Original Article

Impact of Paper Information Leaflets on Dental Anxiety and Well-Being in Czech Patients: A Randomized Clinical Trial

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Aim: Dental anxiety and well-being significantly influence patients' oral health and quality of life. This study investigated whether providing paper information leaflets (PILs) before performing dental procedures improved psychological well-being and reduced anxiety in Czech patients. Materials and Methods: This parallel-group, single-blind randomized, prospective clinical trial was conducted at a private dental clinic in the Czech Republic in 2020. A total of 167 adult patients were randomly assigned to either the experimental group (n = 82), receiving both verbal information and a PIL, or the control group (n = 85), receiving only verbal information before their dental procedure (fillings, endodontic treatment, prosthetic restorations, or extractions). Pre- and post-procedure psychological well-being and anxiety were assessed using study-specific questionnaires. Data analysis was conducted in R using RStudio, with a significance level set at P < 0.05. Between-group differences were assessed while controlling for gender and education. Linear regression was used to analyze pre-procedure anxiety, and logistic regression was used to analyze post-procedure well-being outcomes (reporting "everything was fine," "unpleasant mouth sensations," and "quick adjustment"). The Benjamini-Hochberg correction was applied to control for multiple comparisons. Sensitivity analysis used the "best-worst and worst-best case" method to evaluate nonrandom missing data. Power analysis determined a minimum of 64 participants per group for a two-tailed t test. Results: Baseline anxiety levels, measured on a 1-6 scale, were similar between the PIL group (mean 4.26, SD 1.11) and the control group (mean 4.36, SD 1.17; $\beta = -0.11$, P = 0.54). Post-procedure, while fewer patients in the PIL group reported that "everything was fine" (28/82 vs. 39/85), this difference was not statistically significant after correction for multiple comparisons (uncorrected P = 0.038, $\alpha_{\text{FDR}} = 0.01$). No significant differences were found between groups regarding "unpleasant mouth sensations" (P = 0.84) or "quick adjustment" (P = 0.52). **Conclusion:** Providing PILs in addition to verbal information did not significantly impact pre-procedure anxiety or post-procedure well-being in this sample of Czech dental patients. These findings indicate that verbal communication alone may be sufficient for managing patient anxiety and promoting well-being in this context. Further research using validated instruments and exploring different communication strategies is warranted.

KEYWORDS: Anxiety management, dental anxiety, dental care, doctor-patient communication, information leaflet, patient education, well-being

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Introduction

ental anxiety is a phenomenon that affects millions of people worldwide and has a profound impact not only on oral health but also on an individual's overall well-being. [1-3] Research indicates that anxiety and fear of visiting the dentist can lead to delays or complete avoidance of necessary dental care, which subsequently worsens the patient's health status and increases the costs of subsequent treatment. [4] However, dental anxiety is not merely a concern of individual health; it also has broader social and economic implications. [5.6]

Well-being is defined as the overall mental comfort and health of the patient. It plays a crucial role in dental care and can significantly affect both the treatment process and its outcomes. Modern approaches in dentistry increasingly take into account not only the physical aspects of treatment but also the psychological and emotional needs of patients.^[7,8] Research indicates that patients who feel well and are in a good psychological state are more willing to attend regular preventive checkups. They also cooperate better during necessary procedures.^[9,10]

One effective method to reduce anxiety and fear associated with dental treatment and to promote patient well-being is to provide sufficient information about the treatment.[11,12] Providing information to patients is a cornerstone of doctor-patient communication.[13] The gold standard approach remains informing patients through verbal communication.[14,15] However, in the current modern era, other available means aimed at patient education, including highly technological options, can also be utilized. These include AI technologies, such as ChatGPT;[16,17] informational videos viewed through virtual reality technology;[18] and mobile applications on smartphones and tablets.^[19] Despite the current digital age, patients still often prefer well-established traditional non-digital techniques.[20] A study comparing the use of paper and digital information leaflets showed that 54.6% of patients preferred both formats (paper and digital), 33.3% preferred the paper format, and 12% preferred the digital leaflet.[21] Nondigital information sources are perceived as more accessible and useful, particularly favored by older patients and those with higher education.[22,23]

Information leaflets are globally recognized tools; they provide written, comprehensive information to educate patients about their illnesses, medication usage, and lifestyle adjustments.^[24,25]

To our knowledge, no studies in the Czech Republic, a Central European country, have examined the

impact of patient information on dental anxiety and well-being in dentistry. We aimed to fill this gap in knowledge by investigating the relationship between patient information, well-being, and anxiety among adult patients during dental care. We examined the differences between providing information verbally only and a combination of verbal communication and paper information leaflets (PILs).

Since validated standardized questionnaires assessing dental anxiety and well-being were not available in the Czech Republic (although spiritual well-being was later validated by Tavel *et al.*^[26]), we developed and piloted our own questionnaires. We also created the PILs based on data from current scientific literature and piloted them as well. This study represents the first prospective study of this kind in the Czech Republic.

The aim of our study was to determine whether providing patients with additional information through PILs, alongside verbally communicated information about a procedure, reduces anxiety or enhances well-being related to the dental treatment. We thus formulated two primary hypotheses: (1) providing information through PILs reduces patient anxiety before the dental procedure and (2) PILs increase patient well-being after the dental procedure.

MATERIALS AND METHODS

STUDY DESIGN

This single-blind, prospective, parallel randomized clinical trial was conducted at a private dental clinic (Czech Republic, Central Europe), which was the workplace of the first author, from January to December 2020. The dental clinic focused on treatments within the scope of general dental practice. The same dentist (the first author) provided the information and performed the treatments as well.

ETHICAL CONSIDERATIONS

All procedures performed were carried out in accordance with the ethical standards of the institution and the principles of the Helsinki Declaration of 1975, as revised in 2013. All participating patients were informed in advance about their inclusion in the research, were provided with all the criteria of the study, and then subsequently signed a written informed consent for participation.

The number for the Clinical Trials Registry - India registration is REF/2024/09/092562.

RESEARCH SAMPLE

The sample consisted of adult patients treated at a private dental clinic. The inclusion criteria were as

follows: age over 18 years, consent to participate in the study, and the need for one of the following dental treatments: dental filling, endodontic root canal treatment, prosthetic restoration using fixed dental crowns and bridges or removable dental prostheses, or extraction of erupted teeth. Children and patients unable to read the leaflet (due to health or intellectual limitations) were excluded from the study. Participants who did not complete the post-treatment questionnaire were also excluded. The study tracked patients' gender, age, highest level of education, and type of dental procedures undergone.

EXPERIMENTAL MORTALITY

The mechanism behind missing data due to participant exclusion in this study is unknown. It may be related to differences in participant motivation associated with the intervention or other factors. Therefore, the use of standard imputation methods to replace the missing data was deemed inappropriate. To address these nonrandom missing data, we applied a sensitivity analysis in accordance with available guidelines, using the "best-worst and worst-best case" method, which allowed us to model extreme scenarios regarding the impact of missing data on the study outcomes, ensuring the robustness of our conclusions under different assumptions about the missing data.

PROCEDURE

In the study, we worked with two groups of patients: (1) a group informed orally without a PIL and (2) a group informed both orally and with a PIL. Patients who attended for the planned treatment received information about the procedure immediately beforehand, either orally (standard) – the group without the PIL (control group) – or through a combination of oral and written information – the group with the PIL (experimental group). After receiving the information (oral or combined oral and written), each patient completed the pretreatment questionnaire (No. 1) and then underwent the dental procedure.

One week after the procedure, the post-treatment questionnaire (No. 2) was administered to the patients. This questionnaire was given either in paper form during the patient's follow-up visit or, more commonly, online through the Google Form platform, where the questionnaire was sent to the patients via email.

RANDOMIZATION AND BLINDING

To minimize bias in the study, 170 participants were randomly assigned to the control or experimental groups using a computer-based random number generator (Random.org). A complete list of eligible participants meeting the inclusion criteria was prepared, with each participant assigned a unique identification number. Randomization was performed in a 1:1 ratio to ensure equal allocation, resulting in 85 participants per group. The allocation list was created by assigning participants to the control or experimental groups based on the generated sequence: participants with even identification numbers were assigned to the control group, while those with odd numbers were assigned to the experimental group.

A single-blind approach was used in this study, meaning that participants were unaware of their group assignments. One group received the PIL as part of the intervention, while the other group did not. The PIL was provided just before the dental procedure was performed, when patients were directed to the waiting room to read it. To ensure that patients with and without the PIL were not mixed, only patients from the same group were scheduled for treatment on a given day. The group that did not receive the PIL was given the same initial communication as the intervention group to ensure no apparent differences between the groups were perceived. The researchers conducting the intervention were not blinded and were aware of the participants' group allocation, as they were responsible for distributing the PILs. To minimize social desirability bias, participants were assured of confidentiality and anonymity in their questionnaire responses, encouraging honest and unbiased feedback.

INSTRUMENTS

Questionnaire development and validation

In the Czech Republic, a standardized questionnaire mapping dental anxiety or psychological well-being was not available. Therefore, we created our own questionnaire, which we piloted on a sample of the Czech population. The pretreatment questionnaire (No. 1) aimed to assess how information about the procedure affects patients' psychological well-being and whether it induces anxiety. Example questions included: "How are you feeling right now?" (patients selected on a scale of 1-6) and "What does it mean to you that you have to undergo the procedure today?" (patients chose from the provided answers). The questionnaire also explored how the information influences patients' awareness of the upcoming procedure and aimed to identify any additional questions they might have regarding the treatment.

The post-treatment questionnaire (No. 2) inquired about the extent of the information provided to the patients and whether it was necessary to seek additional sources of information, and

if so, what those sources were. It assessed the psychological impact of the information on the patients' psychological well-being. Additionally, it explored the patients' subjective feelings (e.g., pain and adjustment) in relation to the procedure they underwent. Example questions included: "What happened after the procedure?" and "Information about the procedure" (where the patient selected from the provided answers). To validate the questionnaires, a multistep process was followed to ensure their comprehensibility and suitability for the target population. Initially, we developed the questionnaires and conducted pilot testing with ten individuals without medical or psychological **Participants** education. were given questionnaires to complete and provided detailed feedback to the researchers on comprehension, ambiguity, and clarity, either through written notes on the questionnaires or verbally. The primary goal was to assess comprehensibility for the general public.

Feedback from participants highlighted areas needing improvement. We adjusted ambiguous questions, simplified complex language, and clarified instructions to address all concerns from the initial pilot test. To validate these changes, a second round of pilot testing was conducted with similar participants to confirm that modifications improved comprehensibility. The second phase yielded mostly positive evaluations, with participants providing only minimal, stylistic comments that were easily addressed. Based on these positive evaluations, the final version of the questionnaires was deemed suitable for the general public and used in the main research.

Paper information leaflets

PILs were created in five versions: dental filling, endodontic root canal treatment, fixed prosthetic tooth replacement (crown and bridge), removable prosthetic tooth replacement, and tooth extraction. The text of the PILs was simplified to ensure clarity for the general public. The source of information was current dental literature. The PILs were supplemented with images, and the final versions were printed in color. Subsequently, the materials were pilot-tested in a manner similar to the questionnaires (see above).

STATISTICAL ANALYSIS

Data analysis was performed using the R programming language with the RStudio interface. Two primary hypotheses were tested.

Hypothesis 1: Providing information through PILs reduces patient anxiety before the dental procedure

Data were extracted from the pretreatment questionnaire (No. 1) from the first question, "How are you feeling right now?" Patients selected from a scale of smileys ranging from 1 to 6. Linear regression was used as the statistical test.

Hypothesis 2: PILs increase patient well-being after the dental procedure

Patients had the option to choose from eight responses, with the possibility of selecting multiple answers. From these responses, we selected three for our analysis to assess the patient's psychological well-being. Three responses were chosen to reduce the number of statistical tests and minimize the risk of false-positive results. Therefore, within this hypothesis, we examined whether patients who received a PIL were more or less likely to report the following after the procedure: 1) everything was fine, 2) I had an unpleasant feeling in my mouth, and 3) I got used to it quickly. The question was recoded into a format with responses as dummy variables. The selected variables were then tested using logistic regression. Data were obtained from the post-treatment questionnaire (No. 2).

Prior to regression analysis, we conducted betweengroup differences by controlling for confounding factors such as gender and education. We also compared participants who completed both questionnaires with those who completed only one. If the groups differed significantly, these variables were added as covariates to the aforementioned regression models to account for initial differences between the groups and increase the accuracy of the estimates.^[27] To control the false discovery rate, the Benjamini–Hochberg correction was used.[28] This correction was applied only to the tests of coefficients related to the intervention effect, not to the tests of covariates. Sensitivity analysis was performed using the "best-worst and worst-best case" method to assess the impact of nonrandom missing data. Analyses were corrected for multiple comparisons to further ensure robustness. The level of statistical significance was set at P < 0.05.

The sample size calculation, based on a power analysis, assumed a medium effect size (Cohen's d=0.5), a significance level (α) of 0.05, and 80% power, resulting in a minimum requirement of 64 participants per group for a two-tailed independent samples t test. This medium effect size was chosen based on prior studies in the field reporting similar intervention outcomes. To account for an expected drop-out, the target sample size was increased to 85 participants per group, resulting in a total planned recruitment of 170 participants.

RESULTS

RESEARCH SAMPLE

The initial sample consisted of 167 patients in total [Table 1]. The intervention group comprised 82 (49%) patients who received a PIL before treatment. The control group, which received standard care, included 85 (51%) patients. Overall, the sample consisted of 22% more women than men, and most patients were of middle age. The majority of patients had either secondary education (43%) or higher education (41%). The representation of other education categories was low, so for further analysis, we grouped participants into "lower" education (primary and secondary) and "higher" education (tertiary, including college and university). There were 20% more patients with tertiary education in the control group (P < 0.05). The groups did not differ significantly in other variables.

EXPERIMENTAL MORTALITY

A total of 167 respondents participated in the first stage of measurement, completing the pretreatment questionnaire [Table 2]. Of these individuals, 144 participants completed the post-treatment questionnaire, resulting in a response rate of 86%. Of the total number of patients who completed the study, 76 (53%) received a PIL and 68 (47%) did not [Table 3].

Among the respondents who did not complete the study, there was a 26% higher proportion of men (P < 0.05), 27% more who did not receive PIL (P < 0.05), and 23% fewer patients with dental fillings (P < 0.05). Experimental mortality was not dependent on education (P = 0.17) or age (P = 0.78).

The mechanism of missing data is unknown. It could be related to different motivations associated with the intervention or other factors, making imputation methods unsuitable for this study.^[29]

Hypothesis 1: providing information through PILs reduces patient anxiety before the dental procedure

For more effective evaluation of the results, we divided the patients into two groups based on their feelings: negative feelings (with anxiety – smileys 1–3) and positive feelings (without anxiety – smileys 4–6). The average value on the 1–6 scale reported by the entire monitored group of patients was 4.31 (SD 1.14). Patients with PIL had an average value of 4.26 (SD 1.11), while patients without PIL had an average value of 4.36 (SD 1.17). The groups did not differ significantly in the levels of positive or negative feelings before the procedure ($\beta = -0.11$, P = 0.54).

Hypothesis 2: PILs increase patient well-being after the dental procedure

Among the patients who reported that everything was fine (a total of 67), there were 28 with PIL compared to 39 without PIL [Table 4]. Contrary to expectations, patients who received PIL reported an uneventful course less frequently (P = 0.038, $\alpha_{\rm FDR} = 0.01$); however, this trend was not significant after correcting for multiple comparisons.

The total number of patients who reported an unpleasant feeling in their mouth was 34, with 19 patients having received PIL and 15 without PIL. No significant difference was found between these groups (P = 0.84).

Table 1: Total sample						
Variable	Total, $N = 167^1$	Froup	P value ²			
		Control, $N = 85$	Experimental, $N = 82$			
Gender, n (%)				0.77		
Male	65 (39)	34 (40)	31 (38)			
Female	102 (61)	51 (60)	51 (62)			
Education, n (%)				0.011		
Lower	94 (56)	56 (66)	38 (46)			
Higher	73 (44)	29 (34)	44 (54)			
Age, median (IQR)	35 (28–44)	35 (28–44)	33 (28–44)	0.91		
Procedure, n (%)				0.21		
Dental filling	76 (46)	34 (40)	42 (51)			
Endodontic treatment	22 (13)	10 (12)	12 (15)			
Tooth extraction	48 (29)	31 (36)	17 (21)			
Dental crown	15 (9)	8 (9.4)	7 (8.5)			
Dental bridge	6 (3.6)	2 (2.4)	4 (4.9)			

¹n (%); Median (IQR)

²Pearson's chi-squared test; Wilcoxon rank sum test; Fisher's exact test

Table 2: Experimental mortality

Variable	Total, $N = 167^1$	Experimenta	al mortality	P value ²
		$N_0, N = 144$	Yes, $N = 23$	
Gender, n (%)				0.020
Male	65 (39)	51 (35)	14 (61)	
Female	102 (61)	93 (65)	9 (39)	
Education, n (%)				0.17
Lower	94 (56)	78 (54)	16 (70)	
Higher	73 (44)	66 (46)	7 (30)	
Age, median (IQR)	35 (28–44)	35 (28–44)	35 (28–45)	0.78
Procedure, n (%)				0.044
Dental filling	76 (46)	70 (49)	6 (26)	
Endodontic treatment	22 (13)	18 (12)	4 (17)	
Tooth extraction	48 (29)	41 (28)	7 (30)	
Dental crown	15 (9)	12 (8.3)	3 (13)	
Dental bridge	6 (3.6)	3 (2.1)	3 (13)	
Intervention, <i>n</i> (%)				0.017
No	85 (51)	68 (47)	17 (74)	
Yes	82 (49)	76 (53)	6 (26)	

 $^{^{1}}n$ (%); median (IQR)

Table 3: Description of the sample completed in the study

Variable	Total, $N = 144^{1}$	Lea	Leaflet		
		$N_0, N = 68$	Yes, $N = 76$		
Gender, n (%)				0.47	
Male	51 (35)	22 (32)	29 (38)		
Female	93 (65)	46 (68)	47 (62)		
Education, n (%)				0.039	
Lower	78 (54)	43 (63)	35 (46)		
Higher	66 (46)	25 (37)	41 (54)		
Age, median (IQR)	35 (28–44)	35 (28–44)	33 (28–43)	0.89	
Procedure, n (%)				0.29	
Dental filling	70 (49)	29 (43)	41 (54)		
Endodontic treatment	18 (12)	7 (10)	11 (14)		
Tooth extraction	41 (28)	25 (37)	16 (21)		
Dental crown	12 (8.3)	6 (8.8)	6 (7.9)		
Dental bridge	3 (2.1)	1 (1.5)	2 (2.6)		

¹n (%); median (IQR)

²Pearson's chi-squared test; Wilcoxon rank sum test; Fisher's exact test

Table 4. Post treatment questionnaire des	

Variable	Total, $N = 144$	Leaflet	
		$\overline{No, N = 68}$	Yes, N = 76
What happened after the procedure? (multiple possible answers)			
Everything was fine, <i>n</i>	67	39	28
I had an unpleasant feeling in my mouth, n	34	15	19
I was in pain, n	22	11	11
I was more focused on the site of the procedure, n	52	21	31
It was uncomfortable to have something in my mouth that I am not used to, n	8	3	5
I got used to it quickly, n	33	14	19
It was harder for me to talk, n	17	5	12
I had problems when eating and/or drinking, n	29	15	14

A total of 33 patients reported that they got used to it quickly after the procedure, with 19 patients having received PIL and 14 without PIL. Again, no significant difference was observed between these groups (P = 0.52).

²Pearson's chi-squared test; Wilcoxon rank sum test; Fisher's exact test

Table 5: Results of research questions (all models account for gender and education effects)

Model	OR	β	Conf. low	Conf. high	P value	$\alpha_{_{\mathrm{FDR}}}$
Everything was fine	0.483	-	0.241	0.956	0.0378	0.01
I had an unpleasant feeling in my mouth	1.088	_	0.493	2.423	0.8353	0.05
I got used to it quickly	1.297	_	0.586	2.926	0.5233	0.03
"How are you feeling right now?"	-	-0.1114	-0.469	0.246	0.5393	0.02

OR = odds ratio, β = beta coefficient, Conf. low = lower bound of the confidence interval, Conf. high = upper bound of the confidence interval, α_{FDR} = adjusted alpha value for the false discovery rate

All statistical models account for the effects of gender and education [Table 5]. A sensitivity analysis using the "best–worst and worst–best case" method found no evidence for either of the two hypotheses.

DISCUSSION

In the first measurement (Hypothesis 1) of our study, patients who received additional information in the form of PILs, along with verbal information, did not significantly differ from those who were only verbally informed in terms of positive and negative feelings before the procedure. The claim that PILs reduce dental anxiety compared to verbal communication was not confirmed. In the second measurement (Hypothesis 2), patients who received PILs reported an uneventful procedure less frequently than expected. However, this trend was not significant after correcting for multiple comparisons. There was no significant difference found between patients who reported an unpleasant feeling in their mouth after the procedure and those who reported quickly getting used to it. Our hypothesis that PILs increase patient well-being after a dental procedure was not confirmed in this measurement either.

When comparing patients who had already experienced a specific type of dental treatment with those who had not yet undergone such a procedure, it became evident that the second group could develop a high level of fear and an intention to avoid treatment.[30] This suggests that patients' fear may increase when they have little knowledge of what to expect.[31] It was also found that patients with a lower level of education have higher levels of dental anxiety.[32] Our study included patients mostly with high school and university or college education. The control group had 20% more patients with university or college education (P < 0.05). It is possible that the higher level of education among patients influenced their awareness of the treatment process. Consequently, providing information through PILs may not have been significantly beneficial for them. Patients in the control group had an even higher level of education, which could have contributed

to their better outcomes after treatment compared to the intervention group, despite not receiving PILs. However, this claim is not supported by the study findings by Muneer *et al.*^[6], which found that individuals with a higher level of education reported higher anxiety levels.

Our study did not confirm differences between written and verbal information in reducing anxiety, similar to the following studies. However, these studies showed that providing information in general had an effect on reducing anxiety. The format of the information provided did not play a significant role. Cabbar et al.[33] compared the effects of simplified verbal information and more detailed written information in patients undergoing third molar extraction and dental implant placement. All groups experienced a decrease in anxiety after the procedure (measured by the State Anxiety Inventory, STAI-S). However, there was no significant difference between the groups with and without written information. Amini et al.[34] studied three groups of patients undergoing hernia surgery and cholecystectomy in Iran. The control group received only very brief information before surgery. The two observed groups were given detailed information, either verbally or through an informational brochure. Both observed groups showed a significant reduction in anxiety (measured by State-Trait Anxiety Inventory, STAI) before being transferred to the operating room, compared to the control group. However, there was no significant difference between the two observed groups. This indicates that providing information, regardless of the method, was effective in reducing anxiety before surgical operations.

The following study demonstrated a positive effect of verbally provided information on reducing anxiety compared to written information. Research conducted on patients undergoing magnetic resonance imaging in India showed that providing verbal information significantly reduced their anxiety (measured by STAI) more than reading PILs.^[35]

The results of the following studies contradict our findings, where written information had a positive effect

on reducing anxiety or increasing well-being. Sancak and Akal^[36] divided patients undergoing third molar extraction into three groups. The first group received verbal information about the treatment process, the second group received written information, and the third group had prior experience with this surgical procedure. Both preoperatively and postoperatively, the STAI-S scores were similar across all groups, showing no decrease in anxiety on this scale. However, there was a decrease in anxiety on the modified dental anxiety scale (MDAS) in the second and third groups. Landier et al.[37] concluded that verbal information, supported by PILs, reduced anxiety and simultaneously increased the satisfaction of the parents of pediatric patients undergoing surgery. The study by Ferreira and Figueiredo-Braga^[38] showed that, compared to verbal information alone, providing a written brochure had a positive effect on the well-being of patients suffering from neurological dysphagia. A study by Symon and Crichton^[39] followed 80 mothers with infant sleep problems. They were provided with verbal and written information describing strategies to improve infant sleep, and this increased their well-being.

The levels of anxiety and stress can vary with different types of dental procedures. Huynh et al., [40] in their systematic review, compared stress levels during endodontic root canal treatment with those in other dental procedures. They concluded that endodontic treatment is more stressful compared to restorative and cleaning procedures. Tooth extraction is another procedure that causes increased anxiety among patients, and its level is influenced by factors such as gender and age.[41,42] In our study, we compared patients undergoing all commonly performed dental procedures, including conservative, prosthetic, and surgical treatments. It can be assumed that if we had a larger sample of patients, allowing us to divide them into groups according to the type of procedure, the results might have been different for patients undergoing tooth extractions and endodontic root canal treatment. In these groups, the levels of anxiety would likely have been higher than in other patient groups. We found no significant differences between groups based on gender and age.

Another variable that may influence the effectiveness of providing information is timing. Information can be given either just before the procedure or with some prior notice. Schwartz-Arad *et al.*^[43] provided information to patients just before dental implant placement using audio recordings. They found that the stressful and anxiety-inducing situation created by the surgical procedure significantly reduces the ability to process relevant

information. Their conclusion suggests that information should not be provided immediately before the planned procedure. In our study, we provided PILs just before the procedure. It is possible that if we had provided the PILs in advance, in accordance with Schwartz-Arad's conclusion, such as a week before the planned procedure, patient anxiety might have been lower.

As mentioned above, Sancak and Akal's[36] study found that two types of anxiety questionnaires led to different conclusions. This suggests that patients may respond differently to various questionnaires designed for similar purposes, which can affect the outcomes. It would be most beneficial to use the same validated questionnaires across all studies on anxiety or well-being to allow for adequate comparison and evaluation. The MDAS is a simple and concise questionnaire consisting of five questions, making it suitable for measuring dental anxiety in dental practice.[44] At the time of our study, no validated questionnaire for dental anxiety and wellbeing was available in the Czech Republic. Therefore, we developed and piloted our own questionnaires on a sample of the Czech population. It is possible that if we had used other questionnaires for dental anxiety and well-being, the results might have been different.

The results indicate that providing PILs before dental treatment may not directly impact anxiety levels and well-being but could contribute to better patient awareness and satisfaction.[37] Improved patient awareness may also lead to better adherence to instructions during and after dental procedures.[11,45] However, compared to the use of PILs, communication strategies that emphasize relationship-building, gauging patient values, and validating emotions appear more effective in reducing anxiety and disagreements and enhancing patient satisfaction.[46-48] These findings imply that while PILs can be valuable for delivering information and increasing satisfaction, their impact could be significantly enhanced when combined with empathetic, personalized communication from clinicians.[49,50]

To our knowledge, no research comparable to ours has been conducted in the Czech Republic so far. This makes our study groundbreaking in the context of the Czech Republic. The way this study connects the often overlooked and inseparable relationship between medical care and the patient's mental experience in our conditions is its strength. It examines the effect of PILs on patients undergoing all basic dental procedures. PILs and questionnaires were used, which were piloted on a sample of the local population. The study had a prospective design, with patients being monitored throughout the entire investigation.

We identify several limitations in our study. Standardized questionnaires for dental anxiety and well-being were not used. The standardization of the questionnaires may not fully account for differences in participant interpretation, such as those influenced by cultural background or education level. Additionally, the sample demographics may limit the generalizability of our findings as the study sample may not represent the broader population.

This was a single-blind study; the treating dentist knew which patients had access to PILs and who did not, which could have influenced the way he communicated with them. The study included a relatively small number of respondents, making it impossible to divide them into groups based on the type of procedure, which could have impacted the results. This study lacks baseline anxiety levels in the statistical analysis. This parameter was not measured, limiting our ability to account for its influence on the results.

Future research should examine these findings across different cultural contexts. In the Czech Republic, it should be validated by using commonly used scales such as the STAI, the MDAS, and the well-being scale. Future studies should incorporate these validated scales as cross-checking results with established scales will improve comparability across studies. Providing patient PILs several days in advance may allow patients to review them calmly, potentially reducing anxiety. Baseline anxiety measurement should be included to better control for potential confounding factors and improve result interpretation.

CONCLUSION

Providing additional information about a dental procedure in the form of a PIL did not affect patient anxiety or well-being beyond what was achieved with verbal communication alone. Therefore, the overall relationship between the dentist and the patient and the clarity of the information provided may be more critical for patient well-being than the form in which the information is delivered. To bring about a meaningful change in patient anxiety and wellbeing, dentists should emphasize effective verbal communication, such as demonstrating empathy, fostering trust, and responding to patients' individual concerns. Although PILs can serve as a supplementary informative tool, they should not replace the irreplaceable human connection that occurs during face-to-face communication. For clinical practice and patient education strategies, this highlights the need for a balanced approach where written materials are

seen as adjuncts to, rather than substitutes for, highquality verbal interactions. It is up to each dentist to decide how to integrate PILs into their patient communication, but the priority should always be to ensure that verbal communication remains the primary means of providing reassurance and building patient confidence.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

AUTHORS CONTRIBUTIONS

All authors have contributed to the drafting of the manuscript and have read and approved the final version.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

This research was approved by the Ethical Committee of University Hospital Pilsen and Faculty of Medicine in Pilsen, Charles University (June 6, 2024, Reference Number: 145/24).

PATIENT DECLARATION OF CONSENT

Informed consent was obtained from all participants involved in the study.

DATA AVAILABILITY STATEMENT

Data are available upon request.

Abbreviations

PIL(s) Paper information leaflet(s)

VR Virtual reality

MRI Magnetic resonance imaging STAI State-trait anxiety inventory MDAS Modified dental anxiety scale

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