Effects of an Innovative Psychotherapy Program for Surgical Patients

Bridging Intervention in Anesthesiology—A Randomized Controlled Trial

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ABSTRACT

Background: The stepped care program Bridging Intervention in Anesthesiology (BRIA) aims at motivating and supporting surgical patients with comorbid mental disorders to engage in psychosocial mental healthcare options. This study examined the efficacy of BRIA.

Methods: This randomized, parallel-group, open-label, controlled trial was conducted in the preoperative anesthesiological assessment clinics and surgical wards of a large university hospital in Germany. A total of 220 surgical patients with comorbid mental disorders were randomized by using the computer-generated lists to one of two intervention groups: BRIA psychotherapy sessions up to 3 months postoperatively (BRIA) *versus* no psychotherapy/computerized brief written advice (BWA) only. Primary outcome was participation in psychosocial mental healthcare options at month 6. Secondary outcome was change of self-reported general psychological distress (Global Severity Index of the Brief Symptom Inventory) between baseline and month 6.

Results: At 6-month follow-up, the rate of patients who engaged in psychosocial mental healthcare options was 30% (33 of 110) in BRIA compared with 11.8% (13 of 110) in BWA ($P = 0.001$). Number needed to treat and relative risk reduction were 6 (95% CI, 4 to 13) and 0.21 (0.09 to 0.31), respectively. In BRIA, Global Severity Index decreased between baseline and month 6 ($P < 0.001$), whereas it did not change significantly in BWA ($P = 0.197$).

Conclusions: Among surgical patients with comorbid mental disorders, BRIA results in an increased engagement in subsequent therapy options and a decrease of general psychological distress. These data suggest that it is reasonable to integrate innovative psychotherapy programs into the context of interdisciplinary surgical care. **(ANESTHESIOLOGY 2015; 123:148-59)**

CLINICALLY significant mental distress is highly prevalent in surgical patients.[1–4] It is prone to a chronic course and is associated with perioperative complications and increased morbidity and mortality, leading to worse surgical outcomes and higher healthcare costs.[3–13] Depression, anxiety, and substance use disorders are the most frequent comorbid mental disorders in surgical patients.[1–4] Although psychotherapy is available, effective, and well established in patients with medical illness,[14] it is not offered as a regular service for surgical patients with mental disorders. To help patients to get access to successful psychosocial therapy

What We Already Know about This Topic

- The perioperative period may be an important opportunity to address treatment of mental disorders including substance abuse

What This Article Tells Us That Is New

- In 220 surgical patients with comorbid mental disorders (primarily mood, anxiety and adjustment disorders, or alcohol or tobacco abuse), those randomized to psychotherapy sessions perioperatively and up to 3 months postoperatively were more likely to participate in psychosocial mental health care 6 months after surgery than those randomized to brief written advice only

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options, innovative, cost-efficient, and interdisciplinary approaches are needed that bridge the gap between surgical treatment in the hospital and psychosocial health care including psychotherapy, psychiatry, psychosocial counseling, and self-help groups.

The approach of Bridging Intervention in Anesthesiology (BRIA) aims primarily at motivating and supporting surgical patients with comorbid mental disorders to participate in psychosocial mental healthcare options.[3] It is based on the assumption that the time before and after surgery is a so-called teachable moment.[15] Teachable moments are health-related critical life events that motivate patients to reconsider and change harmful health behavior and that induce both the need for and the acceptance of therapeutic support. The stepped care program of BRIA comprises computer-assisted screening for psychological distress including computerized tailored brief written advice (BWA),[16] motivational interviewing,[17,18] and basic elements of cognitive behavioral therapy and social casework. Implemented in the preoperative anesthesiological assessment clinic, BRIA intends to reach patients from diverse surgical fields. The major therapeutic elements of the psychotherapy program are summarized in table 1. A recent feasibility study found that BRIA can be successfully integrated into the context of anesthetic and surgical hospital care.[3] Preliminary outcome data showed that more than 30% of the patients who participated in at least two BRIA therapy sessions engaged in subsequent psychosocial healthcare options.[3]

We report results of the first randomized controlled trial (RCT) comparing the BRIA psychotherapy sessions (BRIA) *versus* no psychotherapy/computerized BWA only. We hypothesized that the BRIA sessions produced at 6-month follow-up (1) higher rates of patients who engaged in subsequent psychosocial mental healthcare options and (2) a greater decrease of self-reported general psychological distress.

Materials and Methods

Study Design and Setting

This randomized, parallel-group, open-label, controlled trial is based on a superiority design. It was approved by the ethics committee of the Charité–Universitätsmedizin Berlin, Berlin, Germany (EA1/014/11), conducted according to the principles expressed in the Declaration of Helsinki, and registered with ClinicalTrials.gov identifier: NCT01357694 (principle investigator: C.D.S.; date of registration: May 18,

Table 1. Major Therapeutic Elements of the Stepped Care Approach of BRIA

Step I: Computer-assisted psychosocial self-assessment and BWA for all patients

Components

- Multiple-choice questions that can be answered by use of mouse, without requiring any input from keyboard
- Duration: Approximately 25 min per patient
- Items: Standardized psychological screening tests and single items concerning psychological distress, social, lifestyle, and psychological factors related to mental health and psychosocial therapy

Objective

- To offer computerized tailored BWA to all participants of the screening

Topics of BWA

- For patients without clinically significant psychological distress: Positive feedback of screening test results indicating healthy lifestyle
- For patients with clinically significant psychological distress: Detailed, individually tailored feedback of test results indicating psychological distress; if required suggestions concerning therapy and behavior changes
- Domains: Depression, anxiety, general psychological distress, substance use problems (alcohol, illicit drugs, or tobacco), well-being, quality of life, other health factors such as weight, sleep, and physical exercise

Step II: BRIA psychotherapy sessions for patients with comorbid mental disorders

Components

- Inpatient therapy sessions during hospital stay, outpatient sessions after discharge
- Bedside visits and sessions in therapy rooms
- Duration up to 50 min per session
- Outpatient BRIA sessions up to 3 months postoperatively, booster sessions up to 6 months postoperatively

Objectives

- To motivate patients with mental disorders and support them in participating in subsequent psychosocial healthcare options
- To initiate the improvement of patients' psychological symptoms and well-being

Topics of therapy sessions

- Detailed psychological assessment and clarification of diagnoses of mental disorders according to ICD-10
- Development of therapeutic alliance and activation of resources
- Enhancement of motivation for therapy participation and behavior change
- Emotional relief and individually oriented crisis interventions
- Introduction of relaxation and stress management techniques
- Guided discovery of reciprocal relationships between behavior, cognition, emotion, and medical conditions
- Elaboration of a biopsychosocial model of disease and health
- Introduction in the concept of coping and problem skills training
- Information on psychosocial mental healthcare options and teaching of skills how to apply for programs of psychosocial health care

BRIA = Bridging Intervention in Anesthesiology; BWA = brief written advice; ICD-10 = International Classification of Diseases and Health-Related Problems, 10th revision.

2011). Recruitment of participants took place between May 2011 and August 2012; outcome data were collected from November 2011 to February 2013. All patients gave written informed consent.

The BRIA project was conducted in the preoperative assessment clinics of the university hospital Charité–Universitätsmedizin Berlin, Campus Charité Mitte and Campus Virchow-Klinikum, Berlin, Germany. It consisted of two studies based on the stepped care approach of BRIA: (1) a large prospective observational study in the form of the preoperative computer-assisted psychosocial self-assessment; (2) the BRIA psychotherapy RCT that was nested in the prospective observational study. The computer-assisted preoperative self-assessment took place from Monday to Friday between 9.00 AM and 5.00 PM to cover the complete opening hours of the assessment clinics. Patients undergoing preoperative clinical examination by an anesthesiologist were assessed for inclusion and exclusion criteria of the observational study and, in case of eligibility, asked for participation. Upon receipt of written informed consent, eligible patients completed the computer-assisted self-assessment. Immediately after the completion of the screening, the patients' data were analyzed automatically and all patients received a computerized, individually tailored, detailed feedback on their screening results in the form of a BWA, which included, if required, general suggestions concerning therapy and behavior changes (table 1).

Participants and Eligibility Criteria

All participants of the self-assessment whose screening results indicated clinically significant psychological distress, no current participation in psychotherapy or addiction therapy, and interest in the RCT were visited by a study psychotherapist during the first days after surgery to assess the inclusion and exclusion criteria of the RCT. Those patients who fulfilled the eligibility criteria and wanted to participate in the RCT were carefully instructed concerning the RCT. They were informed that they were recommended to get psychosocial support in case their current elevated psychological distress would persist for a longer time based on their screening results. However, they were not given any formal telephone numbers, addresses of therapists, or specific plans how to seek help. They were also informed that all participants of the RCT would be asked at 6-month follow-up whether they would have engaged in any program of psychosocial mental health care other than the study interventions. They were told that participants of the RCT would be allocated in a randomized way to a psychotherapy intervention (BRIA) and an intervention without psychotherapy sessions (BWA). Finally, they were informed that patients allocated to the BWA group would be offered therapy sessions after the 6-month follow-up assessment. Those patients who provided written informed consent to participate completed baseline postoperative psychological questionnaire and clinical diagnostic interview assessment, which included a brief feedback on the diagnostic results.

Inclusion criteria for participating at the preoperative computer-assisted self-assessment were defined as follows: written informed consent to participate after having been properly instructed, patient of the preoperative anesthesiological assessment clinic, and age 18 yr or older. Additional inclusion criteria of the RCT were defined as follows: written informed consent to participate in the RCT after having been properly instructed, acute significant preoperative psychological distress, that is, scoring above of at least one of the cutoff values of a set of six scales or subscales of four established psychological screening tests covering the domains of depression, anxiety, well-being, and alcohol use disorders (table 2), and/or being a tobacco smoker, and/or having consumed illicit drugs during the last 12 months. The screening tests comprised the questionnaires World Health Organization 5-item Well-Being Index,[19] Patient Health Questionnaire-4,[20] Hospital Anxiety and Depression Scale,[21,22] and Alcohol Use Disorder Identification Test.[23,24]

Exclusion criteria for participating at the preoperative computer-assisted self-assessment were as follows: surgery with an emergency or urgent indication; inability to attend the preoperative assessment clinic (bedside visit); insufficient knowledge of German language; members of the hospital staff; admitted in police custody; accommodation in an institution by official or court order; being under guardianship; psychiatric, neurological, or other condition associated with limited legal capability, or limited capability of being properly instructed or giving informed consent. Additional exclusion criteria of the RCT were as follows: severe acute mental disorder (acute episode of psychotic disorder and severe substance use disorder including serious withdrawal symptoms), severe acute suicidal ideation, homelessness, participating in psychotherapy or addiction therapy, and participation in a psychopharmacological clinical trial at baseline assessment or 1 month before, respectively. After complete description of the study to the patients, written informed consent was obtained. Patients with acute severe psychiatric conditions were offered immediate crisis interventions because randomization was considered as unethical.

Randomization, Concealment of Allocation, and Blinding

After having completed baseline procedures, the patients were allocated in a 1:1 ratio in a randomized way to receive one of the two study interventions: (1) The BRIA psychotherapy sessions (n = 110) and (2) no additional intervention after the BWA (n = 110). Computer-generated block randomization with a block size of 4 was carried out by the trial statistician (K.-D.W.). The allocation to BRIA sessions *versus* BWA was conducted after the completion of baseline assessment during the first days after surgery.

At month 6, the primary outcome (participation in psychosocial mental healthcare options) was assessed *via* a semi-structured telephone interview, and the secondary outcome (self-reported general psychological distress with the total score Global Severity Index [GSI] of the Brief Symptom

Table 2. Standardized Self-report Screening Questionnaires Used in the Computer-assisted Self-assessment to Measure Clinically Significant Psychological Distress

Name	Description	Cutoff Score
WHO-5[19]	Short depression screening tool of the WHO. Domain: Psychological well-being/depression (mood, interests, energy, sleep, and psychomotor functioning). Time frame: Past 14 days. Five items, 6-point Likert scale from 0 to 5; total score from 0 to 25; higher scores indicating better well-being.	WHO-5 sum score <14
PHQ-4[20]	Ultrabrief screening tool with subscales for depression, PHQ-2, and for anxiety, GAD-2, one single item for impairment rating. Domains: Depression, anxiety. Time frame: Past 14 days. Five items, 4-point Likert scale from 0 to 3; for PHQ-2 and GAD-2, each two items, ranges from 0 to 6.	PHQ-2 sum score: ≥3 GAD-2 sum score: ≥3
HADS[21,22]	Short screening tool for symptoms of depression and anxiety in physically ill patients: Subscales for depression (HADS-D) and anxiety (HADS-A). Domains: Depression, anxiety. Time frame: Past 7 days. Fourteen items, 4-point Likert scale from 0 to 3; for HADS-D and HADS-A, each seven items, ranges from 0 to 21.	HADS-D sum score: ≥9 HADS-A sum score: ≥11
AUDIT[23,24]	WHO screening instrument for alcohol-related problems. Domain: Hazardous and harmful alcohol consumption and alcohol-related problems. Time frame: Past 12 months. Ten items, 5-point Likert scale from 0 to 4; total score from 0 to 40.	AUDIT sum score: ≥8 for men; ≥5 for women

AUDIT = Alcohol Use Disorder Identification Test; GAD-2 = Generalized Anxiety Disorder Scale-2; HADS = Hospital Anxiety and Depression Scale; HADS-A = Hospital Anxiety and Depression Scale, anxiety subscale; HADS-D = Hospital Anxiety and Depression Scale, depression subscale; PHQ = Patient Health Questionnaire; WHO = World Health Organization 5-item Well-Being Index.

Inventory [BSI]) was assessed by postal self-report questionnaires. The research assistants who assessed the telephone interview and collected the questionnaire data were unaware of the treatment assignment to guarantee rater blinding. At the beginning of the interview, evaluators explicitly asked the patients not to reveal treatment assignment.

Intervention

Bridging Intervention in Anesthesiology sessions were provided by a team of certified psychologists (two licensed psychotherapists and five psychotherapists in training). The first session was arranged only after patients had completed postoperative baseline assessment, the earliest the day after surgery at the bedside. Therapy sessions were offered during inpatient hospital stay and in an outpatient setting, either face-to-face or by telephone, for a period of up to 3 months after discharge. The duration of a session could be determined by the individual need of the patients and exceeded 50 min only in exceptions. Patients with high subjective psychological distress were offered additional booster sessions for up to 6 months after baseline assessment. Important topics of the BRIA program are displayed in table 1.

Measurements and Data Collection

Primary Outcome. The primary outcome assessed the participation of patients in psychosocial mental healthcare options 6 months after inclusion in the RCT. This outcome measure was assessed *via* a semistructured telephone interview by research assistants unaware of treatment assignment. Before their first interview, evaluators were trained in the application of the interview guideline, and during the 16 months of assessment, the evaluators held regular calibration meetings with the first (L.F.K.), third (A.-L.S.), and the last author (H.K.). Participation in psychosocial mental health care was defined as undergoing, being on a waiting list, or having completed a psychosocial mental healthcare program other than BRIA itself during the 6 months after inclusion in the RCT, for example, psychotherapy, psychiatric treatment, psychosocial counseling, and self-help groups.

Secondary Outcome. The secondary outcome assessed self-reported general psychological distress, which was measured with the total mean score GSI of the BSI.[25,26] The BSI is a 53-item short form of the Symptom Checklist 90-R, an internationally widely used and validated self-report scale of psychological distress, which has shown feasibility in patients with medical conditions and sound psychometric properties in both patient and community samples.[25,26] The 53 items measure severity of diverse psychological symptoms during the past 7 days and are rated on a 5-point Likert scale from 0 (not at all) to 4 (extremely). The GSI reflects both the number of symptoms and intensity of perceived distress and has shown validity as a measure of general psychological distress.[25,27] At baseline, the BSI was assessed during the first days after surgery as a paper–pencil questionnaire. At 6-month follow-up, it was assessed as a postal paper–pencil questionnaire. In the current study, the BSI showed good

reliability with Cronbach's alphas of 0.95 at baseline and 0.96 at 6-month follow-up.

Other Measures. The preoperative computer-assisted self-assessment included single-item questions concerning diverse sociodemographic and clinical characteristics and a set of standardized screening questionnaires covering the domains of depression, anxiety, well-being, and alcohol use disorders (table 2). Medical data were obtained 6 months after the preoperative assessment from the electronic patient management system of the hospital. The medical measures are briefly described in table 3; details on psychological and medical measures also can be found in articles about the BRIA feasibility study.[3,4,28,29] The study psychotherapists assessed clinical characteristics in a semistructured clinical interview and made diagnoses of mental disorders according to *International Classification of Diseases, Tenth Revision*, at postoperative baseline assessment using the Short Diagnostic Interview for Mental Disorders (MiniDIPS), a German adaptation of the Anxiety Disorders Interview Schedule.[30,31]

Sample Size Calculation

Epidemiological estimations suggest that approximately 10% of people with mental disorders participate in psychosocial therapy in Germany.[32] Outcome data of the BRIA feasibility study showed that more than 30% of the patients who had BRIA sessions engaged in subsequent psychosocial healthcare options.[3] For the sample size calculation, we conservatively assumed rates of successful psychosocial healthcare engagement of 12 and 30% for BWA and BRIA, respectively. Analyzing these data with a two-sided Fisher exact test, at alpha = 5% and a power of 80%, sample size calculations with nQuery 7.0 resulted in sample sizes of $n_1 = n_2 = 88$ patients in each of the two treatment groups. Assuming an attrition rate of 20% at 6-month assessment, we designed the study to recruit a total of N = 220 participants.

Statistical Analyses

Imputation of Missing Data. Data were analyzed according to intention-to-treat and per-protocol analyses. No missing data had to be imputed of the preoperative self-assessment because of forced responses for all questions. For intention-to-treat analysis, missing data of the binary primary outcome variable were conservatively imputed as "not engaged in subsequent psychosocial mental healthcare options." Because data of the secondary outcome variable "BSI-GSI" were available at baseline for all of the 220 participants, missing data at the 6-month assessment could be imputed by the corresponding GSI scores of the baseline assessment of BSI-GSI. Missing data included both data of patients lost to follow-up and data of patients who discontinued the intervention.

Data Analyses. Data were entered into a computerized database, and statistical analyses were performed with IBM SPSS Statistics (U.S.A.), Version 21, and SAS (U.S.A.), Version 9.1. Results were expressed as relative frequencies in percent and median and range of the 25th to 75th percentiles (interquartile range [IQR]). The scores and corresponding 95% CIs of the parameters, number needed to treat and relative risk reduction, were calculated with the confidence interval calculator.*

Concerning the binary primary outcome variable "engagement in subsequent psychosocial mental healthcare options," the treatment groups were compared with Fisher exact test.

Concerning the continuous secondary outcome variable "change of general psychiatric distress (BSI-GSI) between baseline assessment (T1) and 6-month follow-up (T2)," treatment groups were compared with a nonparametric analysis of longitudinal data in a two-factorial design.[33] This analysis included the T1 and T2 measures of GSI as dependent variables, the time points T1 and T2 as within-subject factor, and the group allocation "BRIA *versus* BWA" as between-subject factors. The statistical interaction between the factors "time" and "treatment group" indicated whether the two groups differed concerning the change of GSI between T1 and T2. The BSI-GSI scores were additionally, after rank transformation (because of characteristics of the distribution), analyzed with repeated-measures ANOVA and with a linear mixed-model approach modeling change from baseline to month 6 and group allocation as between-subject factor. Additional analyses explored whether a potential decrease of general psychiatric distress might be mediated by engagement in subsequent psychosocial mental healthcare options. This analysis used the intention-to-treat data set and included the T1 and T2 measures of GSI as dependent variables, the time points T1 and T2 as within-subject factor, and the group allocation "engagement in subsequent psychosocial mental healthcare options" as between-subject factors. The statistical interaction between the factors "time" and "engagement" indicated whether patients who were successful *versus* not successful concerning the primary outcome differed from each other concerning the change of GSI between T1 and T2.

Statistical comparisons of the treatment groups concerning baseline data were tested with Fisher exact test and Mann–Whitney test. For all statistical tests, a two-tailed *P* value less than 0.05 was considered statistically significant.

Results

Sample Selection, Attrition, and Baseline Characteristics

A total of 5,102 patients participated in the preoperative computer-assisted self-assessment. Of these, 638 patients were assessed for eligibility to participate in the RCT with 96 patients not meeting eligibility criteria, 166 declined to participate, and 156 not participating for other reasons, resulting in 220 participants who were randomized to BRIA and BWA (fig. 1). The participants of BRIA and BWA did not differ significantly regarding number of patients lost to

* Available at: http://www.pedro.org.au/english/downloads/confidence-interval-calculator/. Accessed January 25, 2014.

Table 3. Baseline Demographics and Clinical Characteristics

	BRIA Sessions (n = 110)	BWA Only (n = 110)	*P* Value
Age (yr)	45.0 [33.8–55.0]	42.5 [30.0–52.0]	0.119
Female	69 (62.7)	65 (59.1)	0.679
University entrance qualification	53 (48.2)	54 (49.1)	1.00
Employment status			
Employed	73 (66.4)	67 (60.9)	
Unemployed	12 (10.9)	12 (10.9)	
Pension/invalidity pension	12 (10.9)	11 (10.0)	
Undergoing education/training	6 (5.5)	12 (10.9)	
Residual group*	7 (6.4)	8 (7.3)	0.676
Living together status			
Living with a partner, married	43 (39.1)	29 (26.4)	
Living with a partner, not married	19 (17.3)	20 (18.2)	
Not living with a partner	48 (43.6)	61 (55.5)	0.110
Physical health (ASA classification)			
I	29 (26.4)	28 (25.5)	
II	67 (60.9)	71 (64.5)	
III	14 (12.7)	11 (10.0)	
IV	—	—	0.811
BMI	25.6 [23.5–28.4]	25.1 [22.4–29.1]	0.475
Surgical field			
Neuro, head, and neck surgery	22 (20.0)	32 (29.1)	
Abdomino-thoracic surgery	51 (46.4)	37 (33.6)	
Peripheral surgery	37 (33.6)	41 (37.3)	0.117
Medical comorbidity (CCI)			
0: None	74 (67.3)	76 (69.1)	
1: Low	19 (17.3)	19 (17.3)	
2: Moderate	5 (4.5)	9 (8.2)	
3: High	12 (10.9)	6 (5.5)	0.366
Extent of surgical procedure (POSSUM operative severity item)			
1: Minor	34 (30.9)	33 (30.0)	
2: Moderate	35 (31.8)	34 (30.9)	
4: Major	26 (23.6)	32 (29.1)	
8: Major+	15 (13.6)	11 (10.0)	0.735
Hospital length of stay	4.0 [2.0–8.0]	3.5 [2.0–6.0]	0.667
Preoperative psychological distress			
PHQ-2	2.00 [1.00–3.00]	2.00 [1.00–3.00]	0.806
GAD-2	2.00 [1.75–4.00]	2.00 [1.00–4.00]	0.999
HADS-D	7.50 [4.00–10.25]	7.00 [4.00–10.00]	0.477
HADS-A	10.00 [7.00–12.00]	9.00 [6.75–12.00]	0.213
WHO-5	10.00 [6.00–13.25]	9.00 [5.00–12.00]	0.023
Subjective health†	59.00 [40.00–75.25]	59.50 [35.75–80.00]	0.641
AUDIT	1.00 [1.00–5.00]	3.00 [1.00–6.00]	0.134
AUDIT-C	2.00 [1.00–4.00]	3.00 [1.00–5.00]	0.173
Current smoker	44 (40.0)	46 (41.8)	0.891
Number of cigarettes per week in smokers	78.00 [51.25–140]	105.5 [35.00–140]	0.773
Any illicit substance use during last year	16 (14.5)	16 (14.5)	1.00
Primary diagnosis of mental disorder			
Emotional disorders	91 (82.7)	87 (79.1)	
Mood disorder	37 (33.6)	40 (36.4)	
Anxiety disorder	31 (28.2)	26 (23.6)	
Adjustment disorder	19 (17.3)	13 (11.8)	
Somatoform disorder	1 (0.9)	4 (3.6)	
Eating disorder	1 (0.9)	2 (1.8)	
Personality disorder	1 (0.9)	2 (1.8)	
Psychological factors associated with diseases classified elsewhere‡	1 (0.9)	0 (0.0)	

(Continued)

Table 3. Continued

	BRIA Sessions (n = 110)	BWA Only (n = 110)	*P* Value
Substance use disorders	19 (17.3)	23 (20.9)	
Tobacco use disorder	12 (10.9)	12 (10.9)	
Alcohol use disorder	5 (4.5)	10 (9.1)	
Illicit substance use disorder	1 (0.9)	0 (0.0)	
Multiple substance use disorder	1 (0.9)	1 (0.9)	0.675§
Previous suicide attempts‖	13 (11.8)	9 (8.3)	0.501
Previous psychosocial therapy	49 (44.5)	49 (44.5)	1.00
General psychological distress: BSI-GSI	0.77 [0.50–1.22]	0.76 [0.43–1.17]	0.986

Data are presented as n (%) or median [25–75th percentiles].

* Working at home, gap year, not specified; † Visual analog scale, 0 to 100 with higher scores indicating better subjective health; ‡ Psychological and behavioral factors associated with disorders or diseases classified elsewhere (ICD-10 F54); § *P* refers to the comparison of the two intervention groups regarding the distribution of all of the 11 psychiatric diagnoses that were made; ‖ n = 219 because of missing data.

ASA = American Society of Anesthesiologists physical status classification: (I) Healthy patient; (II) mild systemic disease, no functional limitation; (III) severe systemic disease with definite functional limitation; (IV) severe systemic disease that is a constant threat to life; AUDIT = Alcohol Use Disorder Identification Test (range, 0–40). AUDIT-C = AUDIT subscore for risky alcohol consumption (range, 0–12); BMI = body mass index; BRIA = Bridging Intervention in Anesthesiology; BSI-GSI = Brief Symptom Inventory, total score General Severity Index (range, 0–4); BWA = brief written advice; CCI = Charlson Comorbidity Index; GAD-2 = Generalized Anxiety Disorder Scale-2, anxiety subscale of the Patient Health Questionnaire-4 (range, 0–6); HADS-A = Hospital Anxiety and Depression Scale, anxiety subscale (range, 0–21); HADS-D = Hospital Anxiety and Depression Scale, depression subscale (range, 0–21); PHQ-2 = Patient Health Questionnaire-2, depression subscale of the Patient Health Questionnaire-4 (range, 0–6); POSSUM = Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity, item operative severity; WHO-5 = World Health Organization 5-item Well-Being Index with higher scores indicating better subjective well-being (range, 0–25).

follow-up of the primary outcome (n = 4 *vs.* n = 5; *P* = 1.00), number of patients lost to follow-up of the major secondary outcome (n = 12 *vs.* n = 20; *P* = 0.180), and number of patients who discontinued the intervention (n = 1 *vs.* n = 3; *P* = 0.622) (fig. 1). In each intervention group, out of the patients lost to follow-up, one participant with cancer died from disease progression. One participant of BWA discontinued the intervention because of an acute psychological crisis (fig. 1). He called the study psychotherapists and received crisis intervention and subsequent therapy sessions.

Table 3 summarizes preoperative demographic, medical, and psychological characteristics of the 220 participants of the RCT and data on primary diagnoses of mental disorders, previous psychosocial therapy, suicide attempts, and the baseline BSI-GSI score indicating general psychiatric distress. Apart from a slight difference in the preoperative well-being score, the participants of BRIA and BWA did not differ statistically significantly regarding the characteristics (table 3).

Primary and Secondary Outcomes

Six months after inclusion in the RCT, the rate of patients who engaged in subsequent psychosocial mental healthcare options was statistically significantly higher in the participants of BRIA than in the participants of BWA (table 4). In BRIA, the success rate amounted to 30% according to intention-to-treat analysis and to 31.4% according to per-protocol analysis compared with 11.8% (intention-to-treat analysis) and 12.7% (per-protocol analysis) in the BWA group (*P* = 0.001 for intention-to-treat and per-protocol analyses). The number needed to treat was 6 (95% CI, 4 to 13) for intention-to-treat and 5 (3 to 13) for per-protocol analyses. The relative risk and the relative risk reduction of not engaging in subsequent psychosocial mental healthcare options were 0.79 (95% CI, 0.69 to 0.91) and 0.21 (0.09 to 0.31), respectively, for intention-to-treat, and 0.79 (0.68 to 0.91) and 0.21 (0.09 to 0.32), respectively, for per-protocol analyses.

Participants of BRIA and BWA did not differ regarding the categories and status of psychosocial mental health care that they engaged in. The most frequent category was psychotherapy (16 of 33 in BRIA and 8 of 13 in BWA), followed by psychosocial counseling (15 of 33 in BRIA and 4 of 13 in BWA), self-help groups (1 of 33 in BRIA and 1 of 13 in BWA), and psychiatric treatment (1 of 33 in BRIA and none in BWA) (*P* = 0.606). In the BRIA group, 31 of 33 patients participated in therapy and 2 of 33 were on a waiting list compared with 11 of 13 and 2 of 13, respectively, in the BWA group (*P* = 0.565).

Concerning the secondary outcome "general psychological distress," the two groups differed significantly with respect to the change of GSI between T1 and T2 (interactions: *P* = 0.014 for intention-to-treat and *P* = 0.018 for per-protocol analyses; table 4). The BSI-GSI score decreased significantly between baseline and 6-month follow-up in the BRIA group (*P* < 0.001 intention-to-treat and per-protocol analyses), whereas it did not change substantially in the BWA group (*P* = 0.197 intention-to-treat; *P* = 0.163 per-protocol analyses). The results showed similar statistical significance when the rank-transformed BSI-GSI scores were analyzed using a mixed-model approach (interactions: *P* = 0.015 for intention-to-treat and *P* = 0.020 for per-protocol analyses) and repeated-measures ANOVA (interactions: *P* = 0.013 for intention-to-treat and *P* = 0.047 for per-protocol analyses).

Exploratory analyses of the intention-to-treat data set compared the decrease of general psychiatric distress of those patients who engaged successfully in subsequent psychosocial mental healthcare options (n = 46) and those who did not

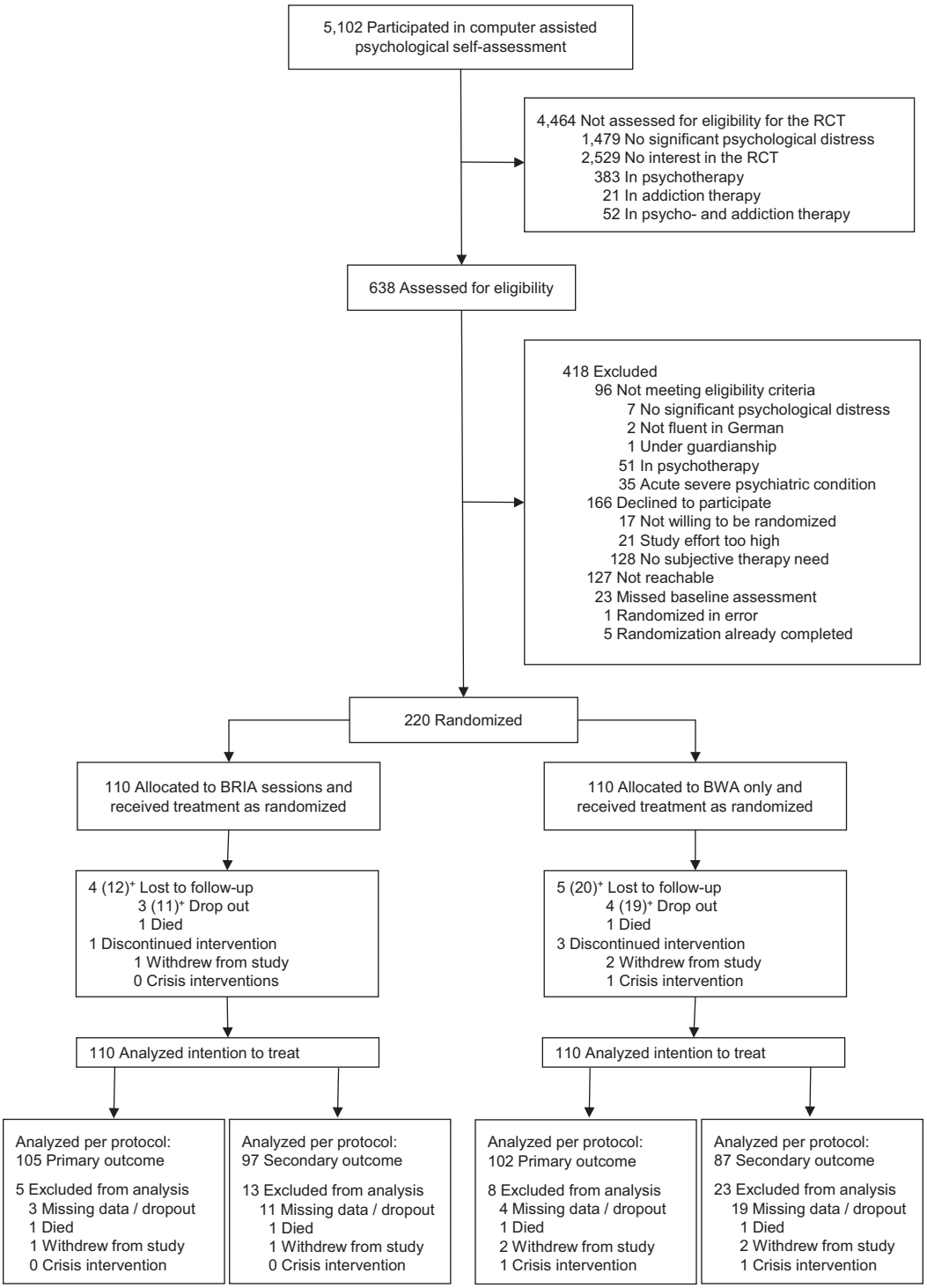

Fig. 1. Flow of participants through the trial. +Numbers in brackets refer to patients lost to follow-up and dropouts concerning the secondary outcome. Numbers of patients lost to follow-up differ between primary and secondary outcomes because the primary outcome was assessed *via* a telephone interview and the secondary outcome as a postal questionnaire. BRIA = Bridging Intervention in Anesthesiology; BWA = brief written advice; RCT = randomized controlled trial.

engage (n = 174). There was no statistically significant interaction effect between the factors "time points 1 and 2" and "successful engagement in subsequent psychosocial mental healthcare options" ($P = 0.176$). Thus a mediator effect of treatment engagement on the decrease of GSI-BSI can be ruled out.

Data on Therapy Sessions

Out of the 110 patients in the BRIA group, 98 (89.1%) had at least one BRIA therapy session. The median number of therapy sessions per patient was 3 with an IQR of 1 to 7, a minimum of 0 and a maximum of 17 sessions. The median

Table 4. Primary and Secondary Outcomes

	BRIA Sessions (n = 110)		BWA Only (n = 110)		*P* Value*
	Baseline	6-month Follow-up	Baseline	6-month Follow-up	
Primary outcome					
Engagement in psychosocial mental healthcare option					
Intention-to-treat analysis	—	33 of 110 (30.0)	—	13 of 110 (11.8)	0.001
Per-protocol analysis	—	33 of 105 (31.4)	—	13 of 102 (12.7)	0.001
Secondary outcome					
General psychological distress: BSI-GSI					
Intention-to-treat analysis	0.77 [0.50–1.22], n = 110	0.59 [0.28–1.03], n = 110	0.76 [0.43–1.17], n = 110	0.80 [0.40–1.11], n = 110	0.014
Per-protocol analysis	0.74 [0.45–1.16], n = 97	0.51 [0.26–0.97], n = 97	0.72 [0.42–1.17], n = 87	0.76 [0.36–1.04], n = 87	0.018

BRIA *vs.* BWA only; intention-to-treat and per-protocol analyses; n (%); median [25–75th percentiles].

* For the analyses of the primary outcome, *P* refers to Fisher exact test; for the analyses of the secondary outcome, *P* refers to the interaction between the two factors "time" and "treatment group" using a nonparametric analysis of longitudinal data in a two-factorial design.[33]

BRIA = Bridging Intervention in Anesthesiology; BSI-GSI = Brief Symptom Inventory, total score General Severity Index (range, 0–4); BWA = brief written advice.

cumulative time spent in therapy sessions amounted to 83.5 min per patient (IQR, 28.8 to 285.5), and the median duration of a session was 27.3 min (IQR, 12.3 to 52.1).

Discussion

We found that BRIA psychotherapy sessions were superior to "no psychotherapy/computerized BWA only" regarding primary and secondary outcomes. Among surgical patients with mental disorders, BRIA sessions resulted in both an increased engagement in subsequent therapy options and a decrease of general psychological distress.

BRIA combines diverse therapy elements of brief intervention, motivational interviewing, and cognitive behavioral therapy. Meta-analyses found considerable average effect sizes for motivational interviewing and combinations of motivational interviewing and cognitive behavioral therapy ranging from small (d = 0.27) to medium (d = 0.40).[34] Concerning the primary outcome "treatment engagement at 6-month follow-up," BRIA demonstrated a success rate of 30% compared with 11.8% in BWA, resulting in a relative risk reduction of 0.21 and a number needed to treat of 6. These effect sizes are based on binary outcome data; however, they can be converted into a Cohen's d of 0.6, which is generally regarded as a medium effect size.[35–37] Thus, the efficacy of BRIA may be interpreted as comparable with other psychosocial interventions in patients without or with medical illness that are in the moderate range of effect sizes according to comprehensive meta-analyses.[14,38–40] One might object that the success of BRIA could be positively influenced by the recruitment process of the RCT that selected for those patients who were willing to participate in a therapy trial and thus also be more willing to seek psychosocial support. However, our current results are very similar to the results of the BRIA feasibility study, which, as an observational study of a pilot project, had rather unrestricted eligibility criteria and showed a success rate of more than 30% of engagement in subsequent psychosocial healthcare options.[3]

Our data indicate that BRIA also contributes to the initiation of the recovery of the comorbid mental disorders of surgical patients. Even after a median of only three therapy sessions, BRIA led to an improvement of psychological symptoms as measured by a statistically significant decrease of the median BSI-GSI from 0.77 at baseline to 0.59 at 6-month follow-up. Interestingly, this improvement was not mediated by treatment engagement in psychosocial therapy programs other than BRIA itself. Although there are no statistical methods available to convert median differences into Cohen's d, a cautious interpretation of the original data suggests that BRIA has a small but clinically significant effect on the improvement of psychological symptoms. This is consistent with the therapy process model of BRIA that assumes that the recovery of mental distress should only be initiated during BRIA but should proceed to a stronger extent not before the successful completion of the subsequent therapy that patients have engaged in. As a consequence, a stronger decrease of psychological symptoms might only occur after 6 months and might have been observable not before follow-ups at 12 or even 18 months.

Systematic reviews and meta-analyses of motivational interviewing have shown no RCTs of psychological interventions that combine motivational interviewing and cognitive behavioral therapy to treat surgical patients with diverse comorbid mental disorders.[34,38,40] However, there are five RCTs of interventions based on motivational interviewing for surgical patients with substance use disorders[41–43] and/

or symptoms of posttraumatic stress disorder.[44,45] It has to be mentioned that there have been RCTs on psychosocial interventions in patients with specific medical conditions, primarily chronic conditions such as cardiovascular disease, cancer, diabetes mellitus, and neurological conditions, and the samples of these trials also included surgical patients.[14,46–48] In addition, there is a tradition of studies on interventions to reduce state anxiety, depression, pain, and perceived stress in surgical patients without mental disorders, for example, by relaxation training, behavioral interventions, and hypnotherapy.[49–52] Taken together, before this study, no evidence from RCTs was available for the efficacy of psychotherapy programs that motivate and support surgical patients with comorbid mental disorders to participate in psychosocial mental healthcare options.

This RCT leaves several questions unanswered, which may be important subjects of future research but are beyond the scope of this study. As the first RCT of an innovative therapy program, we demonstrated that BRIA psychotherapy sessions work in terms of superiority over "no psychotherapy/computerized BWA only." However, it is not known whether there are other psychosocial interventions that are equally or even more effective. Thus, future studies could develop alternative, adapted, or briefer psychosocial approaches and compare them with BRIA regarding diverse outcomes. It would also be important to examine the specific impact of the different therapy elements and topics of BRIA to determine their clinical significance. New trials should in particular investigate psychotherapeutic interventions that start as early as possible in the time before an elective surgery so that it also can be examined whether improving mental health outcomes can have a positive impact on surgical outcomes. At the current state of research, we can only assume that postoperative BRIA sessions may contribute to improve surgical outcomes of potential subsequent surgical treatments. It also has to be mentioned that more research is needed on the basic assumption that the setting of elective surgery is a unique teachable moment that facilitates change of harmful health behavior.[15,53] For example, future studies may investigate whether the time before and after an elective surgery is a stronger teachable moment than other health-related critical life events, for example, nonsurgical medical treatment in outpatient primary care settings. Finally, although motivational interviewing has been developed in the United States and its combination with cognitive behavioral therapy is applied all over the world,[34] it has to be kept in mind that the current approach of BRIA has been tested in the setting of a large European university hospital. Only future projects will find out how BRIA may be integrated into healthcare systems of other countries.

Methodological Limitations

The sample comprised 220 surgical patients who had diverse mental disorders, primarily depression, anxiety disorders, adjustment disorders, and substance use disorders. The primary outcome and the sample size were adequate concerning the major objective of BRIA, motivating and supporting surgical patients with any mental disorder to participate in subsequent therapy programs. Whereas the success in engagement can be interpreted as an effect of medium size, the difference between BRIA and BWA concerning the decrease of general psychological distress is rather small. Apart from conceptual reasons suggesting a stronger decrease of psychological symptoms only after the successful completion of therapy options that patients engaged after BRIA, there are also methodological issues that have to be mentioned. The question arises of whether the secondary outcome "general psychological distress" was suitable to measure change of symptoms in a sample that consisted of small subsamples of patients with heterogeneous disorders. However, to determine the effects of disorder-specific secondary outcomes in diagnostic subgroups, a larger total sample would have been necessary. To adequately examine whether BRIA would be effective regarding the improvement of disorder-specific symptoms, trials will be necessary that include surgical patients with only specific mental disorders, for example, depressive disorders, alcohol use disorders, tobacco use disorders, or anxiety disorders.

Clinical Implications and Conclusions

Previous articles stated that there is a general lack of services offering psychotherapy as part of the clinical routine care of surgical patients with mental disorders.[7,8,10,54] This RCT shows the first evidence of the efficacy of BRIA, an innovative psychotherapeutic bridging intervention that addresses surgical patients with clinically significant psychological distress and mental disorders. In a stepped care approach, BRIA combines screening, brief intervention, and an offer to extend therapy sessions to motivate and support patients to engage in subsequent psychosocial mental healthcare options. One might wonder about the cost–benefit ratio of screening a large sample of surgical patients to get to a relatively small group of patients who have additional mental disorders and who are interested in psychotherapy sessions. However, as outlined in table 1, in clinical practice, all patients who participate in the short computer-assisted psychosocial self-assessment may profit from the stepped care approach. Patients without clinically significant psychological distress get a positive feedback on their healthy lifestyle. Those patients with clinically significant psychological distress who are not interested in therapy sessions at this moment receive the advice to seek psychosocial help and are invited to address the BRIA team in case they would reconsider their decision during or after their hospital stay. Finally, patients who are willing to get help can directly use the low-threshold service of BRIA. This approach is patient oriented because possible psychotherapy starts immediately on patients' own initiative. However, the program is also efficient in terms of synergistically combining prevention, effective current short-term treatment, and existing services of long-term mental health care.

To conclude, we confirmed the results of the BRIA pilot study by showing that BRIA is feasible and effective. From our perspective, additional RCTs should be conducted to investigate whether the present results can be replicated. So far, the evidence of this study suggests that it is reasonable to integrate this novel psychotherapy program into a context of clinical care that is dominated by somatic medical procedures.

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Competing Interests

The authors declare no competing interests.

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