	My dentist would want me to have my mouth checked for cancer.
Anxiety about screen procedure	3	3-15 [‡]	0.93	0.82	How do you feel about having a check for mouth cancer (patient answers using three types of ratings including: anxiety, worry and concern).
Intention to accept screen	2	2-14 [‡]	0.51	0.59	How likely would you agree to have an oral health screen (to check your mouth for cancer).

*KR-20,
[†]High score denotes positive quality
[‡]Low score denotes positive quality
^αComprises three pairs of questions. The ratings of each pair were multiplied to give a product, resulting three quantities summed (see text for further details).

example wording (see Table 1). Short descriptions of the scales are provided below. Copies of the questionnaire are available from the authors. Attitude towards possible negative consequences of having an oral cancer screen was assessed by two questions: 'the dentist checking my mouth for oral cancer will... (1) ...be a waste of time, (2) ... give me discomfort'. A five point Likert 'strongly agree' to 'strongly disagree' response format was used. The sense of control that the patient may think s/he possesses in accepting the screen was tapped by four questions, using the same answering format.

The assessment of beliefs about whether other people would sanction the respondent to accept a mouth cancer screen was tapped using three pairs of items in accordance with recommendations.¹⁵ Each pair consisted of two statements. First, that a significant person [doctor, dentist or family member] 'would want me to have my mouth checked for cancer' and second, that 'generally speaking I usually do what my [doctor, dentist, family] wants me to do'. The strongly agree/disagree 5-point Likert scale was employed for each item of the pair. Both items in the pair were multiplied to derive a product, ranging from 1 to 25. All three pairs were summed to produce a scale ranging from 3 to 75. A high score would represent a low pressure to conform to the recommendation to having a screen.

The anxiety to mouth screen scale comprised three items which were summed to give a scale ranging from 3 to 15 (low to high anxiety) using the common stem: 'How do you feel about having a check for mouth cancer?' Patients responded to each item by a 5-point rating scale with verbal anchors for anxiety ('not anxious' to 'extremely anxious'), worry ('not worried' to 'extremely worried') and concern ('not concerned' to 'extremely concerned').

The intention to accept a mouth cancer screen scale was assessed with two questions: 'how likely would you agree to have an oral health screen to check your mouth for cancer' and 'how likely would you refuse to have a check for oral cancer'. A 7-point rating scale was employed for both items and coded 1 'extremely unlikely' to 7 'extremely likely'. The second question was reversed scored. The scores of both items were summed. The resultant scale ranged from 2 to 14 denoting the intention to not accepting to fully accepting a mouth cancer screen, respectively.

Questions to ascertain the age, gender, smoking status (currently smokes tobacco, smoked tobacco previously, never smoked), alcohol consumption status (currently drinks, does not drink alcohol), attendance history (regularly attends every 6 months, only when in trouble or never) were included from the previous version of the questionnaire. The level of agreement for these questions was high (kappas ranged from 0.9 to 1 derived from test-retest sample).

Procedure

The Local Research Ethical Committee reviewed and gave approval to the study. Recruitment occurred between October 1999 and September 2000. Trained interviewers arrived at the practices on days where non-specialist, that is routine services, were provided. Interviewers were instructed to follow written instructions on arrival at the practice for allocation of sessions to control or experimental condition. Session allocation was previously recorded from random number computer generated assignment. Instructions included advice to continue practice visits until 25 patients from each study condition had been successfully collected. Surplus participants (ie > 25 per condition) were included. The study was explained to the participants using an information sheet and invited to enter the study. After obtaining consent, the patients in the experimental group were given the leaflet to read and returned to the researcher. All participants, including the control group, completed the questionnaire.

Statistical analysis

Data was analysed by *SPSS for Windows v10™*. *t* tests were performed with all outcome measures across experimental and control groups following inspection of distributions to detect any marked violations from normality. We were reassured that the large sample size employed in this study would ensure that the sampling distribution of the mean (Central Limit Theorem) will be near normal (see Altman, p154 and others).¹⁶⁻¹⁸ A check was made for equal variances across groups using Levene's test. Adjusted degrees of freedom were employed and associated *t* values reported if unequal variances indicated. Univariate analysis of variance was used to determine the influence of practice setting (random intercept model) on the knowledge scale scores.¹⁹ Two tailed tests and an alpha level of 0.05 were applied. Where repeated testing was required, Bonferroni adjustment to the significance level was calculated.

RESULTS

A high level of participation in the project was achieved. A total of 949 patients were approached, of whom 88 refused. Reasons for refusal included: no spectacles for reading ($n = 33$), not interested or too busy ($n = 22$); did not have time ($n = 21$); medical condition ($n = 7$); and does not take part in surveys ($n = 5$). The response rate was 91%. The gender of the refuser was noted and their approximate age (in 20-year age bands). The refusers were of similar gender composition to the respondents ($\chi^2 = 1.65$; $df = 1$; $P = 0.2$). Age level of refusers was higher than respondents ($\chi^2 = 39.97$; $df = 5$; $P < 0.001$). Data with full information was analysed leaving 769 respondents (see trial profile in Fig. 1). The number of dropouts due to missing data was independent of group assignment ($\chi^2 = 2.57$, $P = 0.13$).

To establish if the randomisation procedure had successfully achieved equivalence between experimental and control groups, a number of variables were examined (Table 2). Age, gender, setting of the waiting room (dental or medical) and self reported health behaviours (alcohol and tobacco consumption, dental visiting behaviour) were found not to be statistically different between groups (all P 's > 0.05).

Table 3 shows the means, 95% confidence intervals, P levels and effect sizes (standardized Cohen's d) for the six outcome variables across the two groups. The most significant effect of reading the leaflet was upon knowledge level ($t = 17.85$, $df = 767$, $P < 0.001$). Almost five extra question items (mean = 4.77, 95%CI = 4.24, 5.29) were correctly answered, on average, after access to the leaflet. The effect size was high ($d = 1.29$).²⁰ Intention to accept a screen was more positive in patients who had read the leaflet

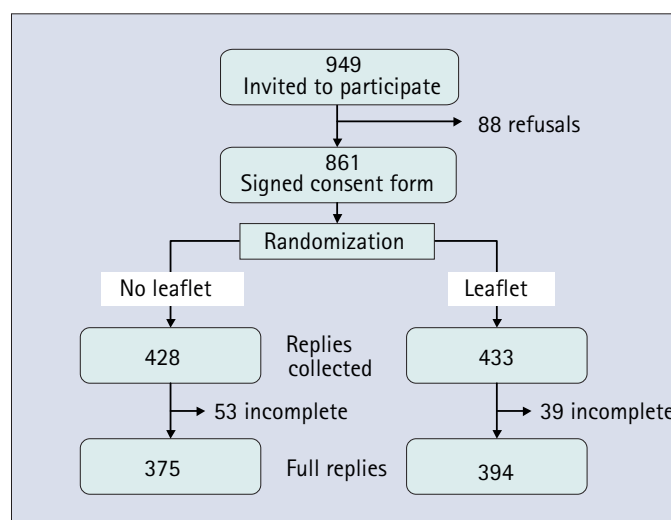


Fig. 1 Trial profile

Table 2 Comparison between experimental (leaflet) and control (no leaflet) groups on demographic, clinic type, and self-reported health behaviours

		Leaflet		No leaflet	
		N	%	N	%
Gender	Female	219	55.6	233	62.1
	Male	175	44.4	142	37.9
Clinic	Dental	245	62.2	232	61.9
	Medical	149	37.8	143	38.1
Dental visiting*	Every 6 months	285	75.2	259	72.5
	Less than every 6 months	94	24.8	98	27.5
Alcohol consumption	Yes	280	71.1	277	73.9
	No	114	28.9	98	26.1
Tobacco	Yes	114	28.9	101	26.9
	No	280	71.1	274	73.1
Age (in years)	Mean (SD)	42.63 (14.86)		42.76 (16.50)	
Base		394	100	375	100

*Self reported behaviour, data missing: n = 33

($t = 3.02$, $df = 759$, $P = 0.003$). The strength of the effect was low (mean difference = 0.43, 95%CI = 0.10, 0.78, $d = 0.22$). Bonferroni adjustment indicated with six tests that the significance level should be altered to 0.008. All remaining outcome variables failed to achieve significance under this more stringent statistical treatment. The results are briefly presented. Patients from the leaflet group had stronger beliefs that health personnel and family would expect them to accept the screen (mean difference = -0.83, 95%CI = 0.14, 1.51; $t = -2.35$, $df = 767$, $P = 0.019$; $d = 0.17$). Furthermore, patients exposed to the leaflet believed that the screen would be less of a waste of time and not painful (mean difference = 0.245, 95%CI = 0.019, 0.47; $t = -2.13$, $df = 767$, $P = 0.038$, $d = 0.15$). Both beliefs about control over whether to have the screen and anxiety associated with the screen were not influenced by leaflet access in the patients involved in this study (both t 's less than 1.8, $P > 0.05$).

To test if the effect of practice was a feature of the uptake of new knowledge from the leaflet a univariate analysis of variance was performed with knowledge as the dependent variable and

the experimental/control variable entered as a fixed effects independent variable. Practice was entered as a random effects independent variable.¹⁹ The main effect of practice and the interaction effect of practice with the experimental/control group breakdown were not statistically significant ($F[15,742] = 0.904$, $P = 0.527$; $F[15,742] = 2.03$, $P = 0.091$ respectively) showing that the general influence of the practice setting was not featured in the message uptake of the leaflet. The practice variable was summarized into 'dental' and 'medical' practice type. Knowledge scores from patients in the dental practice were 0.46 greater (95%CI of the difference: -0.18, 1.10) than those obtained in the medical practice ($F[1,768] = 2.61$, $P = 0.107$). Analysis of variance confirmed that the knowledge scale was independent of which setting the leaflet was used, that is the leaflet by practice type interaction was insignificant ($F[1,768] = 0.025$, $P = 0.875$).

The leaflet had varied effects on the answering of the knowledge scale. Chi square tests were performed for each item searching for the association between correct response and group membership (experimental vs control). The significance level was

Table 3 Means, SE,95%CIs, P levels and effect sizes (Cohen's d) for outcome variables across no leaflet (n = 375) and leaflet (n = 394) groups

	Group	Mean	Std. error	95% Confidence interval		P level	Effect size
				Lower	Upper		
Knowledge about oral cancer	no leaflet	26.11	0.19	25.73	26.48	0.001	1.29
	leaflet	30.87	0.18	30.51	31.24		
Attitudes about negative consequences	no leaflet	3.97	0.08	3.81	4.13	0.038	0.15
	leaflet	3.73	0.08	3.57	3.88		
Attitudes about lack of control	no leaflet	7.91	0.09	7.72	8.10	0.078	0.13
	leaflet	7.67	0.09	7.49	7.86		
Normative beliefs	no leaflet	13.34	0.25	12.84	13.83	0.019	0.17
	leaflet	12.51	0.24	12.03	12.99		
Anxiety about screening procedure	no leaflet	5.58	0.13	5.31	5.85	0.069	0.13
	leaflet	5.23	0.13	4.97	5.50		
Intention to accept screen	no leaflet	11.61	0.12	11.36	11.86	0.003	0.22
	leaflet	12.15	0.12	11.91	12.39		

Table 4 Per cent improvement in correct answers to knowledge items (first 10 in rank order)

	Wording of item	Leaflet (a)	Non leaflet (b)	Improvement*(c)	95% CI of Improvement
1	Sign of mouth cancer: a red patch in the mouth	80.1	45.5	34.6	28.4 to 40.4
2	More likely to get mouth cancer if a man	61.0	27.9	33.0	26.6 to 39.1
3	A check up for mouth cancer is carried out using X rays [†]	79.7	46.7	33.0	26.7 to 38.8
4	More likely to get mouth cancer if drink alcohol heavily	70.4	39.0	31.5	25.0 to 37.6
5	Sign of mouth cancer: a white patch in your mouth	83.8	51.2	32.7	26.6 to 38.4
6	Sign of mouth cancer: a yellow patch in your mouth [†]	71.1	41.8	29.3	22.9 to 35.5
7	Sign of mouth cancer: a painless ulcer	73.4	46.7	26.7	20.3 to 32.9
8	More likely to get mouth cancer if aged over 50 years old	66.1	42.5	23.6	17.0 to 29.9
9	Sign of mouth cancer: a rash on the face [†]	91.0	71.4	19.6	14.5 to 24.7
10	In the UK about 300 people get mouth cancer every year	83.1	63.6	19.5	13.7 to 25.2
20	More likely to get mouth cancer if chew tobacco	73.2	62.0	11.2	5.0 to 17.4
21	More likely to get mouth cancer if smoke tobacco	85.7	75.4	10.3	5.0 to 15.6

*Improvement in per cent knowledge correct: columns (a) – (b) = (c); [†]correct answer false

changed to 0.001 to account for the 36 tests conducted. As seen in Table 4, the strongest influence was reflected in the question about a red patch in the mouth being a sign of mouth cancer as shown by 35% improvement in those with access to the leaflet compared with controls ($\chi^2 = 110.3$; $df = 1$; $P < 0.001$). Other questions that demonstrated high per cent correct following leaflet reading by patients (all $\chi^2 > 19$; $df = 1$; $P < 0.001$) were the signs of oral cancer, namely: white (84%) and yellow (71%) patches in the mouth, painless ulcer (74%) and risk factors including heavy consumption of alcohol (71%) and being male (61%). Some questions were moderately better with leaflet access including smoking (11% improvement, $\chi^2 = 15.1$; $df = 1$; $P < 0.001$) and chewing tobacco (12% improvement, $\chi^2 = 11.8$; $df = 1$; $P < 0.001$). The average improvement in knowledge – expressed as the median percentage correct of all 36 questions – between those patients who had read the leaflet and those who had not was 14 (min,max: 0,35; IQR = 14.8). This level of improvement compares well with the original study which reported a median per cent improvement in knowledge of 10 (min,max: -3,40; IQR = 15.2). The correlation (Spearman's rho) between the improvement percentages for the 36 items in both studies was 0.91 ($P < 0.001$).

DISCUSSION

The findings from this study confirm previous reports in two respects. First, the improvement in knowledge from access to the leaflet was about the same in the current and previous survey.⁶ This was demonstrated by the near identical level, in both studies, of extra items (approximately 5) answered correctly in the experimental compared with the control group. The effect sizes from both studies, 1.15 in the original and 1.29 in the current study, indicated that the leaflet boosted knowledge at a consistent level (combined effect = 1.22, 95%CI: 1.11 to 1.33 using fixed effects model).²¹ In addition, the rank order of items arranged in magnitude of the percent improvement from access to the leaflet was similar in both studies.⁶

Second, the intention of patients to accept an oral cancer screen was increased with access to the leaflet. The effect size was small but parallels the finding from the previous study that used a single question to assess this 'behavioural' construct.⁷

Anxiety about the screening procedure was not influenced by leaflet exposure unlike the original study. Although this result was disappointing, it is important to note that the leaflet did not raise anxiety contrary to popular belief that informing patients about cancer will automatically raise anxiety. On close inspection of the means of the anxiety rating it can be seen that a trend existed for reassurance following reading of the leaflet compared with those with no access. A possible explanation for the limited effect of the

leaflet on anxiety may be that more time is required for patients to assimilate the new information to influence any distress felt about considering accepting an oral health screen.

The influence of the leaflet on the other outcome variables was less. The leaflet did appear to have an influence on the beliefs of patients about the difficulties associated with having an oral cancer check. These concerns, of focusing on the procedure being painful and time wasting, were more evident in the control group without leaflet access.

The extent that dental and medical personnel use educational aids for their patients in the oral cancer field is poorly understood.³ However, some evidence from the smoking cessation area suggests that dentists prefer to use leaflets rather than direct face-to-face interventions.²² Even complex information systems such as touch screen methods perform no better in providing knowledge than a well-designed leaflet.²³ Direct face-to-face communication between patient and clinician is to be recommended,^{24,25} however where other methods, perhaps as a default, are used in the form of written information it is important that well-designed materials are used. The argument that knowledge bears no relationship to actual behavioural change is now so well rehearsed that it almost does not require repeating.²⁶ The difficulty with this statement is that it may be over stressed, and that in particular cases there is still an important place for the dissemination of knowledge.^{4,27} Informing the public about oral cancer may be such a case as patients are not well informed, generally, about the possibility of oral cancer, its signs, and risk factors.^{2,28,29} Neither are they clear that their dentist can check for presence of a malignant lesion.³⁰ In this context, it is an important principle of health promotion to inform patients about this potential disease to allow patients to respond as they wish.^{4,27}

STUDY LIMITATIONS

Some limitations of the study are noted. Participation rate was high although drop-out analysis indicated older members of the practice refused. In addition, some patients who consented did not complete the full questionnaire. This second version of the questionnaire was a development of the original reported previously.⁵ The number of items had been increased by about 20% which may have been responsible for some non-response. However, the extent of the loss was similar across the experimental and control groups thereby reducing the possibility of bias. The study findings were applicable to patients attending their primary care facility in the North West of England. Caution should be employed when generalising more widely, although there was no association of practice (and indirectly deprivation) with knowledge level. It is worth noting that the study describes

only the immediate effect of the leaflet and further work has started to shed light on the longer term effects.³¹

CONCLUSION

This study supports previous work by the authors in confirming the strength of effect of a well-designed information leaflet. The main influence was to increase knowledge about signs and associated risks of oral cancer. The introduction of this minimal intervention was non-intrusive, inexpensive and time neutral. Questions remain unanswered however, including: what is the duration of the effect of this written information, and what implications does the improvement have on patient and dentist behaviour?

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