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ORIGINAL ARTICLE

Short-term intervention to reduce anxiety before coronary artery bypass surgery – a randomised controlled trial

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Aims and objectives. The aim of this study was to evaluate an intervention with individualised information and emotional support before coronary artery bypass grafting in a controlled randomised trial.

Background. Anxiety is a typical phenomenon in patients who are to undergo cardiac surgery. Preoperative anxiety has been shown to correlate to adverse postoperative outcomes. Emotional support could be an effective measure to reduce preoperative anxiety.

Design and methods. Patients with planned first coronary artery bypass grafting were randomised into an intervention group ($n = 139$) and a control group ($n = 114$). The patients of the control group were routinely informed as usual. The patients of the intervention group received a dialogue with individualised information and emotional support one day before surgery in addition to standard care. This intervention of ~30 minutes was based on a supportive psychotherapy model and was delivered by trained nurses. The primary outcome was the change in anxiety before operation. The secondary outcomes consisted of changes in postoperative anxiety, time on intensive care unit and in-hospital mortality.

Results. Significantly reduced anxiety was found in the intervention group patients compared to control patients before coronary artery bypass grafting ($p < 0{\cdot}001$) and five days after surgery ($p < 0{\cdot}001$). Both groups did not differ in in-hospital mortality and duration of stay in the intensive care unit.

Conclusions. Our short-term psychosocial intervention in patients undergoing coronary artery bypass grafting had a beneficial effect on reducing pre- and postoperative anxiety that was better than routine information alone.

Relevance to clinical practice. These results advocate training for nurses and physicians to provide emotional support to patients before coronary artery bypass grafting.

What does this paper contribute to the wider global clinical community?

- A psychosocial intervention with information and emotional support can reduce preoperative anxiety. The intervention was applied to patients with short waiting times for coronary artery bypass grafting (CABG).
- The results of this randomised trial endorse the training of medical personnel to offer psychosocial support to CABG patients.

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Introduction and background

Fear is experienced by many patients scheduled for major cardiac surgery. The operation presents a biographical break (Lindsay *et al.* 2000) and causes uncertainties regarding the upcoming surgery, time in the hospital and postoperative life. Patients with depressions and anxiety prior to the operation suffer from higher rates of postoperative adverse events and depression (Székely *et al.* 2007). Approximately 20% up to 50% of patients experience clinically significant anxiety in the last few days at the end of the waiting period before aortocoronary bypass surgery (Koivula *et al.* 2002, Rymaszewska *et al.* 2003, Krannich *et al.* 2007). In 2013, approximately 55,000 CABG surgeries were performed in Germany. A study in a large German cardiac centre found clinically significant preoperative anxiety in approximately one-third of CABG patients (Krannich *et al.* 2007). In Germany, most patients are admitted for CABG within 7–10 days after indication and undergo surgery one or two days after admission. This leaves a narrow timeframe for a structured in-hospital psychoemotional support and presents a major challenge to an effective intervention Therefore, results of other studies which assume waiting periods of several weeks (Lamarche *et al.* 1998, Arthur *et al.* 2000) are difficult to compare. According to a survey in Germany, 62% of cardiac surgery patients would appreciate preoperative interventional psychosocial support by a psychologist or a chaplain (Rosendahl *et al.* 2013). Another German study found that 44% of almost 300 patients would need psychosocial support at the day of admission for cardiothoracic surgery (Sachs *et al.* 2014). Thus, a request remains for specific interventions to reduce preoperative anxiety that is adapted to the individual needs of CABG patients. Various sources of anxiety and fear were explored in a precedent study at our hospital. The concerns most frequently voiced were nonspecific fear or uncertainty, fear of medical intervention, medical objects or the intensive care unit (ICU), fear of immobility or restriction and fear of complications or failure of the surgery (Feuchtinger *et al.* 2014).

In accordance with these results, we developed a short-term psychosocial intervention with information and emotional support to reduce preoperative anxiety in CABG patients. The aim was to address the specific concerns and needs of the patient hereby providing information and emotional support. We evaluated this intervention in a randomised controlled clinical trial. The patients' issues of the foregoing study corresponded to the questions of the State-Trait Operation Anxiety (STOA) inventory and offered the opportunity to use a validated instrument. For this reason, the STOA questionnaire was employed in the current trial.

Further, a visual analogue scale (VAS) was used as an additional instrument for assessing preoperative anxiety. The VAS have been previously shown to be a valid tool for this purpose (Kindler *et al.* 2000).

The study aimed to test the following hypotheses:

1 After the intervention, intervention group patients experience significantly less preoperative anxiety than control group patients.

2A Intervention group patients are less anxious five days after surgery compared to control group patients.

2B Intervention group patients have lower in-hospital mortality and shorter stay in the intensive care unit (ICU) than control group patients.

Methods

This study is reported according to the 2010 version of the CONSORT statement (Schulz *et al.* 2011). The investigation conforms to the principles outlined in the Declaration of Helsinki. The study was approved by the Ethics Review Committee of Freiburg University. All patients gave their informed consent prior to participation.

Clinical trial registration

- DRKS-ID: DRKS00000696
- Date of Registration in DRKS: 2011/01/19
- Partner Registry-ID: UKF001262 (Clinical Trials Register of the Medical Center, University of Freiburg)
- Date of Registration in Partner Registry: 2007/06/26
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Approval of the Ethics Committee: Approved, No. 175/07, Ethics Committee of Albert-Ludwigs-University Freiburg

Trial design

This study was designed as an open interventional randomised controlled trial with 1:1 parallel assignment to the intervention and control arms. No important changes were made to the methods after the trial began.

The 'State-Trait Operation Anxiety' (STOA) inventory was used to assess anxiety. It consists of two scales, which describe trait anxiety (STOA-T, 20 items) and cognitive and affective components of state anxiety (STOA-S, five items each) (Krohne *et al.* 2005). Each item can be ranked 'almost never' – 'sometimes' – 'often' – 'almost always'. In addition, an unanchored 10-cm visual analogue scale for current anxiety ranging from 'no fear' to 'very high fear' was used.

Patients completed the STOA-T, STOA-S and VAS at T0 after informed consent and prior to randomisation. In addition, sociodemographic data were recorded. In the evening after the intervention, at T1, and five days postoperatively at T2, the STOA-S and VAS were completed again.

Patient eligibility criteria

Patients scheduled for elective first coronary artery bypass grafting, also combined with valve surgery and/or MAZE, were enrolled. Male and female patients were eligible. Inclusion criteria included: (1) aged ≥18 years, (2) able to communicate (knowledge of the German language, comprehension of the study) and (3) able to give written consent.

Exclusion criteria included severe physical and/or mental burden due to illness (Karnofsky index <20).

Study setting

This study was conducted at the two sites of the Department of Cardiovascular Surgery, Heart Center, University of Freiburg, which has 28 ICU, 25 intermediate care and 59 regular inpatient beds. Approximately 800 CABGs are completed annually.

Intervention

In a preliminary study, we interviewed 24 adult inpatients after admission to our hospital who were scheduled for CABG. Semi-structured interviews focused on issues related to fear and anxiety regarding the operation and patients' coping strategies. Responses were analysed by qualitative content analysis and were used to develop the intervention which was tested in this study.

Recruitment and process

Patients were recruited from April 2010 to January 2012 until the predefined number of patients was reached.

Our schedule does not include outpatient visits with a cardiac surgeon or other personnel on behalf of our department. Our hospital has a large rural commuting area. Patients are admitted by their general practitioner or cardiologist or, in difficult cases, by another (peripheral) hospital. They are informed in writing on admission procedures if there is enough time prior to the hospital admission. However, most patients are admitted within one week after indication. When the patients registered at arrival during the recruitment for the trial, written information on the study was handed over to eligible patients. Usual preoperative care includes taking the history and physical examination at admission by physicians and nurses, information on surgery and anaesthesia by surgeons and anaesthetists including informed consenting, and nursing preparations for surgery. Preoperative information on the course of actions regarding surgery, postoperative transfer to the ICU, on the hospital stay in general and on the discharge management is provided by nurses as part of the admission process. If time allows, physiotherapists have a first training session with the patient on the ward. During the trial, potential study patients were subsequently approached by the study nurse and orally informed of the study. This generally occurred during the evening before the operation. After obtaining informed consent, patients were randomised to the intervention or control group. The patients were asked to complete the STOA-S and STOA-T questionnaires and VAS for their anxiety. In addition, sociodemographic and clinical data were obtained from patients and from their charts respectively. Thereafter, the intervention was implemented. It consisted of a dialogue with additional information regarding surgery and postoperative care and emotional support. The intervention was centred on the specific fears reported by the patient. The intervention generally required 30 min and was conducted by a trained nurse. The intervention was performed according to a manual that was specifically developed for this study (Table 1).

Communication with the control group patients was restricted to routine medical and organisational information. The attending health care team was not blinded to the group assignment.

In preparation for this study, all cardiovascular surgeons received training in basic doctor–patient communication skills and how to inform the patient about the planned surgery. This training was done with the intention to equal-

Table 1 Elements of the treatment manual for the psychosocial intervention to reduce preoperative anxiety before coronary artery bypass grafting (CABG) using information and emotional support

Theoretical background
Elements of supportive psychotherapy (Wise & Rundell 2002)
Patient-orientated communication skills (Mead & Bower 2000)
Empathy, authenticity and unconditional appreciation (Rogers 1975)
Aims of the information and the emotional support
To improve the emotional condition of the patient, specifically to reduce her/his preoperative anxiety
To evaluate the patient's need for and to provide the requested information
To promote cooperation between the patient and the medical team
To promote the patient's confidence in her/his anaesthesiologists and surgeons
To encourage the patient to use resources for support, e.g. via spouse or significant others
To reduce patient distress in the ICU
To improve the cooperation between the patient and ICU nurses
Setting
General ward of a cardiovascular surgery department (heart surgery step down unit)
Day prior to CABG
30 minute duration
Undisturbed environment
Adherence and fidelity to the treatment manual established by training, supervision and review of treatment protocols
Psychosocial intervention
Open dialogue
Guided by the patient's available resources
Reinforcement of the patient's confidence in the competence and experience of the medical team and a positive surgery outcome
Differentiation between patients demonstrating vigilance or cognitive avoidance
Short relaxation exercise using positive imagination directed to the time after surgery
Promotion of emotional expression by patients with severe emotional burden
Acceptance of denied negative emotions
Information regarding the ICU stay according to the patient's need for information
Information regarding postoperative ventilation and pain management
Focusing on the patient's specific fears based on the completed questionnaire

ise anxiety-reducing effects of the regular preoperation information.

Training to deliver intervention therapy

Study nurses underwent a training with actor-patients, which was conducted twice over the course of the study. All study nurses received regular group supervision once per month by one of the authors (KF). Randomly selected sessions were audiotaped and reviewed by a trained research assistant. This guaranteed treatment fidelity, adherence to the treatment manual and uniformity of the intervention.

Outcomes measures

Various sources of preoperative anxiety affecting patients on the day before CABG were explored in a precedent study (Feuchtinger *et al.* 2014). We found that patient concerns were reflected in the 'State-Trait Operation Anxiety' (STOA) inventory (Krohne *et al.* 2005). Although state anxiety describes the current anxiety and regards the specific situation, trait anxiety reflects more general views, is linked to personality and previous experiences and contributes to the manifestation of state anxiety (Endler & Kocovski 2001).

Patients completed the STOA-T, STOA-S and VAS at T0 – after giving informed consent and before randomisation. The instruments for state anxiety, that is STOA-S and VAS, were completed again at T1 – in the evening after the intervention and at T2 – on postoperative day five.

The STOA questionnaire demonstrated good to excellent reliability. Cronbach's alpha was 0·902 for the trait anxiety scale (STOA-T), 0·898 for the affective anxiety scale and 0·860 for the cognitive anxiety scale (STOA-S).

The primary endpoint of our study was the change in state anxiety at T1. Secondary outcomes of the study examined the changes in state anxiety at T2, in-hospital mortality and duration of stay in the ICU. In addition, patients of the intervention group were asked gauge the helpfulness of the intervention at T2. No changes were made to trial outcomes after the study began.

Sample size and randomization

Sample size was calculated based on previously published interventional studies using the Spielberger Sate-Trait Anxiety Inventory-State (STAI-S). The programme 'Power and Precision' was used. We estimated that the study would have 95% power to detect a significant group-with-measurement-point-interaction in a MANOVA with a weak to moderate effect size of $f = 0{\cdot}25$ (alpha = 0·05). We calculated these values with 20% missing values to avoid problems related to underpowering by missing values. Therefore, we inferred a sample size of 252 participants. No interim analysis was planned.

A computerised randomisation was employed. An e-mail was sent by the study nurses to a specified address which was used for this purpose only. Assignment to the groups

was done by a programme based on index numbers on the mail server. Preliminary tests confirmed a 1:1 randomisation to intervention and control arms. No blocking applied.

The statistician (RL) was blinded to the randomisation for the data analysis. Patients were not blinded for control or intervention condition.

Implementation

Patients scheduled to undergo CABG received a patient information form at admission. Following completion of preoperative diagnostics, informed consenting to surgery and anaesthesia, and nursing procedures, patients were verbally informed of the study by the study nurse and asked for participation. After giving informed consent, patients were randomised as described above. The intervention or the usual information was then given to the intervention and the control group patients respectively. We decided to provide only the established routine information to the control patients because we assumed that patients would address their anxiety and fears during the course of a longer talk. This would have required an appropriate response by the nurse for ethical reasons and spoiled our study. All data were documented on paper CRFs and manually transferred to the database by independent assistants.

Informed consent

The study was approved by the Ethics Review Committee of Freiburg University. All patients gave their informed consent.

Statistical methods

Statistical analyses were performed using SPSS STATISTICS, version 21.0 (IBM, Armonk, NY, USA). Descriptive statistics were used to estimate the frequencies, means and standard deviations of the study variables. Differences between study groups and the two study sites were assessed with ANOVAs for continuous variables and chi-square tests for categorical variables. Multivariate analysis of variance was adjusted for the STOA-T and the measured values for affective anxiety, cognitive anxiety, VAS at T0 as covariates and was used to examine the effect of the intervention. Data analysis was conducted as an intention-to-treat-analysis so that every subject was analysed within the group to which he or she was assigned by randomisation. Because missing values existed in the database, we used 10 multiple imputations with AMOS 21.0 for all data for data analysis (Little & Rubin 1989). No differences in the statistical results from the primary analysis were detected within these 10 data sets, so the results of the multiple imputations were able to conform the results of the analysis, even with missing data. Only the results for the incomplete data set are shown below. We used the listwise deletion approach.

Results

Participant flow

A total of 253 patients were enrolled in the study. Participant flow through the study is shown in Fig. 1. The most common reason for missing data in the pre- and postoperative periods was inaccessibility of the patient: informed consenting to operation or anaesthesia had not been completed yet, the patient had left the ward or felt too worn out after all the tasks of preparing for surgery. However, these reasons were not documented in a structured fashion.

Baseline data

Two-hundred eight male (82·2%) and 45 female (17·8%) patients were included in the study. The mean age was 68 ± 10 years (median: 70 years, range: 39–88 years, 95% CI: 67–70 years). The sociodemographic data for each group are shown in Table 2. No significant differences in these characteristics were observed between the two study groups. There were also no significant between-group differences at the first study time-point or in the group*site interaction for trait anxiety, affective component of state anxiety and VAS. There was a significant group effect only for cognitive anxiety ($F = 5{\cdot}239$, $df_1 = 1$, $df_2 = 247$, $p = 0{\cdot}023$). Two of the patients who were randomised to the control group received intervention due to their need for information and support. Three patients who were randomised to the intervention group did not receive intervention for logistic reasons: Two patients were not available, and for one patient, the operation was postponed.

Primary hypothesis: outcomes at T1 – Changes regarding anxiety

We observed a significant effect between the two groups with a more pronounced decrease in the intervention group in a multivariate analysis of covariance (Table 3). When the T0 values were controlled by the analysis of covariance the affective subscales of the STOA-S (F [1,299] = 14·284, $p < 0{\cdot}001$) were significantly lower in the intervention group. Also the cognitive subscales of the STOA-S (F [1,299] = 17·457, $p < 0{\cdot}001$) and the VAS (F [1,299] = 12·207, $p < 0{\cdot}001$) showed significantly lower values. The model explains

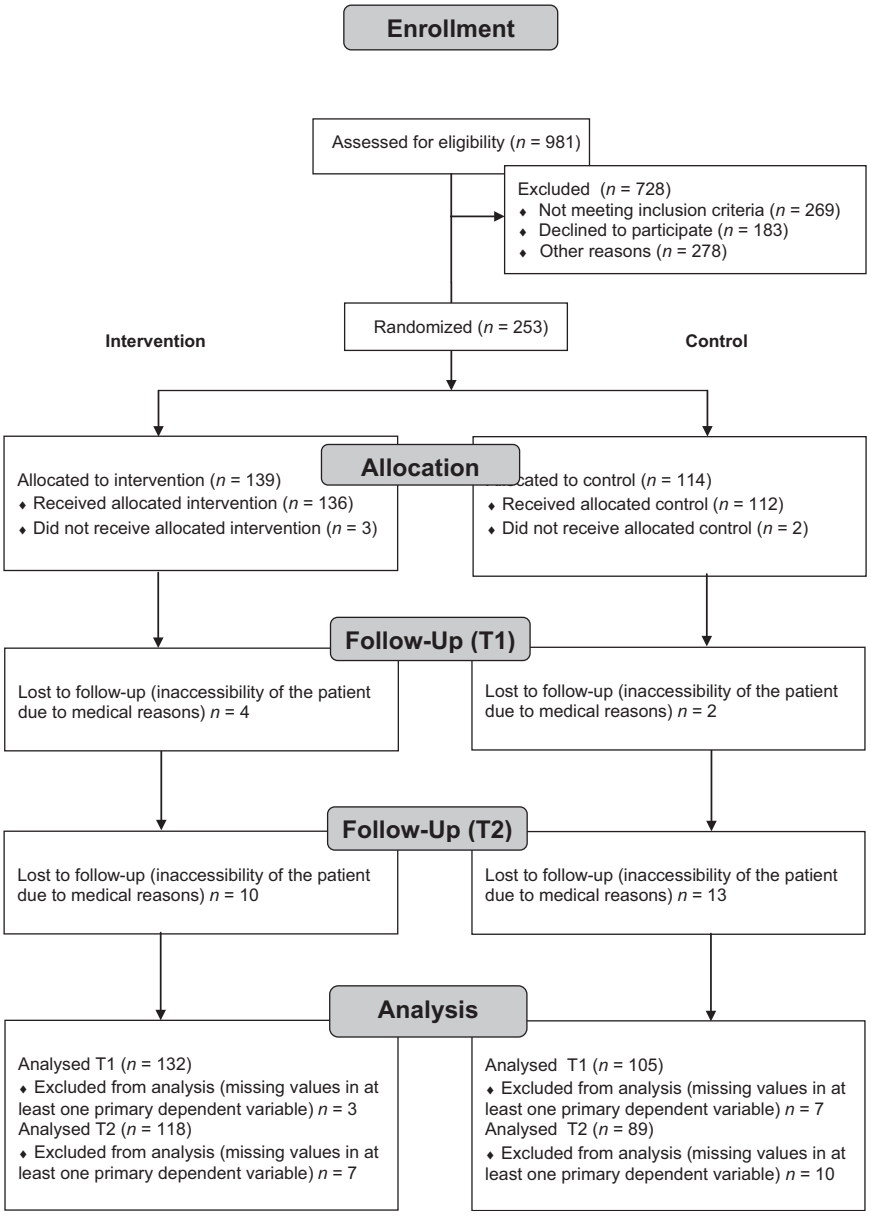

Figure 1 Participant flow.

between 70·7 and 81·3% of the adjusted variance at these dependent variables (Table 3).

Secondary hypothesis A: Outcomes at T1 and T2 – Changes regarding anxiety

For the second hypothesis, part A, we performed a repeated-measures multivariate ANOVA with trait anxiety (STOA-T), affective and cognitive anxiety (STOA-S) and VAS at T0 as covariates. We found significant effects of time (before and after operation) for affective anxiety (F [1,199] = 26·215, $p < 0·001$) and cognitive anxiety (F [1,199] = 31·312, $p < 0·001$). To be highlighted is that in all three dependent outcome variables we still have a significant effect of the group factor. For affective anxiety (F [1,199] = 4·974, $p = 0·027$), cognitive anxiety (F [1,199] = 4·695, $p = 0·031$) and VAS (F [1,199] = 7·572, $p = 0·006$) we can show stable effects of the intervention. The values of the dependent variables are presented in Table 4.

Secondary hypothesis B: Outcomes at T2 – Differences regarding in-hospital mortality and duration of stay in the ICU

The intervention and control groups did not differ significantly in in-hospital mortality ($p = 0·473$), three patients of the intervention group and five control group patients died. Further, duration of stay in the ICU was comparable

Table 2 Sociodemographic Information

	Intervention group		Control group		Total		
	Mean	SD	Mean	SD	Mean	SD	*p*-value (ANOVA)
Age	69·0	9·3	67·5	10·3	68·4	9·8	Group ($p = 0·367$)
Total							Site ($p = 0·427$)
							Interaction effect ($p = 0·244$)
	n	Per cent	*n*	Per cent	*n*	Per cent	*p*-Value (χ^2)
Site							
Site 1	54	55·1	44	44·9	98	54	$p = 0·967$
Site 2	85	54·8	70	45·2	155	85	
Total	139	54·9	114	45·1	253	139	
Gender							
Female	29	20·9	15	13·4	44	14·4	Site 1 ($p = 0·199$)
Male	110	79·1	97	86·6	207	85·6	Site 2 ($p = 0·318$)
							Total ($p = 0·122$)
NYHA	2·5	0·8	2·3	0·8	2·4	0·8	Site 1 ($p = 0·006$)
							Site 2 ($p = 0·626$)
							Total ($p = 0·060$)
Nationality							
Germany	129	92·8	109	95·6	238	94·1	Site 1 ($p = 0·367$)
Other	10	7·2	5	4·4	15	5·9	Site 2 ($p = 0·655$)
							Total ($p = 0·347$)
Marital status							
Married	103	74·1	82	71·9	185	73·1	Site 1 ($p = 0·178$)
Other	36	25·9	32	28·1	38	26·9	Site 2 ($p = 0·517$)
							Total ($p = 0·698$)
Household							
Single household	25	18·0	25	21·9	50	19·8	Site 1 ($p = 0·417$)
Cohabiting	99	71·2	71	62·3	170	67·2	Site 2 ($p = 0·439$)
Other	15	10·8	18	15·8	33	13·0	Total ($p = 0·296$)
Education level							
Secondary school (9 years)	81	61·8	75	67·6	156	64·5	Site 1 ($p = 0·243$)
Junior high school (10 years)	24	18·3	15	13·5	39	16·1	Site 2 ($p = 0·364$)
High school (13 years)	19	14·5	11	9·9	30	12·4	Total ($p = 0·342$)
University degree	7	5·3	10	9·0	17	7·0	
Religion							
Protestant	48	35·6	36	34·0	84	34·9	Site 1 ($p = 0·632$)
Catholic	71	52·6	58	54·7	129	53·5	Site 2 ($p = 0·501$)
Other	16	11·9	12	11·3	28	11·6	Total ($p = 0·948$)

SD, standard deviation.

($p = 0·702$) with $3·5 \pm 9·3$ days for the intervention group and $3·3 \pm 6·1$ days for the control group. No unintended effects of the intervention were observed.

Patients of the intervention group rated the intervention mostly as very helpful ($n = 70$) or helpful ($n = 41$). A minority considered the intervention less ($n = 5$) or not helpful ($n = 1$).

Discussion

This randomised controlled study examined the effectiveness of a short-term intervention using information and emotional support for patients one day prior to CABG. The primary goal was the reduction of preoperative anxiety. The group of patients who received the intervention reported a moderately more reduced state of anxiety after the intervention and before surgery than the group of patients who received only routine medical and organisational information. Further, the intervention group patients demonstrated a more pronounced reduction in state anxiety five days after surgery than the control group patients. We found no differences in in-hospital mortality and duration of stay in the ICU between the intervention and control groups.

Table 3 Primary endpoint: Analysis of variance for anxiety measured at T1 with T0 values and trait anxiety as covariates

	Factor	*F*	*p*	η^2	Group	T0/M (SD)	T1/M (SD)	*n*
Affective anxiety*	Group	14·284	<0·001	0·059	I	10·08 (3·91)	8·99 (3·35)	132
	Site	0·857	0·356	0·004	C	10·44 (3·45)	10·17 (3·43)	105
	Group*site	3·189	0·075	0·014				
Cognitive anxiety†	Group	17·457	<0·001	0·071	I	10·44 (3·59)	9·08 (3·21)	132
	Site	0·565	0·453	0·002	C	11·30 (3·39)	10·53 (3·44)	105
	Group*site	9·251	0·003	0·039				
Visual analogue scale‡	Group	12·207	0·001	0·051	I	3·57 (2·95)	2·85 (2·53)	132
	Site	0·758	0·385	0·003	C	3·62 (2·75)	3·45 (2·62)	105
	Group*site	1·548	0·215	0·007				
Trait anxiety (covariate)					I	33·05 (8·44)		132
					C	34·50 (9·00)		105

$df_1 = 1$, $df_2 = 229$ for all variables.
*$R^2 = 0{\cdot}754$ (adjusted $R^2 = 0{\cdot}746$).
†$R^2 = 0{\cdot}716$ (adjusted $R^2 = 0{\cdot}707$).
‡$R^2 = 0{\cdot}818$ (adjusted $R^2 = 0{\cdot}813$).
M, mean, SD, standard deviation, I, intervention group, C, control group.

Table 4 Repeated-measures analysis of variance of anxiety measured at T1 and T2 with T0 values and trait anxiety as covariates

	Factor	*F*	*p*	η^2	Group	T0/M (SD)	T1/M (SD)	T2/M (SD)	*n*
Affective anxiety	Time	26·215	<0·001	0·116	I	10·19 (3·90)	9·10 (3·34)	7·97 (2·68)	118
	Group	4·974	0·027	0·024	C	10·40 (3·48)	10·08 (3·43)	8·35 (3·34)	89
	Site	0·264	0·608	0·001					
	Time*group	0·621	0·432	0·003					
	Time*site	0·275	0·600	0·001					
	Group*site	0·887	0·347	0·004					
	Time*group*site	1·083	0·299	0·005					
Cognitive anxiety	Time	31·312	<0·001	0·136	I	10·47 (3·57)	9·09 (3·19)	8·69 (2·82)	118
	Group	4·695	0·031	0·023	C	11·26 (3·35)	10·38 (3·47)	9·29 (4·00)	89
	Site	0·000	0·985	0·000					
	Time*group	0·921	0·338	0·005					
	Time*site	0·485	0·487	0·002					
	Group*site	0·914	0·340	0·005					
	Time*group*site	5·001	0·026	0·025					
Visual analogue scale	Time	0·876	0·350	0·004	I	3·53 (2·88)	2·86 (2·50)	1·01 (1·65)	118
	Group	7·572	0·006	0·037	C	3·62 (2·81)	3·39 (2·69)	1·51 (1·88)	89
	Site	0·599	0·440	0·003					
	Time*group	0·003	0·953	0·000					
	Time*site	2·651	0·105	0·013					
	Group*site	0·872	0·352	0·004					
	Time*group*site	0·900	0·344	0·005					
Trait anxiety (covariate)					I	33·03 (8·35)			118
					C	35·19 (9·31)			89

$df_1 = 1$, $df_2 = 199$ for all variables.
M, mean, SD, standard deviation, I, intervention group, C, control group.

The challenge of our project was the short waiting time for admission for CABG for patients at home and for surgery in-hospital. There is indeed little information on patients' experiences and anxiety in this setting. Previous publications identified the subjective need for psychosocial support (Rosendahl *et al.* 2013, Sachs *et al.* 2014) although they did not examine the influence on clinical outcome. However, a number of other publications showed an association between levels of anxiety and postoperative course (e.g. Székely *et al.* 2007, Lamarche *et al.* 1998, Arthur *et al.* 2000). We took these two prerequisites, the desire for support and the relation of anxiety to adverse outcome, for reasons to develop an anxiety-reducing intervention. Previous randomised studies on reducing preoperative anxiety

used cognitive interventions with informative dialogues, brochures or videos. However, most of these trials measured outcomes postoperatively (Shuldham *et al.* 2002, Dao *et al.* 2011). A recent systematic review found that psychological treatment is slightly better than standard care in reducing postoperative mental distress, however, the evidence is of low quality (Koranyi *et al.* 2014).

Some studies on providing education to CABG patients, which analysed preoperative anxiety, reported no effect (Lamarche *et al.* 1998, Shahmansouri *et al.* 2014). Additionally, a nonrandomised trial examining patients' satisfaction with extended written information on possible surgical complications found no reduction of anxiety (Ivarsson *et al.* 2005).

There are very few examples of randomised trials that actually evaluated preoperative anxiety following a cognitive intervention, e.g. by Lin and Wang (2005) or Van Zuuren *et al.* (2006). Both studies were effective, however, they did not concern cardiac surgery patients.

Further, only a small number of randomised controlled trials assessed the role of emotional support. A study on psychological or spiritual support for CABG patients failed to reduce their anxiety; however, the effects were assessed only postoperatively (Rosendahl *et al.* 2013). Extended attention from the surgeon with individualised oral information and visits twice a day was also not more effective in reducing preoperative anxiety than standard written information in 60 patients awaiting cardiac surgery (Bergmann *et al.* 2001). Other attempts to reduce anxiety have included an exercise programme without psychological intervention (Herdy *et al.* 2008), music interventions (Bradt *et al.* 2013), guided imagery (Halpin *et al.* 2002, Stein *et al.* 2010), hypnosis (Schnur *et al.* 2008) and meditation (Chen *et al.* 2012).

We identified trait anxiety as a significant covariant that affected the effect of the intervention. Trait anxiety represents a firmly grounded individual disposition to react coherently to a certain situation, that is, with in a largely predictable degree of anxiety. When a specific situation matches a patient-inherent facet of trait anxiety, the state anxiety level increases. (Endler & Kocovski 2001) Thus, trait anxiety has a predetermining influence on the actual current anxiety.

Our study differs from previous investigations with regard to the short time frame. This is due to short preoperative periods, which are common in Germany, with short waiting lists and most often admission at the day before surgery. Patients, thus, have to adapt to the thought of an upcoming surgery quickly. Therefore, supportive interventions must fit this narrow schedule to be effective. We implemented a short-term intervention to be administered on the evening before surgery. The reduction of state anxiety was significantly better in the intervention group patients, but overall only moderate. This was most likely due to our 'low dosage' intervention, as well as to an anxiety-reducing effect also present in the control group. Control patients were informed of the study prior to randomisation and thus could be aware of the missed opportunity. Such patients may request more information and emotional support pre- and/or postoperatively. In addition, trait anxiety represented an important covariate. Further, the late evening after the intervention was chosen as the primary endpoint T1 due to the given time frame. Thus, our outcome measured the almost immediate effect of the intervention. We decided against using an endpoint in the early morning before surgery for both organisational and medical reasons. The time-point of measurement also implies that a near-term delay of the operation for unforeseen reasons had no influence on the results.

The intervention was delivered by nurses who completed a special training with booster sessions. For these trainings, a manual was written in addition to a manual of the intervention itself (in German, Fritzsche K, unpublished, 2010). The study nurses were highly motivated and volunteered for the study. Our intervention was designed as an individualised approach focusing on the patients' needs and experiences. The importance of such patient-specific practice has been previously emphasised (Tromp *et al.* 2004). Such an intervention provides an opportunity for social sharing and reduces preoperative distress (Lin & Wang 2005). The information content of the intervention was adapted with consideration to the patients' responses to the questionnaire and the issues they brought up during the intervention. Denial of burdening emotions was accepted, and confidence and certainty were mediated by nonverbal means. Indeed, 95% of the patients of the intervention group considered the dialogue as helpful or very helpful. Although we were not able to prove better clinical outcomes in this group, this observation underlines the value of the intervention for subjective satisfaction of the patients. This is not only important for the individual well-being but also a major competitive factor for hospitals.

Limitations

The study has several methodological limitations. First, patients who refused to participate in the study could have been in particular need of emotional support. The most frequent reason for refusal given was that the patients who were approached for participation already felt weary after the demands of the day due to admission procedures, clinical examinations and medical information provided from several persons. This problem has been observed previously

(Tromp *et al.* 2004), however, it is considered inevitable due to the current structure of health care.

Further, we assume that the preoperative discussion with surgeon and anaesthetist influences the anxiety of the patient. We tried to adjust this effect by a structured team training for the physicians using lectures, case studies and discussion.

Both regular information of the control patients and interventions were delivered by the trained study nurses. Therefore, the risk of a bias was low. Interaction with other medical personnel could have had an effect on the anxiety, too, but we consider the talk to the surgeon and to the anaesthetist and the communication during the preoperative nursing the most important in-hospital factors for preoperative anxiety and therefore did not train other staff-members. In addition, any effects of varying information and other social support can be assumed to be equally distributed between groups by randomisation.

Data on clinical outcome of our intervention were restricted to in-hospital mortality and length of stay on the ICU. We refrained from extensive evaluation of clinical outcome because we wanted to validate the effect of our intervention at first.

The proportion of the randomisation for intervention and control group was not 1, but it was less than 1·5, so we did not consider this to have influenced the study outcomes.

The attending medical team was not intentionally blinded to the assignment to the intervention or control group. However, no conversation with health care professionals was scheduled between the intervention or regular information for the control group and the assessment of the primary endpoint to avoid interference.

Conclusion and relevance to clinical practice

Our study aimed to evaluate a preoperative anxiety-reducing intervention for CABG patients shortly before undergoing surgery. The data indicate that an individualised, short-term psychosocial intervention is more effective to reduce preoperative anxiety surgery than routine information. The results support training for nurses and physicians to provide emotional support to patients before CABG. We assume that our approach can be transferred to other types of surgery. Further research should address the differentiation between cognitive and emotional aspects of presurgery anxiety and also consider patient coping strategies, including the demand for more information or a psychological denial.

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Contributions

CH, US, CB, JF, MS, FB and KF designed the study. CH, US, CB, JF, RL and KF collected and analyzed data. All authors contributed to preparation of the manuscript.

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Conflicts of interest

No conflicts of interest are declared.

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