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Intervention

Effects of patient education and therapeutic suggestions on cataract surgery patients: A randomized controlled clinical trial

Zoltán Kekecs [a,*], Edit Jakubovits [b], Katalin Varga [c], Katalin Gombos [d]

[a] Eötvös Loránd University, Faculty of Education and Psychology, Affective Psychology Department, Budapest, Hungary
[b] Semmelweis University, Faculty of Health Sciences, Hungary
[c] Eötvös Loránd University, Faculty of Education and Psychology, Affective Psychology Department, Hungary
[d] Szent János Kórház és Észak-budai Egyesített Kórházak, Ophthalmology, Hungary

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ABSTRACT

Objective: This paper describes a randomized controlled single blind study testing the effects of a patient education intervention combined with positive therapeutic suggestions on anxiety for cataract surgery patients.
Methods: 84 patients participated in the study. Physiological and behavioral indicators of anxiety were compared between a regularly treated control and an intervention group receiving an audio CD containing information, relaxation, and positive imagery.
Results: We found that the intervention group was calmer throughout the four measurement points of the study ($p = .004$; $d = 0.71$) and they were more cooperative ($p = .01$; $d = 0.60$) during the operation. The groups did not differ in sleep quality before the day of the operation, heart rate during the procedure, and subjective Well-being.
Conclusion: Findings indicate that preoperative information combined with positive suggestions and anxiety management techniques might reduce patient anxiety in the perioperative period of cataract surgery, but further research is needed to investigate the benefits of such interventions and to uncover the underlying mechanisms.
Practice implications: Patient education interventions providing additional anxiety management techniques are recommended for use prior to cataract surgery.

1. Introduction

Anxiety is the most common negative affect associated with surgery as well as a reliable predictor of postoperative mood and pain sensation [1,2]. Former studies confirmed that cataract surgery patients often experience fear and anxiety [3–5] not only during but also before and after the operation, and during post-operative visits [6,7]. The consequences of high perioparative anxiety range from increased pain sensitivity [2], blood pressure and heart rate [8], medication requirement [9], and reduced compliance during the procedure [10]. In addition, researchers found elevated intraocular pressure as a result of stress [11,12].

To decrease perioperative distress and to overcome its negative side-effects the use of psycho-educational intervention is advised in the literature [13,14]. So far only a handful of studies evaluated the effectiveness of such interventions for cataract surgery, even though it is one of the most common elective surgical procedures worldwide [15]. Researchers reported that providing information on the procedure, on the experience of undergoing surgery and on the potential risks decreased anxiety immediately after the operation [16] and one month after the procedure [17].

Another approach for mitigating anxiety during medical procedures is the use of positive verbal suggestions [18–20]. Suggestions are messages in an interpersonal communication which evoke automatic psychological, behavioral or emotional responses in the receiver [21]. They most likely assert their effects through priming mechanisms. Although suggestions are one of the most important tools of hypnosis, suggestive techniques can be successfully used without formal hypnosis induction as well [20]. Studies support that suggestions have beneficial impact on various surgical outcomes [22,23], and specifically on mitigating procedural anxiety (e.g. [24–26]).

The effectiveness of positive suggestions have been already investigated in ophthalmic surgery. One of the studies found that an intervention just before radial keratotomy increased the

* Corresponding author at: Izabella str. 46, 1st Floor, Room 121-128, Budapest H-1064, Hungary. Tel.: +36 30 554 5873; fax: +36 1 461 2691.
E-mail address: kekecs.zoltan@gmail.com (Z. Kekecs).

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subjective Well-being of patients the day after surgery, but did not decrease unnecessary movements during operation and pain experience [27]. Another report showed that relaxing suggestions played during cataract surgery improved patient and surgeon satisfaction and patients' level of relaxation while they did not show beneficial effect on cardiovascular measures and respiration rate [28].

So far no studies evaluated the effectiveness of a combination of preoperative information and positive suggestions in cataract surgery. Furthermore former studies usually looked at a small number of measurement points thus only providing information on a subset of the previously identified stages of perioperative distress [7].

The aim of our present study was to investigate the effectiveness of a preoperative psycho-educational intervention containing both information and positive verbal suggestions on reducing perioperative anxiety while measuring outcomes from pre- during and post-surgery as well as from the first postoperative visit.

2. Method

2.1. Participants

Based on the data retrieved from the study of Holden-lund [24] the a priori calculation in G*Power 3.1.3 [29] determined that a minimum total sample size of 34 would be needed in a repeated measures between subjects design to show a significant difference in postoperative anxiety ($d = -0.98$; $\alpha = 0.01$; $1 - \beta = 80$; *number of measurements* = 4; *correlation among repeated measures* = .50).

The study was carried out between 1st Febuary 2011 and 27th November 2011. We recruited participants from patients enlisted for cataract surgery at the Europmed Orvosi Szolgáltató Kft's Healthcare Center in Budaörs, Hungary. Patients (a) above the age of 17; (b) who could understand Hungarian; (c) who had no prior cataract surgery; and (d) ones with no hearing disability were eligible. Patients with a prior cataract surgery were excluded to avoid heterogeneity in anxiety resulting from the familiarity of the procedure [30,31]. Of the 122 patients who were assessed for eligibility, 111 were randomized and 84 completed the study (30 male and 54 female). (For further details refer to Fig. 1.). All but one of the participants (Arabic) were Caucasian, age ranging from 28 to 92 years ($M = 69.17$; SD = 11.30).

2.2. Procedure

The study was conducted according to the Helsinki Declaration of 1975, as revised in 2000, and has been approved by the Hungarian Medical Science Association's Science and Research Ethics Committee (permit reference number: 6327-0/2011-EKU (200/PI/11.) with attachment: 20391-0/2010-1018EKU (824/PI/10.)). All participants provided signed informed consent.

The recording of baseline characteristics was followed by group allocation. A research assistant randomly assigned participants to a control or an intervention group using 20 non-transparent cards labeled 'control group' or 'intervention group' which were re-shuffled for every participant. To assure blindness of the study team and the hospital staff the assistant was only responsible for group allocation and was not involved in further stages of the study, furthermore patients were instructed not to inform anyone as to which condition they had been assigned to. Subsequently, the intervention group listened to the intervention from a CD player through headphones and received a copy for home use, while control group patients received the regular clinical treatment and did not participate in psychological preparation. The assistant instructed intervention group participants to listen to the recording four times before the surgery to ensure some practice in the relaxation and imagery techniques. They were also told that the last time they should listen to the tape was on the night before the operation.

The intervention script was developed by the eye surgeon who conducted the operations (K. G., fourth author) and a hypnotherapist experienced in using positive suggestions in medical contexts (E. J., second author). The recording was 15 min 27 s in length and was read out by K.G. The script provided information on the phases of the operation and the recovery period, while using positive suggestions and introducing relaxation and imagery techniques. For example the CD encouraged patients to focus their attention on controlling their breathing and to imagine a safe place during the operation. Some examples from the script: 'When you arrive in the forefront of the operating room you'll get a number of eye drops (...) It'll be good to know that with every drop your pupil will get more dilated and dilated and your eye will get more and more anesthetized as long as it's needed.'; 'First your eye will be cleaned with a disinfectant solution (...) Some imagine this like a pleasant cool breeze that washes away not only bacteria but the remaining tension as well.'

In the perioperative room after the initial medical examination, patients got one Xanax pill (0.25 mg of Alprazolam–as an anxiolytic, a standard procedure in the healthcare center). Patients spent approximately 30 min in the perioperative room.[1] To control as many confounding factors as possible, only one surgeon performed all the operations (K. G., fourth author) in the same operating room (OR) with the same surgical staff. After the operation, patients returned to the perioperative room where they rested with their eyes closed for 20 min, and were discharged shortly after a brief examination. The following day patients returned for a postoperative visit where the intervention group patients were asked of the number of times they had listened to the recording at home. Most participants claimed to have listened to the recording four times ($M = 4.21$; SD = 2.16). Although two patients did not listen to the tape at home at all, they were still included in the intervention group as they had listened to the tape once at the medical center.

2.3. Measures

The study included eight measurement points: 1. 'First meeting' (before group allocation); 2. 'Before surgery' (in the perioperative room after the initial medical examination and premedication); 3. 'Surgery 1′ (at first incision); 4. 'Surgery 2′ (at the start of Phacoemulsification, approximately 3 min into the surgery); 5. 'Surgery 3′ (just before the patient left the operating table, approximately 7 min after first incision). 6. 'End of surgery' (immediately after the operation) 7. 'After surgery' (at the end of the 20 min rest period). 8. 'Postoperative visit' (before medical examination at the postoperative visit).

2.3.1. Baseline characteristics

We recorded several baseline characteristics at the First meeting measurement point: To determine any differences in trait anxiety between the two groups we used the trait anxiety subscale of State Trait Anxiety Inventory (STAI) [32] (20 items, Cronbach's $\alpha = .88$). The Low Vision Quality of Life test (LVQoL)

[1] The other medications used before the surgery was as follows: Oxybuprocain 4 mg/ml eye drop 3 times during the last 10 min before operation (an anesthetic), Cyclopentolate hydrochloric 5 mg/ml eye drop used 3 times in the last hour before the operation (a pupil dilator), levofloxacin 5 mg/ml eye drop used 5 times during the last 24 h preceding the operation (an antibiotic). If the anesthesiologist judged it necessary outside the operating theater, 1–3 puffs of Cordaflex spray were used (sprayed under the tongue on the oral mucous membrane, active ingredient: Nifedipine, 5 mg per puff). If high blood pressure occurred in the operating theater Ebrantil was used intravenously (50 mg per dose, active ingredient: Urapidil).

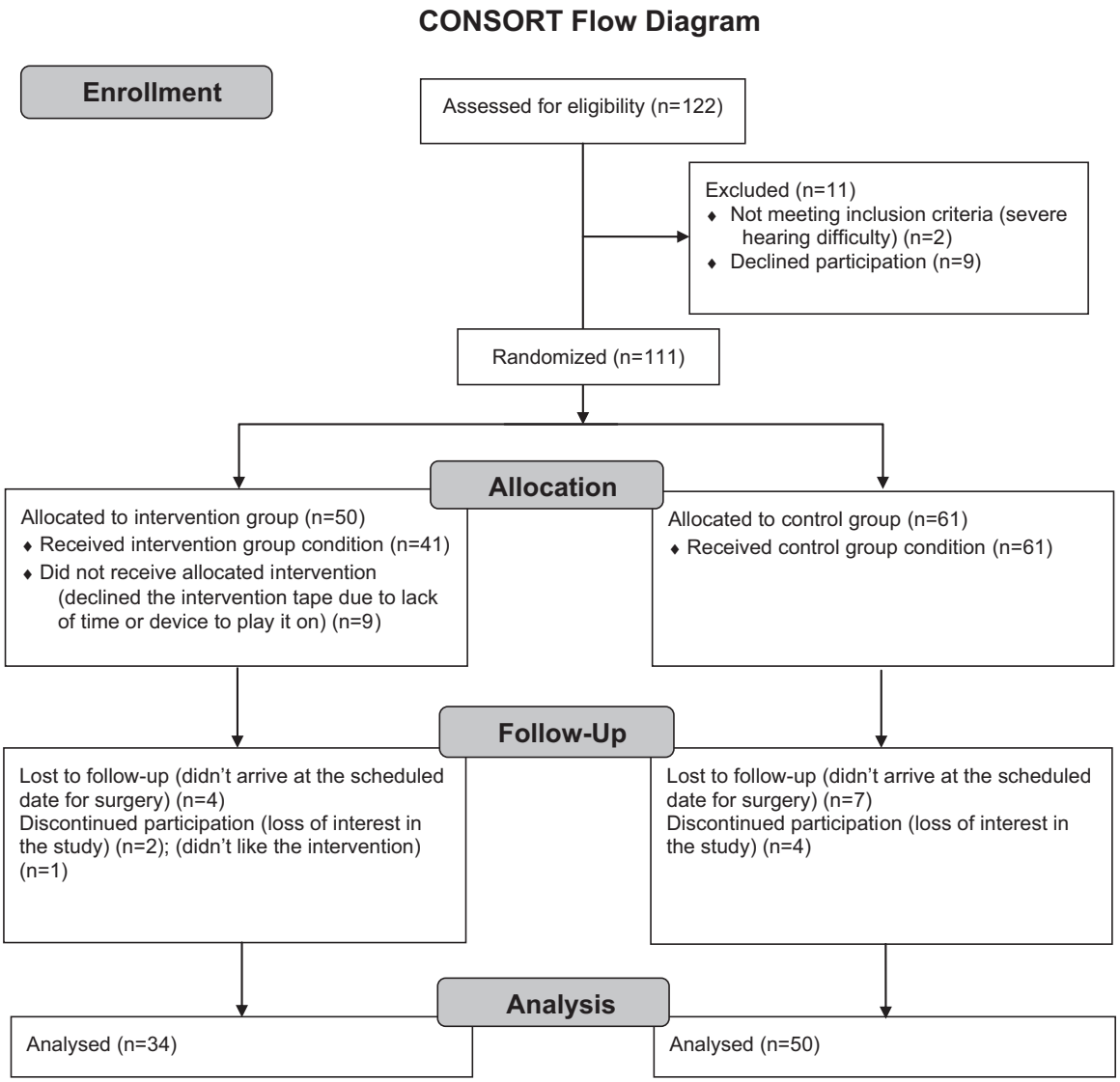

Fig. 1. CONSORT flow diagram.

[33,34] was also applied, which is a 25 item questionnaire (Cronbach's α = .90). A study assistant read out loud both of these tests for all participants individually, as most of them would have trouble reading because of their cataract. In addition, corrected visual acuity scores, age and gender were also recorded, and Well-being and Calmness were assessed (see Section 2.3.2).

2.3.2. Main outcome measures

2.3.2.1. Heart rate and blood pressure. We monitored the heart rate (HR) using an OVA 1 automatic blood pressure monitor from Orvosi Műszerkereskedelmi Rt. in the perioperative room and an Infinity Delta monitor from Dräger Medical Inc in the OR at measurement points Before surgery; Surgery 1; Surgery 2; Surgery 3 and After surgery. Blood pressure was also considered as an outcome measure, but had to be excluded because of the strict antihypertensive regime involved with the operation.

2.3.2.2. Calmness and Cooperativeness. A study assistant herein referred to as the observer had to answer to the following question: 'How would you rate the current state of mind of the subject?' based on the behavior of the patient during the consultation with the surgeon, in the perioperative room before and after the operation and during the first postoperative visit. A 7-point Likert scale was used, ranging from '1: Really anxious' to '7: Totally calm'. Immediately after each operation the surgeon answered the following question: 'How would you rate the state of mind of the subject during the surgery?' using the same Likert scale and she also rated the cooperativeness of the patients during surgery in a similar manner at the end of the surgery.

2.3.2.3. Well-being. Subjective well-being was measured using the Pain Affect Faces Scale [35] at the measurement points: First meeting, Before surgery, After surgery and Postoperative visit. The Faces Scale is a visual scale where a series of 9 schematic line drawn faces are presented to the patient. These faces show different levels of happiness or discomfort from which the patient chooses the one that best represents his current mood. The responses were coded on a 9 point scale, 1 meaning the worst, 9 the best Well-being. Drawings were enlarged so that all of the participants could see the faces and their expressions.

2.3.2.4. Sleep quality. According to the medical staff some of the patients experience sleeping difficulties on the night before surgery, therefore the observer asked the following question of the patient: 'Did you sleep well on the night before the operation?'

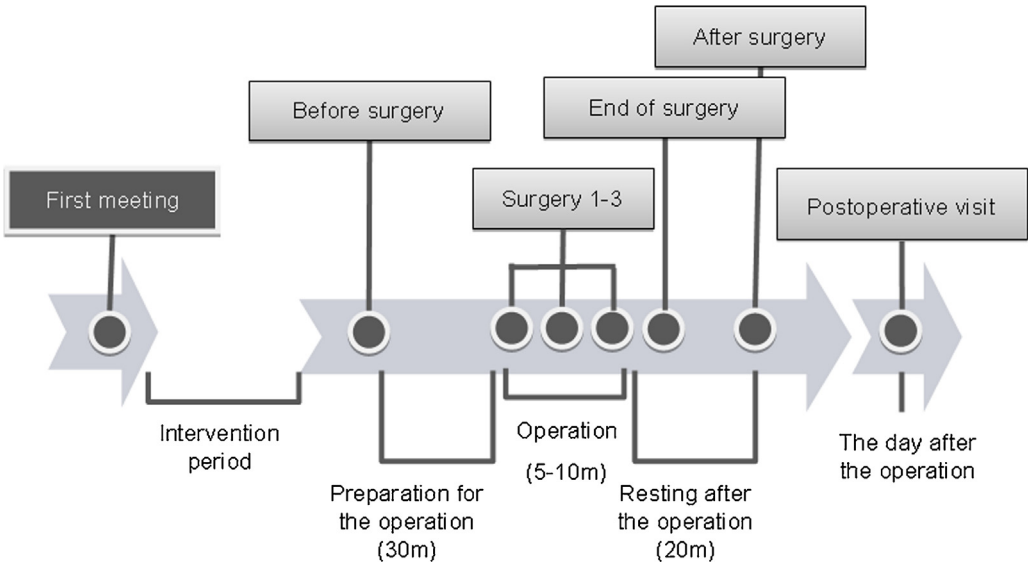

Fig. 2. Timing of the protocol and the measurement points. Note. Measures taken at the specific measurement points: First meeting: STAI-T; LVQoL; Calmness as assessed by the observer; Well-being; Visual acuity; Demographics. Before surgery: Calmness as assessed by the observer; Well-being; Heart rate; Sleep quality; Surgery 1, 2, 3: Heart rate. End of surgery: Calmness as assessed by the surgeon; Cooperativeness as assessed by the surgeon; After surgery: Calmness as assessed by the observer; Well-being; Heart rate Postoperative visit: Calmness assessed by the observer; Well-being (The artwork was created by MS PowerPoint.).

This was measured before surgery, with the possible answers: yes or no. See Fig. 2 for a summary of the measurement points and measures.

2.4. Data analysis

2.4.1. Analysis of baseline differences

To test for any initial group differences we used independent samples *t*-tests (age, STAI-trait, LVQoL, corrected visual acuity), Chi-square test (gender) and Mann–Whitney's *U* test (Calmness, Well-being).

2.4.2. Hypothesis testing

We used mixed ANOVAs to investigate group main effects on HR, Calmness and Well-being throughout all measurement points. Because women tend to have a higher HR [36] and the difference in gender distribution between groups was substantial (although not significant), we entered gender as covariate for the test of HR. The assumptions of the repeated measures ANCOVA were not violated for HR, however according to the Q–Q plots and Kolmogorov–Smirnov tests, error terms did not follow normal distribution for Well-being and Calmness. To counteract this problem we performed rank transformation on the problematic data and ran parametric mixed ANOVA as suggested by Beasley [37]. Furthermore we evaluated group differences using a Chi-square test for Sleep quality and Mann–Whitney *U* test for Cooperativeness as assessed by the surgeon. Critical values of significance were set to $p \leq .01$ using Bonferroni correction to account for multiple comparisons.

2.4.3. Post hoc analyses

If significant group main effect was found in the mixed ANCOVAs, post hoc analyses (ANCOVA or Mann–Whitney's *U* test) were performed on the measurement points separately to determine which of the measurement points were affected by the intervention. We also tested for the influence of the number of times subjects had listened to the recording on the outcome variables by using independent samples *t*-tests for sleep quality and Pearson's correlation (using Spearman's correlation for non-normally distributed variables) for the continuous variables. Bonferroni correction was applied for these post hoc tests separately.

Cohen's effect size was derived using formulas described by Cohen [38] .All statistical tests were performed DeCoster [39] and Friedman [40]. All statistical tests were performed in SPSS 17.1.

3. Results

3.1. Baseline characteristics

The groups did not show baseline differences (see Table 1 for details).

3.2. Hypothesis testing

Repeated measures analysis of HR did not reveal significant group differences ($F(1, 72) = 4.42$; $p = .039$; $d = -0.50$). However our results indicate that patients who received the intervention were calmer throughout the four measurement points ($F(1, 69) = 8.70$; $p = .004$; $d = 0.71$) and more cooperative during the operation ($U(81) = 533.5$; $Z = -2.59$ $p = .010$; $d = 0.60$). Additionally there was no evidence of group effects on Well-being ($F(1, 78) = 3.06$; $p = .084$; $d = 0.40$) and Sleep quality ($\chi^2(df = 1; N = 84) = 0.66$; $p = .416$ $d = 0.21$) (also see Table 2).

3.3. Post hoc analyses

Because of the significant group effect on Calmness, further investigations were made to identify in which stages of the procedure was the difference the most pronounced. The groups showed no significant difference before, during and after the operation ($U(80) = 759$; $Z = -0.90$; $p = .928$; $d = 0.02$; ($U(81) = 553.5$; $Z = -2.41$; $p = .016$; $d = 0.56$); and $U(82) = 739.5$; $Z = -0.77$; $p = .443$; $d = 0.19$ respectively), but they were markedly calmer at the Postoperative visit ($U(78) = 337.5$; $Z = -4.12$; $p \leq .001$; $d = 1.25$).

The number of times listening to the audio CD at home showed no association with the main outcome measures. Results are summarized in Table 3.

Table 1
Characteristics of the study groups at baseline.

	Intervention group Mean, median or count (SD, range or %) $n = 34$	Control group Mean, median or count (SD, range or %) $n = 50$	p value
Age	66.82 (11.47)	70.76 (11)	.118
Female	18 (52%)	36 (72%)	.074
Calmness (1–7)	5 (2–7)	5 (1–7)	.367
STAI – trait anxiety	41.59 (10.13)	44.22 (11.48)	.254
LVQoL	93.56 (15.75)	91.88 (17.42)	.678
Wellbeing (1–9)	7 (2–9)	7 (3–9)	.975
Visual acuity	0.5 (0.04–0.7)	0.3 (0.001–0.7)	.723

4. Discussion and conclusion

4.1. Discussion

Our randomized clinical trial investigated the effectiveness of a patient education intervention on cataract surgery patients. The intervention included information about the operation using positive verbal suggestions in addition to relaxation and imagery techniques. Patients in the intervention group were more cooperative during the procedure according to the surgeon and they appeared to be calmer, particularly at the post-operative visit, although groups did not differ with respect to heart rate during surgery, sleep quality at the night before surgery and subjective Well-being.

Based on these results the intervention might be considered as a tool to alleviate perioperative anxiety. As such, the intervention should be subjected to further, more focused investigation. According to Nijkamp et al. [7], the anxiety of the patients does not stop at the end of surgery, rather it carries on through the post-operative visit and beyond that. Our results imply that the relapse of anxiety at the time of the post-operative visit might be alleviated using a preoperative intervention.

Contrary to other medical fields, patients enlisted for cataract surgery often report that they already have enough information about the procedure [16,41] and thus they do not seek out additional information in the subject. However patients' actual level of understanding the operation and its risks is low, which raises issues about informed consent to the surgery [41,42]. Previous research found that many cataract surgery patients actively avoid patient education as they find new information concerning [41]. Accordingly, another study suggested that patient education about cataract surgery may in fact increase negative expectations in the preoperative period which might counteract or mask early anxiety reduction effects of education interventions [16]. These findings make the search for new methods in cataract patient education relevant. Our approach, using positive therapeutic suggestions in combination with information may be a way to deal with this problem, since shift of focus to the benefits of surgery and positive phrasing of the information content might decrease patients' natural apprehension. Nevertheless, preoperative anxiety appear to be unaffected by the present intervention as well, which could mean that the effects of negative expectations were not averted.

Another novelty of our approach was that we provided techniques that patients could use to overcome anxiety. Additional studies are needed to verify the necessity of more than one presentation of the intervention, in which the number of exposures is more strictly controlled.

We have to take into consideration the medication that was used perioperatively while interpreting our results. The Xanax taken before the operation could have masked some of the anti-anxiety effects of the intervention, which could serve as one

Table 2
Group differences in Heart rate, Calmness, Cooperativeness, Wellbeing and Sleep quality.

Variable name and Measurement point	Intervention group		Control group		p value
	n	Mean, median or count (SD, range or %)	n	Mean, median or count (SD, range or %)	
Heart rate ($F(1, 72) = 4.42$; $p = .039$; $d = -0.50$)					
Before surgery	34	74.79 (13.56)	49	79.86 (13.15)	
Surgery 1	33	69.52 (13.94)	49	74.45 (11.02)	
Surgery 2	33	68.15 (14.55)	48	73.33 (11.42)	
Surgery 3	32	67.16 (10.98)	45	73.89 (12.06)	
After surgery	34	67.09 (16.12)	48	71.56 (11.26)	
Calmness (1–7) ($F(1, 69) = 8.70$; $p = .004^{*}$; $d = 0.71$)					
Before surgery	32	4.5 (2–7)	48	4 (2–7)	
After surgery	34	6 (3–7)	48	6 (1–7)	
End of surgery	33	6 (5–7)	48	4 (1–7)	
Postoperative visit	30	6 (4–7)	48	5 (2–7)	
Cooperativeness in the operating room (1–7) ($U(81) = 533.5$; $Z = -2.59$ $p = .010^{*}$; $d = 0.60$)					
End of surgery	33	7 (4–7)	48	6 (2–7)	
Wellbeing (1–9) ($F(1, 78) = 3.06$; $p = .084$; $d = 0.40$)					
Before surgery	33	6 (3–9)	49	6 (2–9)	
After surgery	34	8 (5–9)	49	7 (1–9)	
Postoperative visit	33	8 (4–9)	49	8 (4–9)	
Sleep quality (Did you sleep well last night?) ($\chi^2(df = 1; N = 84) = 0.66$; $p = .416$ $d = 0.21$)					
Yes		24 (71%)		31 (62%)	
No		10 (29%)		19 (38%)	

Note. Higher score and positive effect size means higher heart rate, calmer, more cooperative patient, better wellbeing and better sleep quality; [a] gender was used as a covariate.

[*] Significant result, critical value was set to $p < .01$ using Bonferroni correction.

Table 3
Association of number of exposures to the intervention with the outcome measures.

Variable name and measurement point	*n*	Correlation coefficient/ *t*-test statistic	*p* value
*Heart rate*number of exposures*			
Before surgery	29	.13[a]	.500
Surgery 1	28	−.05[a]	.820
Surgery 2	28	−.03[a]	.901
Surgery 3	27	−.07[a]	.743
After surgery	29	−.06[a]	.760
*Calmness*number of exposures*			
Before surgery	27	.42[b]	.028
After surgery	28	.17[b]	.396
End of surgery	29	−.04[b]	.825
Postoperative visit	26	.15[b]	.462
*Cooperativeness in the operating room*number of exposures*			
End of surgery	28	−.14[b]	.486
*Wellbeing*number of exposures*			
Before surgery	28	.43[b]	.022
After surgery	29	.08[b]	.667
Postoperative visit	29	−.11[b]	.570
*Sleep quality*number of exposures*	29	0.16[c]	.876

Note. Critical value was set to $p < .0036$ using Bonferroni correction.
[a] Pearson correlation.
[b] Spearman's rank correlation.
[c] *t*-Test statistic.

possible explanation as to why we found no differences in anxiety on the day of the surgery. Further, blood pressure was medically controlled as well, since patients with chronic hypertension took their usual antihypertensive medication on the morning of the operation; and further antihypertensives were also used as needed if the BP of the patient was too high in the perioperative period.

4.2. Strengths and limitations

One of the strengths of our study is that we used multiple measurement points, which enabled us to assess the effectiveness of the intervention on several stages of anxiety [7]. Additionally, patients heard their surgeon's voice in our audio material, which allowed us to rely on surgeon-patient trust and relationship, factors of upmost importance in reducing perioperative anxiety [7,43]. Also this way the operating doctor's voice may have also been associated with the relaxed state elicited by the intervention.

Our study also has a number of limitations. First of all, no baseline measurements were made for the cardiovascular measures before the group allocation, thus we cannot be sure whether the groups differed in HR to begin with or not, although the group allocation was randomized and no dissimilarities were found in other baseline factors. Only one (passive) control condition was used in the study in addition to the intervention condition, which – in a single blind design – prevents us from ruling out expectancy effects, and from differentiating between the effects of different effective components of the intervention (information, relaxation, positive verbal suggestions, etc.). The high drop-out rate introduces further issues in the interpretation of the results, which could have been avoided with an intention-to-treat design. Although we assessed physiological and behavioral indicators of anxiety, we can only make inferences regarding the subjective anxiety level of the patients, which was not directly measured. Although classical self report measures of surgical anxiety (like Yale Preoperative Anxiety Scale [44], the Amsterdam Preoperative Anxiety and Information Scale [45] and STAI State anxiety subscale) were considered for application, they turned out to be unpractical in this special environment, partly due to time constraints and the impaired visual capabilities of the patients. Finally, the results of the verbally administered STAI trait subscale and LVQoL tests have to be interpreted cautiously, because of the possible social desirability effects.

4.3. Conclusion

Our study indicates that preoperative patient education combined with positive suggestions and anxiety management techniques might reduce distress during the postoperative visit and help with patient-surgeon cooperation during the procedure; however there are considerable limitations that warrant further investigation. We encourage more research assessing the effects of such combined anxiety reduction interventions to investigate the effectiveness of different components and the need for multiple intervention presentations.

4.4. Practice implications

Our study provides further support on the anxiety reducing effects of multi-component patient education programs before cataract surgery.

Conflict of interest

None.

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