Clinical Trial Protocol

Title

Long-term effects of the Cognitive Behavioral Analysis System of Psychotherapy (CBASP) compared to Supportive Psychotherapy: 1- and 2- years follow-up

Second study phase of the clinical trial:

A comparison of Cognitive Behavioral Analysis System of Psycho- therapy (CBASP) and System of Supportive Psychotherapy (SYSP) for Early Onset Chronic Depression

Principal Investigator
Elisabeth Schramm, PhD
University Medical Center Freiburg, Germany

Co-Principal Investigator
Martin Härter, MD, PhD
University Medical Center Hamburg-Eppendorf, Germany

Study Coordinatior
Thomas Fangmeier, PhD, Paul Bausch, MSc
University Medical Center Freiburg, Germany

Sponsor
University Medical Center Freiburg
Department of Psychiatry and Psychotherapy, Germany

Date
Original study protocol: 10 February 2012
Last update: 13 July 2017

Contents

1 General Information

1.1 Title and funding

Long-term effects of the Cognitive Behavioral Analysis System of Psychotherapy (CBASP) compared to Supportive Psychotherapy: 1- and 2- years follow-up.

This naturalistic long-term follow-up study is funded by the German Research Foundation (SCHR 443/11-2) and comprises the second study phase of the original clinical trial named "*A comparison of Cognitive Behavioral Analysis System of Psychotherapy (CBASP) and System of Supportive Psychotherapy (SYSP) for Early Onset Chronic Depression*" (SCHR 443/11-1), registered on ClinicalTrials.gov (NCT00970437).

1.2 Sponsor and monitor

Sponsor: University Medical Center Freiburg, Department of Psychiatry and Psychotherapy, Freiburg, Germany
Monitor: University Medical Center Hamburg-Eppendorf, Department of Medical Psychology, Hamburg, Germany

1.3 Persons authorized to sign protocol and amendments

Elisabeth Schramm, PhD
University Medical Center Freiburg, Department of Psychiatry and Psychotherapy
Martin Härter, MD, PhD
University Medical Center Hamburg-Eppendorf, Department of Medical Psychology

1.4 Sponsor's medical expert

Mathias Berger, MD
University Medical Center Freiburg, Department of Psychiatry and Psychotherapy

1.5 Responsible investigators

Elisabeth Schramm, PhD (Principal Investigator)
University Medical Center Freiburg
Department of Psychiatry and Psychotherapy
Hauptstraße 5, 79104 Freiburg, Germany
Phone: +49 761 / 270-6967
Fax: +49 761 / 270-6966
E-mail: Elisabeth.Schramm@uniklinik-freiburg.de

Martin Härter, MD, PhD (Co-Principal Investigator)
University Medical Center Hamburg-Eppendorf
Department of Medical Psychology
Martinistraße 52, 20246 Hamburg, Germany
Phone: +49 40 / 7410-52978
Fax: +49 40 / 7410-54940
E-mail: m.haerter@uke.de

1.6 Trial sites

University Medical Center Freiburg, Department of Psychiatry and Psychotherapy
Elisabeth Schramm, PhD
Hauptstraße 5, 79104 Freiburg, Germany
Phone: +49 761 / 270-6967
E-mail: Elisabeth.Schramm@uniklinik-freiburg.de

University Medical Center Bonn, Department of Psychiatry
Henrik Walter, MD, PhD; Dieter Schoepf, MD
Sigmund-Freud-Straße 25, 53105 Bonn, Germany
Phone: +49 228 / 287-19123
E-Mail: henrik.walter@ukb.uni-bonn.de

University Clinic of Hamburg-Eppendorf and Clinic Center Eilbek, Department of Psychosomatic Medicine and Psychotherapy
Bernd Löwe, MD
Martinistraße 52, 20246 Hamburg, Germany
Phone: +49 40 / 7410-59733
E-mail: b.loewe@uke.uni-hamburg.de

University of Heidelberg, Department of Psychiatry
Matthias Backenstraß, PhD; Klaus-Thomas Kronmüller, MD
Voßstraße 4, 69115 Heidelberg, Germany
Phone: +49 6221/ 56-4439
E-mail: Matthias.Backenstrass@med.uni-heidelberg.de

University of Lübeck, Department of Psychiatry and Psychotherapy
Fritz Hohagen, MD; Susanne Steinlechner, MD
Ratzeburger Allee 160 (Haus 7), 23538 Lübeck, Germany
Phone: +49 451/ 500-2471
E-Mail: Susanne.Steinlechner@psychiatrie.uk-sh.de

Central Institute of Mental Health
Josef Bailer, PhD
J 5, 68159 Mannheim, Germany
Phone: +49 621/1703-6151
E-Mail: josef.bailer@zi-mannheim.de

University of Marburg, Psychological Outpatient Clinic
Winfried Rief, PhD; Katrin Wambach, PhD
Gutenbergstraße 18, 35037 Marburg, Germany
Phone: +49 6421 / 28-23681
E-Mail: wambach@staff.uni-marburg.de

University of Tübingen, Department of Psychology and Psychology Clinic
Martin Hautzinger, PhD

Christophstr. 2, 72072 Tübingen, Germany
Phone: +49 7071 / 29-77301
E-Mail: hautzinger@uni-tuebingen.de

2 Background information

Last update: February 2012

Studies investigating the short- and long-term effects of psychotherapy for chronic major depression are still sparse. Only 16 studies for chronic depression could be identified in a recent meta-analysis (Cuijpers, Andersson, Donker, & van Straten, 2011; Cuijpers et al., 2010). From these studies only five investigated patients with chronic major depression, the rest referred to dysthymia. Furthermore, most of these studies were secondary analyses of subsamples of larger studies. Acute psychotherapy showed a small but statistically significant effect (d = 0.23; 95% CI, 0.06 – 0.41) in comparison to control groups. At least 18 sessions were necessary to achieve optimal effects for psychotherapy. Naturalistic follow-up studies were not reported by Cuijpers and colleagues (2010). For a detailed summary of the different studies see also the proposal for the main intervention study (DFG SCHR 443/11-1) and its published protocol (Schramm, Hautzinger, et al., 2011). In a previous pilot study in 30 chronically depressed patients with early depression onset, we showed that a disorder-specific psychotherapy for patients with chronic depression, the Cognitive Behavioral Analysis System of Psychotherapy (CBASP; McCullough, 2000), outperformed Interpersonal Psychotherapy (IPT) after 16 weeks (22 sessions) (Schramm, Zobel, et al., 2011). The remission rates were 57% for CBASP and 20% for IPT. However, no statistically significant differences on self-rated depression scores between the conditions were found after a one year naturalistic follow-up. In another study for chronically depressed patients, no statistically significant differences were found between the augmentation with CBASP compared to the augmentation with supportive psychotherapy for 12 weeks after initial non-response to a medication algorithm (Kocsis et al., 2009). However, the validity of the study is limited due to the relatively small dosage of psychotherapy with an average of 12 sessions and other questionable design issues (e.g. patients´ treatment preference). The authors of the present study hypothesized that augmentation with CBASP would result in better long-term outcomes (e.g. longer remission time, lower depressive symptomatology, better social adaption) ("Project Information - NIH RePORTER. REVAMP FOLLOW-UP STUDY," 2011). Studies investigating the long-term sustainability of treatments for chronic depression are urgently needed. The current study focuses on the defining characteristic of chronic depression, its long-term chronic course.

3 Trial objectives and purposes

Last update: February 2012

The objectives of the naturalistic 1- and 2-year follow-up assessments are:

- A direct comparison of the long-term effectiveness of CBASP vs. Supportive Psychotherapy.
- The investigation of predictors and potential moderators and mediators of the long-term effects (stability vs. relapse).

3.1 Hypotheses

Patients treated with CBASP (48 weeks, 32 sessions) have better outcomes one and two years after the end of the study intervention in comparison to patients treated with Supportive Psychotherapy (48 weeks, 32 sessions).

3.2 Primary Hypothesis

Patients in the CBASP group have a higher rate of "well weeks" than patients treated with Supportive Psychotherapy during follow-up. "Well weeks" are defined as weeks with no or minimal depression symptoms based on the Longitudinal Interval Follow-up Evaluation (LIFE) Interview.

3.3 Secondary Hypotheses

- Patients treated with CBASP show lower depression scores compared to Supportive Psychotherapy during follow-up.
- The rate of weeks in inpatient and outpatient treatment during follow-up is lower in the CBASP group compared to the Supportive Psychotherapy group.
- The number of suicidal attempts during follow-up is lower in the CBASP group compared to the Supportive Psychotherapy group.
- CBASP is superior to Supportive Psychotherapy with regard to social functioning during follow-up.
- CBASP is superior to Supportive Psychotherapy with regard to quality of life during follow-up.
- Stressful life events and a high degree of traumatic experiences in childhood have a disadvantageous influence on the course of disease during the follow-up.

4 Trial design

Last update: February 2012

4.1 Time course of the study

A summary of the planned timeline of the main study and the follow-up study is displayed in Figure 1.

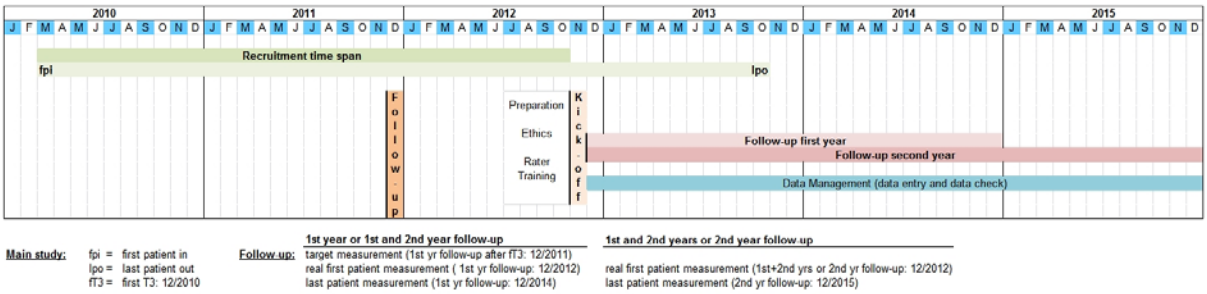


Figure 1. Timeline of the main study and planned recruitment of the follow-up study

Patients are informed at the last measurement point in the main study (after 32 therapeutic sessions) that a follow-up study is planned. Patients are contacted one and two years after the end of the study intervention, irrespective of whether or not the patient completed the intervention study. Patients receive a registered letter with study information and the invitation for participation. Afterwards, information about the aims and the procedure of the

study will be given by telephone and an appointment will be made. In case of participation, patients receive a written informed consent form and the questionnaires. One week later the patient will be invited for the clinician rated interview at the respective trial site.

4.2 Enquiry period

Two follow-up periods were measured: period from last measurement of the main study until one year (one year follow-up) and from one year after T3 until two years after. Due to the late approval of the follow-up study some of the patients have already exceeded the one year follow-up measurement point. For this reason some of them are measured for the whole two years at once.

4.3 Inclusion and exclusion criteria

4.3.1 Inclusion criteria of the intervention study (main study)

- A) Chronic major depressive episode (MDE ≥ 2 years) or
  B) Dysthymia plus superimposed current MDD (double depression) or
  C) Recurrent MDD without complete remission between episodes
- Early onset (age < 21 years)
- Age between 18 and 65 years
- A minimum of at least 20 on the 24-items Hamilton Rating Scale for Depression

4.3.2 Exclusion criteria of the intervention study (main study)

- Acute suicidal tendency
- Psychotic symptoms in history, bipolar disorder, substance abuse/dependence, dementia
- Antisocial disorder, schizotype disorder or borderline personality disorder
- Organic disease, severe cognitive impairment
- Other simultaneous medical treatment or psychotherapeutic treatment
- Non-response to previous CBASP or Supportive Psychotherapy

4.3.3 Inclusion criteria of the follow-up study

- All patients who were randomized for the main study and have given their informed consent to the follow-up assessments

4.4 Clinician-reported assessment instruments

4.4.1 Longitudinal Interval Follow-up Evaluation (LIFE) Interview

The LIFE is used in clinical and epidemiological studies. It is a semi-structured interview for DSM-IV axis I disorders and is used for retrospective inquiry (Wolf, Walker, & Kächele, 2005). It qualifies as a “gold standard” tool for (long-term) follow-up measurements for DSM-IV symptoms and disorders (Wolf et al., 2005). The LIFE was originally developed as a long-term observation for affective disorders (Keller et al., 1987), but the scope of application was extended to further diagnoses. The interview enables a detailed determination and presentation of the beginning and the duration of disorder episodes for long-term follow-up periods. It provides information about remission, relapse and duration of disorder-free intervals. Additionally, information about the impairment of several psychosocial areas is provided (global functioning and treatment-related information). Long-term follow-up periods can be measured with the weekly assessments of the psycho-pathological status (PSR, psychiatric status rating) and its linkage to the operationalization of the DSM-IV

research criteria. The LIFE-interview lasts about 90 minutes; depending on the preliminary efforts and documentations, the entire process can extend up to four hours. The psychometric properties are good to excellent and the interview is translated in cooperation with the research group of Keller and colleagues (see Wolf et al., 2005).
The LIFE-interview comprises the following parts (Wolf et al., 2005):

- The largest part of the LIFE assesses the psychopathology of DSM-IV diagnoses for a period of six or twelve months. Using suitable questions from the interviewer, changes in the symptomatology (change points) for a person can be determined. At each change point the psychopathological status will be estimated on a four- or six-point PSR scale. Using the quantified symptom severity the (i) beginning, (ii) duration, and (iii) remission of a disorder period during the follow-up can be determined with an accuracy of one week.
- Documentation of suicidal intents and attempts.
- Documentation of non-psychiatric diseases (including the corresponding treatment and medication).
- Documentation of psychiatric and psychotherapeutic treatments (weekly).
- Psychosocial variables are rated monthly on a 5- up to 7-point rating scale. They comprise questions on work/employment, familiar relationships, non familiar relationships, sexuality, leisure activities, satisfaction, and general social adaption.
- Monthly registration of global functioning via the Global Assessment of Functioning (GAF) (Endicott, Spitzer, Fleiss, & Cohen, 1976).
- By means of an extra interview protocol, additional biographic or disease-related information will be recorded.

If necessary and possible, the interview will be extended to include the patient's medical records and information from third parties. Using clinical judgement, the information from different sources will be integrated. Longitudinal information on psychopathology is recorded on clearly arranged coding sheets. Additionally, information on the reliability of patients' estimates during the interview of the weekly depression severity, the psychosocial treatment plan, and medical treatment will be ranked by the rater from ´1´ (very good) down to ´5´ (very bad). The LIFE-interview will be conducted by trained interviewers. Expertise with this instrument exists in the study team (e.g., Prof. M. Hautzinger: Kompetenznetz Depression, Hegerl, Hautzinger and colleagues, as well as from Combined Cognitive-Behavioral and Pharmacological Continuation and Maintenance Treatment of Recurrent Depression, Stangier, Hautzinger and others). In another study, the LIFE-interview was used up to three years after the end of intervention (Kordy et al., 2016).

4.4.2 24-Item Hamilton Rating Scale for Depression (HRSD-24) and Quick Inventory of Depressive Symptomatology (QIDS)

The Hamilton Rating Scale for Depression with 24 items (HRSD-24; Hamilton, 1967) and the Quick Inventory of Depressive Symptomatology: Clinician-Rated (QIDS; Rush, Gullion, Basco, Jarrett, & Trivedi, 1996) will be used for measuring depressive symptomatology and its severity form the clinician's perspective. The same instruments were used in the main intervention study.

4.4.3 5-Item Suicide Risk Scale

If there is evidence for suicidal tendencies, the 5-item Suicide Risk Scale will be used for assessing severity. This scale is intended for collecting information during the consultation for clinical judgement. The information from the scale represents a guideline for an action plan if a significant suicidal risk exists.

4.5 Training of outcome assessors

For each trial site, one or two clinical psychologists will be trained for the follow-up interviews. Dr. Markus Wolf (Heidelberg) will perform the rater training for the LIFE-interview and Mrs. Kathrin Mönch (Freiburg) will perform the combined training for the Hamilton Rating Scale for Depression with 24 items (HRSD-24; Hamilton, 1967) and the Quick Inventory of Depressive Symptomatology (QIDS; Rush et al., 1996).
Raters will be certified for the measurement of the depressive symptomatology if the total sum score do not differ more than three points out of 75 from a gold standard (assessment from trainer). One of the first interviews of each rater will be sent to Dr. Markus Wolf for evaluation.
If training of new trainers is necessary, this will be based on reading articles about the LIFE-interview and viewing the video of the LIFE training course that will be recorded during the initial training phase with Dr. Markus Wolf.

4.6 Self-assessment instruments

4.6.1 Munich Event List (MEL)

To what extent life events will affect the course of symptoms during the follow-up period will be investigated by measuring additional variables for the psychosocial areas of the LIFE-interview. These additional variables will be extracted from the Munich Event List (MEL; Maier-Diewald, Wittchen, Hecht, & Werner-Eilert, 1983). The MEL is a retrospective assessment for life events and continuous life conditions in the psychosocial environment. The patient provides information about appearance and frequency of these life events during the past year by means of questions from nine different areas of life (e.g. profession, parents/family, etc.). Beside negative life events also positive life events are asked in the MEL (e.g. marriage, recovery, etc.), lasting situations (phase of health stability, chronical burden), as well as supporting factors. The test-retest reliability is with 95.7% very high. The chronological ranking of the life events by the respondent has a mean reliability of 86%. After seven years, the effect for forgetting is about 60%, primarily regarding slight burden and positive events (Dehmel & Wittchen, 1984). In contrast to the common use of the MEL as observer-rated, here it is adapted for self-assessment without clinician rater.

4.6.2 Inventory of Depressive Symptomatology (IDS-SR)

The Inventory of Depressive Symptomatology – Self Report (IDS-SR; Rush et al., 1996) is used for self-assessment of depression on symptom level. The IDS-SR was used for evaluating acute and long-term therapy outcomes and has acceptable psychometric properties (Rush et al., 2005). It aims to measure all areas of depressive symptoms (DSM-IV criteria), which are defined with constant graduation. The IDS-SR comprises 30 items with a scale from ‘0’

(symptom not present) up to '3' (strongest impairment). Clinically relevant depressive symptomatology is reached if the sum score is equal or higher than 26 (Trivedi et al., 2004).

4.6.3 Quality of Life: Short Form Health Survey (SF-12) and Quality of Life in Depression Scale (QLDS)

Die Medical Outcome Study 36-Item Short Form Health Survey (SF- 36; Ware, Kosinski, & Keller, 1996) is an internationally established instrument for the assessment of health-related quality of life (HRQoL). The 12-item short form (SF-12) is derived from SF-36 and is reliable and valid for clinical and general populations in the USA an in other countries (z.B. Gandek et al., 1998; Sugar et al., 1998; Ware et al., 1996). The SF-12 will be combined with the more disorder-specific Quality of Life in Depression Scale (QLDS). This questionnaire with 34 questions was developed in order to measure the impact of depressive symptoms on quality of life (Hunt & McKenna, 1992). Reliability, construct reliability and internal consistency as well as sensitivity for change are proven for the QLDS for depressive patients (Whalley & McKenna, 1995). All items of the QLDS are rated with "yes" (statement is true) or "no".

4.6.4 Social Adaption Self-Evaluation Scale (SASS)

The SASS collects information on social functioning and impairment of adult depressive patients. Social functioning is defined as quality of the interaction between the person and the social environment. Twenty items on a four-point Likert scale comprise questions about the motivation for social activities, the quantity and quality of existing social relationships, the extend of perceived social support, satisfaction with the social role, as well as competencies for regulation of interpersonal interactions. The construct of social functioning is measured on a single dimension. The SASS has good validity, is easy applicable and sensitive to changes in several areas of social functioning (Weissman, Olfson, Gameroff, Feder, & Fuentes, 2001).

5 Statistical analyses

Last update: August 2017 (details for 5.3 and 5.5)

5.1 Primary endpoint

Rate of well-weeks (weeks with no or minimal depression symptoms) during the two years after termination of the study treatments as measured with the Longitudinal Interval Follow-up Evaluation (LIFE) Interview.

5.2 Secondary endpoints

Depressive symptoms (HRSD-24, QIDS, IDS), functioning (GAF, SASS), and quality of life (SF-12, QLDS) at one and two years after termination of the study.

Rate of weeks in inpatient and outpatient treatments, and number of suicide attempts during the two years after termination of the study treatments as measured with the Longitudinal Interval Follow-up Evaluation (LIFE) Interview.

5.3 Statistical Procedures

Descriptive analysis

All outcomes of interest will be described using descriptive statistics of observed data. Measures of central tendency and dispersion will be reported.

Analysis of the primary outcome

The analysis of the primary outcome will be performed in the intention-to-treat (ITT) sample including all randomized patients and using multiple imputation (see 5.5). The primary outcome rate of well-weeks will be analyzed with a generalized linear mixed model using a negative binomial distribution and a log-link. The independent fixed effects in the model will be treatment group (CBASP, Supportive Psychotherapy), measurement point (1- and 2-years follow-up), their interaction term, and depression severity at inclusion in the main study (HRSD). The measurement points will be treated as repeated measures with an autoregressive residual covariance structure. Trial site will be included as a random effect on the intercept. We will test the primary hypothesis by investigating the statistical significance of the main effect of the treatment group. The effect will be quantified as the ratio of the well-week rates of the treatment groups.
A sensitivity analysis of the primary outcome will be performed using all available data without imputation and utilizing the model described above.

Analyses of secondary outcomes

The secondary outcomes (rate of weeks in inpatient and outpatient treatments, and number of suicide attempts) will be evaluated with the same model as the primary outcome. The secondary metric outcomes (HRSD-24, QIDS, IDS, GAF, SASS, SF-12, QLDS) were all measured in the main study and will be analyzed with a linear mixed model using all measurement points (main study and 1- and 2-years follow-up). Apart from the different number of measurement points and the distribution of the outcome, the same model will be used as for the primary outcome.

Pre-specified mediation analysis

If the study treatment is shown to have an effect on the rate of weeks in inpatient and outpatient treatments in the follow-up period (see above), a mediation analysis will be performed using the study treatment as the independent variable, the primary outcome as the dependent variable, and the rate of weeks in inpatient and outpatient treatments during follow-up as the mediator. The aim of this analysis is to separate between the direct effect of the study treatment and the indirect effect that is mediated by utilization of treatments outside the study during follow-up.

5.4 Level of Significance

For all analyses, a two-sided alpha level of .05 will be used. For all estimated parameters, 95% confidence intervals will be calculated.

5.5 Dealing with missing data

Rates of count outcomes (measured only in the follow-up study) will be imputed via multiple imputation based on demographic and clinical baseline data, group membership, the rates of the other count outcomes throughout the follow-up study, and the course of all metric outcomes throughout the main and the follow-up study. 50 datasets will be generated and analyzed.

Missing data for the metric outcomes will be implicitly estimated by using maximum likelihood estimation, assuming data are missing at random conditional on information in the model.

5.6 Plans to avoid systematic errors

5.6.1 Registration

The intervention study (main study) was registered in a public clinical trial register (clinicaltrials.gov) and was supplemented with the follow-up study.

5.6.2 Blinding

Outcome assessors (raters) were blinded to treatment allocation during the intervention study. Patients are informed verbally and in writing that they should not give any information about their treatment conditions during the main study. The rater in the follow-up study are also blinded to treatment allocation.

5.6.3 Control of influences due to qualification differences of the raters

All raters have a comprehensive psychological training (in sense of academic studies) and at least one year clinical experience in the application of the Structured Clinical Interview for DSM IV (SCID). They also have a training in the LIFE interview as well as a rater training for the Hamilton Rating Scale for Depression. An additional analysis for inter-rater-reliability will be made. Inter-rater reliability will be calculated for each measurement period. Video or audio files from a LIFE interview will be selected. The selected interview will be rated by all active rater. For the Hamilton Rating Scale for Depression was the same procedure as in the main intervention study.

5.6.4 Control of confounding factors

The influence of the trial sites will be controlled for in the analyses (see 5.3).

5.6.5 Control of measurement errors

Guidelines for the rating scales are available. Determination of the inter-rater-reliability will take place on the basis of at least four recorded HRSD or LIFE-interviews, respectively. Monitoring will take place regularly in order to guarantee the integrity of data as planned.

5.7 Data Management

T. Fangmeier, PhD, and P. Bausch, MSc of the University Medical Center Freiburg, Germany are responsible for data management.

5.8 Data Storage

All data (documents for the LIFE-interview, HRSD-24, QIDS as well as the questionnaires for the self-assessment) are collected at the respective trial site. Data will be sent per fax to a fax server. All data is stored in the study center Freiburg and is monitored for completeness and correctness. In case of necessary corrections data are matched with the trial site or the data will be submitted supplementary.
All data is entered by two independent persons. From this, two parallel data sets (A and B) are generated. Via an automated test program both data sets will be checked for equality. If there are different values between the two data sets, the original questionnaire (fax file) will be consulted in order to correct the data entry in data set A or B. After this, the two data sets will be checked again with the test program. The sequence 'test-correction-test' is repeated until there are no more differences between the two corresponding data sets A and B. This test is performed for all instruments/questionnaires. The resulting final data set will be thoroughly compared to the original paper-pencil data by a third independent person. Finally, the data set will be adapted to the data set in the main intervention study (for example: recoding or naming of variables).

5.9 Biometry

The statistical analyses of the data will be conducted at the University Medical Center Hamburg, Germany, by the trial statistician, PD Dr. L. Kriston, in assistance with Ramona Meister, MSc. We aim to enhance objectivity by the separation of people responsible for data management (Freiburg) and data analysis (Hamburg).

6 References

Cuijpers, P., Andersson, G., Donker, T., & van Straten, A. (2011). Psychological treatment of depression: results of a series of meta-analyses. *Nord J Psychiatry, 65*(6), 354-364. doi:10.3109/08039488.2011.596570

Cuijpers, P., van Straten, A., Schuurmans, J., van Oppen, P., Hollon, S. D., & Andersson, G. (2010). Psychotherapy for chronic major depression and dysthymia: a meta-analysis. *Clin Psychol Rev, 30*(1), 51-62. doi:10.1016/j.cpr.2009.09.003

Dehmel, S., & Wittchen, H.-U. (1984). Anmerkungen zur retrospektiven Erfassung von Lebensereignissen und Lebensbedingungen bei Verlaufsuntersuchungen - Bewerten und Vergessen. *Zeitschrift für Klinische Psychologie und Psychotherapie, 13*, 88-110.

Endicott, J., Spitzer, R. L., Fleiss, J. L., & Cohen, J. (1976). The global assessment scale. A procedure for measuring overall severity of psychiatric disturbance. *Arch Gen Psychiatry, 33*(6), 766-771.

Gandek, B., Ware, J. E., Aaronson, N. K., Apolone, G., Bjorner, J. B., Brazier, J. E., . . . Sullivan, M. (1998). Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. International Quality of Life Assessment. *J Clin Epidemiol, 51*(11), 1171-1178.

Hamilton, M. (1967). Development of a rating scale for primary depressive illness. *Br J Soc Clin Psychol, 6*(4), 278-296.

Hunt, S. M., & McKenna, S. P. (1992). The QLDS: a scale for the measurement of quality of life in depression. *Health Policy, 22*(3), 307-319.

Keller, M. B., Lavori, P. W., Friedman, B., Nielsen, E., Endicott, J., McDonald-Scott, P., & Andreasen, N. C. (1987). The Longitudinal Interval Follow-up Evaluation. A

comprehensive method for assessing outcome in prospective longitudinal studies. *Arch Gen Psychiatry, 44*(6), 540-548.

Kocsis, J. H., Gelenberg, A. J., Rothbaum, B. O., Klein, D. N., Trivedi, M. H., Manber, R., . . . Investigators, R. (2009). Cognitive behavioral analysis system of psychotherapy and brief supportive psychotherapy for augmentation of antidepressant nonresponse in chronic depression: the REVAMP Trial. *Arch Gen Psychiatry, 66*(11), 1178-1188. doi:10.1001/archgenpsychiatry.2009.144

Kordy, H., Wolf, M., Aulich, K., Burgy, M., Hegerl, U., Husing, J., . . . Backenstrass, M. (2016). Internet-Delivered Disease Management for Recurrent Depression: A Multicenter Randomized Controlled Trial. *Psychotherapy and psychosomatics, 85*(2), 91-98. doi:10.1159/000441951

Maier-Diewald, W., Wittchen, H.-U., Hecht, H., & Werner-Eilert, K. (1983). *Die Münchener Ereignisliste (MEL) - Anwendungsmanual*. München: Max-Planck-Institut für Psychiatrie.

McCullough, J. P. (2000). Treatment for Chronic Depression. Cognitive Behavioral Analysis System of Psychotherapy. . *Guilford Press, New York, NY.*

Project Information - NIH RePORTER. REVAMP FOLLOW-UP STUDY. (2011). (Vol. 18.Nov 2011).

Rush, A. J., Gullion, C. M., Basco, M. R., Jarrett, R. B., & Trivedi, M. H. (1996). The Inventory of Depressive Symptomatology (IDS): psychometric properties. *Psychol Med, 26*(3), 477-486.

Rush, A. J., Trivedi, M. H., Carmody, T. J., Ibrahim, H. M., Markowitz, J. C., Keitner, G. I., . . . Keller, M. B. (2005). Self-reported depressive symptom measures: sensitivity to detecting change in a randomized, controlled trial of chronically depressed, nonpsychotic outpatients. *Neuropsychopharmacology, 30*(2), 405-416. doi:10.1038/sj.npp.1300614

Schramm, E., Hautzinger, M., Zobel, I., Kriston, L., Berger, M., & Harter, M. (2011). Comparative efficacy of the Cognitive Behavioral Analysis System of Psychotherapy versus supportive psychotherapy for early onset chronic depression: design and rationale of a multisite randomized controlled trial. *BMC Psychiatry, 11*, 134. doi:10.1186/1471-244X-11-134

Schramm, E., Zobel, I., Dykierek, P., Kech, S., Brakemeier, E. L., Kulz, A., & Berger, M. (2011). Cognitive behavioral analysis system of psychotherapy versus interpersonal psychotherapy for early-onset chronic depression: a randomized pilot study. *J Affect Disord, 129*(1-3), 109-116. doi:10.1016/j.jad.2010.08.003

Sugar, C. A., Sturm, R., Lee, T. T., Sherbourne, C. D., Olshen, R. A., Wells, K. B., & Lenert, L. A. (1998). Empirically defined health states for depression from the SF-12. *Health Serv Res, 33*(4 Pt 1), 911-928.

Trivedi, M. H., Rush, A. J., Ibrahim, H. M., Carmody, T. J., Biggs, M. M., Suppes, T., . . . Kashner, T. M. (2004). The Inventory of Depressive Symptomatology, Clinician Rating (IDS-C) and Self-Report (IDS-SR), and the Quick Inventory of Depressive Symptomatology, Clinician Rating (QIDS-C) and Self-Report (QIDS-SR) in public sector patients with mood disorders: a psychometric evaluation. *Psychol Med, 34*(1), 73-82.

Ware, J., Jr., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care, 34*(3), 220-233.

Weissman, M. M., Olfson, M., Gameroff, M. J., Feder, A., & Fuentes, M. (2001). A comparison of three scales for assessing social functioning in primary care. *Am J Psychiatry, 158*(3), 460-466. doi:10.1176/appi.ajp.158.3.460

Whalley, D., & McKenna, S. P. (1995). Measuring quality of life in patients with depression or anxiety. *Pharmacoeconomics, 8*(4), 305-315.

Wolf, M., Walker, C., & Kächele, H. (2005). LIFE - Longitudinal Interval Follow-up Evaluation DSM-IV-Version. In B. Strauß & J. Schumacher (Eds.), *Klinische Interviews und Ratingskalen* (pp. 231-236). Göttingen: Hogrefe.

eTable 1. Changes in the study protocol

Domain	Original study Protocol	Implemented change	Rationale/Comments
Measurement points	1 year and 2 years after treatment termination	for some patients, 1 year measurements were implemented later than 1 year after treatment termination	Funding for the follow-up phase was somewhat delayed, so that measurements could not start in time. Deviation from the scheduled measurements in days was added as fixed covariate to all models.
Secondary outcomes	HRSD-24, QIDS, IDS, GAF, SASS, SF-12, QLDS, LIFE count outcomes, suicidal behavior	dropped SASS; added response, remission, and life events	SASS was not considered essential for assessment of effectiveness. Response, remission, and life events were judged clinically relevant. All changes in the outcomes were implemented prior to analysis.
Site effects	as random	as fixed	Due to non-convergence, we modelled site as fixed effect.
Multiple imputation	50 imputations	20 imputations	Due to disproportionate computational effort without apparent benefits, we used 20 imputations.
Sensitivity analyses	undefined	a priori planned per-protocol analyses; post-hoc analyses in available cases	The per-protocol analyses were planned prior to analyzing any data. The analyses in available cases were added post-hoc, in order to obtain a more comprehensive picture on the robustness of the results of the primary analyses.

eTable 2. Observed data and results of the intent-to-treat analysis for the clinical binary outcomes

	Observed data						Intent-to-treat effect estimate			
	CBASP			SP						
	n	events	(%)	n	events	(%)	odds ratio	(95% CI)	p	d
Suicidal behavior										
1 year after treatment	106	0	(0.0)	101	2	(2.0)	--			
2 years after treatment	99	0	(0.0)	92	0	(0.0)	--			
Response with regard to clinician-rated depressive symptom severity (HRSD)										
End of treatment	120	63	(52.5)	110	45	(40.9)	--			
1 year after treatment	100	56	(56.0)	97	46	(47.4)	1.10	(0.94 to 1.29)	.24	0.05
2 years after treatment	97	58	(59.8)	91	44	(48.4)	1.09	(0.92 to 1.30)	.31	0.05
Remission with regard to clinician-rated depressive symptom severity (HRSD)										
End of treatment	120	44	(36.7)	110	28	(25.5)	--			
1 year after treatment	100	40	(40.0)	97	28	(28.9)	1.11	(0.97 to 1.28)	.13	0.06
2 years after treatment	97	39	(40.2)	91	30	(33.0)	1.05	(0.89 to 1.25)	.54	0.03
Response with regard to self-rated depressive symptom severity (IDS-SR)										
End of treatment	101	41	(40.6)	95	21	(22.1)	--			
1 year after treatment	93	35	(37.6)	95	22	(23.2)	1.17	(1.00 to 1.36)	.049	0.09
2 years after treatment	93	32	(34.4)	88	21	(23.9)	1.09	(0.94 to 1.26)	.24	0.05
Remission with regard to self-rated depressive symptom severity (IDS-SR)										
End of treatment	106	33	(31.1)	96	10	(10.4)	--			
1 year after treatment	98	27	(27.6)	97	14	(14.4)	1.13	(1.00 to 1.27)	.054	0.07
2 years after treatment	97	25	(25.8)	90	11	(12.2)	1.07	(0.97 to 1.18)	.19	0.04

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; HRSD, Hamilton Rating Scale for Depression; IDS-SR, Self-Rated Inventory of Depressive Symptomatology; SP, supportive psychotherapy

eTable 3. Observed data and results of the intent-to-treat analysis for the life event outcomes

	Observed data						Intent-to-treat effect estimate			
	CBASP			SP						
	n	events	(%)	n	events	(%)	odds ratio	(95% CI)	p	d
Education and training										
1 year after treatment	98	28	(28.6)	96	27	(28.1)	1.00	(0.88 to 1.13)	.98	-0.00
2 years after treatment	91	27	(29.7)	86	23	(26.7)	1.04	(0.90 to 1.19)	.62	0.02
Parents and family										
1 year after treatment	98	59	(60.2)	96	58	(60.4)	1.03	(0.88 to 1.21)	.74	0.02
2 years after treatment	91	50	(54.9)	87	47	(54.0)	1.02	(0.85 to 1.23)	.83	0.01
Social contacts and spare time activities										
1 year after treatment	97	93	(95.9)	96	88	(91.7)	1.01	(0.95 to 1.07)	.80	0.00
2 years after treatment	91	85	(93.4)	87	82	(94.3)	0.98	(0.88 to 1.10)	.77	-0.01
Partnership and love affairs										
1 year after treatment	98	83	(84.7)	96	87	(90.6)	0.98	(0.91 to 1.05)	.52	-0.01
2 years after treatment	91	80	(87.9)	87	76	(87.4)	1.01	(0.92 to 1.09)	.89	0.00
Pregnancy and children										
1 year after treatment	98	38	(38.8)	96	36	(37.5)	1.01	(0.85 to 1.19)	.95	0.00
2 years after treatment	91	40	(44.0)	87	27	(31.0)	1.12	(0.92 to 1.37)	.26	0.06
Death of relatives										
1 year after treatment	98	17	(17.3)	96	15	(15.6)	1.01	(0.92 to 1.11)	.85	0.01
2 years after treatment	91	19	(20.9)	87	9	(10.3)	1.06	(0.96 to 1.18)	.27	0.03
Job and housekeeping										
1 year after treatment	98	85	(86.7)	96	81	(84.4)	1.01	(0.94 to 1.08)	.89	0.00
2 years after treatment	91	72	(79.1)	87	76	(87.4)	0.96	(0.87 to 1.06)	.45	-0.02
Financial issues										
1 year after treatment	98	49	(50.0)	96	48	(50.0)	0.98	(0.83 to 1.16)	.84	-0.01
2 years after treatment	91	41	(45.1)	87	45	(51.7)	0.94	(0.79 to 1.13)	.52	-0.03
Habitation										
1 year after treatment	98	74	(75.5)	96	71	(74.0)	1.00	(0.88 to 1.14)	.97	-0.00
2 years after treatment	64	27	(29.7)	63	24	(27.6)	0.98	(0.83 to 1.15)	.77	-0.01
Court and conflict with law										
1 year after treatment	98	9	(9.2)	95	11	(11.6)	0.99	(0.94 to 1.05)	.83	-0.00
2 years after treatment	91	5	(5.5)	87	9	(10.3)	0.98	(0.93 to 1.05)	.63	-0.01
Health										
1 year after treatment	98	56	(57.1)	95	53	(55.8)	1.01	(0.86 to 1.18)	.92	0.00
2 years after treatment	91	45	(49.5)	87	44	(50.6)	0.99	(0.83 to1.19)	.94	-0.00
Any life event										
1 year after treatment	98	98	(100.0)	96	96	(100.0)	--			
2 years after treatment	91	91	(100.0)	87	87	(100.0)	--			

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; SP, supportive psychotherapy

eTable 4. Observed data and results of the per-protocol analysis for the count outcomes

	Observed data						Per-protocol effect estimate			
	CBASP			SP						
	n	mean	(SD)	n	mean	(SD)	rate ratio	(95% CI)	p	d
Well weeks (primary outcome)										
total	83	46.98	(37.54)	56	44.16	(37.55)	1.17	(0.87 to 1.57)	.31	0.12
year 1	89	22.74	(20.32)	62	19.94	(20.15)	1.27	(0.92 to 1.76)	.15	0.19
year 2	83	23.49	(21.44)	56	23.61	(20.37)	1.08	(0.77 to 1.50)	.67	0.06
Weeks in treatment										
total	83	49.45	(41.50)	56	42.64	(43.67)	1.00	(0.72 to 1.38)	.98	0.00
year 1	89	21.12	(22.85)	62	21.06	(22.47)	0.94	(0.65 to 1.34)	.72	-0.05
year 2	83	27.57	(23.94)	56	23.54	(24.66)	1.06	(0.73 to 1.53)	.76	0.04
Weeks in outpatient treatment										
total	83	48.22	(40.42)	56	41.39	(42.80)	1.00	(0.72 to 1.38)	.97	0.00
year 1	89	20.33	(22.18)	62	20.10	(22.14)	0.94	(0.65 to 1.35)	.72	-0.05
year 2	83	27.19	(23.94)	56	23.13	(24.36)	1.06	(0.73 to 1.54)	.77	0.04
Weeks in inpatient treatment										
total	83	1.42	(4.70)	56	1.32	(4.73)	0.59	(0.29 to 1.20)	.15	-0.41
year 1	89	0.98	(4.32)	62	0.97	(3.58)	0.73	(0.35 to 1.52)	.40	-0.25
year 2	83	0.37	(1.71)	56	0.48	(1.96)	0.48	(0.22 to 1.04)	.063	-0.58
Weeks in pharmacological treatment										
total	83	32.95	(39.11)	56	23.88	(37.32)	1.41	(0.87 to 2.28)	.17	0.27
year 1	89	12.73	(20.48)	62	11.21	(19.17)	1.29	(0.75 to 2.22)	.35	0.20
year 2	83	19.95	(23.56)	56	14.38	(21.76)	1.53	(0.88 to 2.68)	.13	0.33
Weeks in psychotherapeutic treatment										
total	83	29.53	(37.02)	56	31.50	(40.13)	0.77	(0.48 to 1.22)	.26	-0.21
year 1	89	12.72	(19.94)	62	14.27	(20.04)	0.78	(0.47 to 1.29)	.33	-0.20
year 2	83	15.89	(21.82)	56	17.82	(23.43)	0.76	(0.45 to 1.29)	.31	-0.21

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; SD, standard deviation; SP, supportive psychotherapy

eTable 5. Observed data and results of the per-protocol analysis for the continuous outcomes

	Observed data						Per-protocol effect estimate			
	CBASP			SP						
	n	mean	(SD)	n	mean	(SD)	mean difference	(95% CI)	p	d
Clinician-rated depressive symptom severity (HRSD)										
Randomization	89	27.60	(5.23)	62	27.55	(6.25)	--			
Treatment onset	89	24.21	(7.96)	62	25.73	(6.70)	--			
End of treatment	89	14.27	(9.47)	62	17.35	(10.04)	--			
1 year after treatment	85	12.96	(9.45)	59	14.15	(9.92)	-0.79	(-3.58 to 2.00)	.58	-0.08
2 years after treatment	82	12.85	(9.01)	56	13.82	(10.15)	-0.94	(-4.04 to 2.25)	.55	-0.10
Clinician-rated depressive symptom severity (QIDS)										
Randomization	99	14.86	(3.45)	72	15.06	(3.28)	--			
Treatment onset	99	13.06	(4.25)	72	14.35	(3.95)	--			
End of treatment	99	7.48	(5.68)	72	8.79	(5.77)	--			
1 year after treatment	89	7.16	(5.24)	62	7.69	(5.25)	-0.32	(-1.85 to 1.21)	.68	-0.06
2 years after treatment	78	6.95	(5.21)	53	7.38	(5.71)	-0.29	(-2.06 to 1.47)	.74	-0.05
Clinician-rated level of functioning (GAF)										
Treatment onset	86	55.07	(10.03)	59	53.25	(8.28)	--			
End of treatment	86	66.74	(13.64)	62	63.13	(12.88)	--			
1 year after treatment	87	68.68	(14.85)	61	66.93	(13.99)	1.30	(-3.12 to 5.71)	.56	0.09
2 years after treatment	64	69.28	(14.79)	45	69.07	(14.44)	0.48	(-4.58 to 5.54)	.85	0.03
Self-rated depressive symptom severity (IDS-SR)										
Treatment onset	83	37.16	(10.90)	62	40.55	(8.10)	--			
End of treatment	82	22.42	(14.04)	55	29.15	(14.51)	--			
1 year after treatment	82	25.23	(14.45)	59	28.95	(15.51)	-3.86	(-8.09 to 0.37)	.074	-0.26
2 years after treatment	82	25.61	(14.26)	55	28.43	(15.68)	-3.23	(-7.98 to 1.52)	.18	-0.22
Global physical health-related quality of life (SF-12-PCS)										
Treatment onset	82	45.30	(10.04)	59	46.39	(9.84)	--			
End of treatment	77	47.15	(10.94)	54	47.52	(9.97)	--			
1 year after treatment	78	46.12	(10.21)	57	46.92	(10.18)	-0.44	(-3.70 to 2.82)	.79	-0.04
2 years after treatment	80	45.12	(10.23)	52	45.67	(10.74)	-0.49	(-3.82 to 2.84)	.77	-0.05
Global mental health-related quality of life (SF-12-MCS)										
Treatment onset	82	26.48	(7.30)	59	25.70	(8.37)	--			
End of treatment	77	38.41	(13.86)	54	33.19	(12.65)	--			
1 year after treatment	78	37.80	(13.28)	57	36.41	(11.76)	0.93	(-3.00 to 4.85)	.64	0.07
2 years after treatment	80	39.21	(13.26)	52	37.92	(12.24)	1.60	(-2.63 to 5.83)	.46	0.12
Depression-specific quality of life (QLDS)										
Treatment onset	84	18.10	(7.94)	62	21.05	(6.03)	--			
End of treatment	82	10.36	(9.27)	56	14.58	(9.63)	--			
1 year after treatment	82	11.12	(9.72)	59	13.38	(10.05)	-2.07	(-4.79 to 0.66)	.14	-0.21
2 years after treatment	82	10.55	(9.33)	55	12.19	(10.17)	-1.88	(-5.00 to 1.34)	.24	-0.19

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; GAF, Global assessment of Functioning; HRSD, Hamilton Rating Scale for Depression; IDS-SR, Self-Rated Inventory of Depressive Symptomatology; QIDS, Quick Inventory of Depressive Symptomatology; QLDS, Quality of Life in Depression Scale; SD, standard deviation; SF-12-MCS, Mental

Component Summary of the 12-Item Short-Form Health Survey; SF-12-PCS, Physical Component Summary of the 12-Item Short-Form Health Survey; SP, supportive psychotherapy

eTable 6. Observed data and results of the per-protocol analysis for the clinical binary outcomes

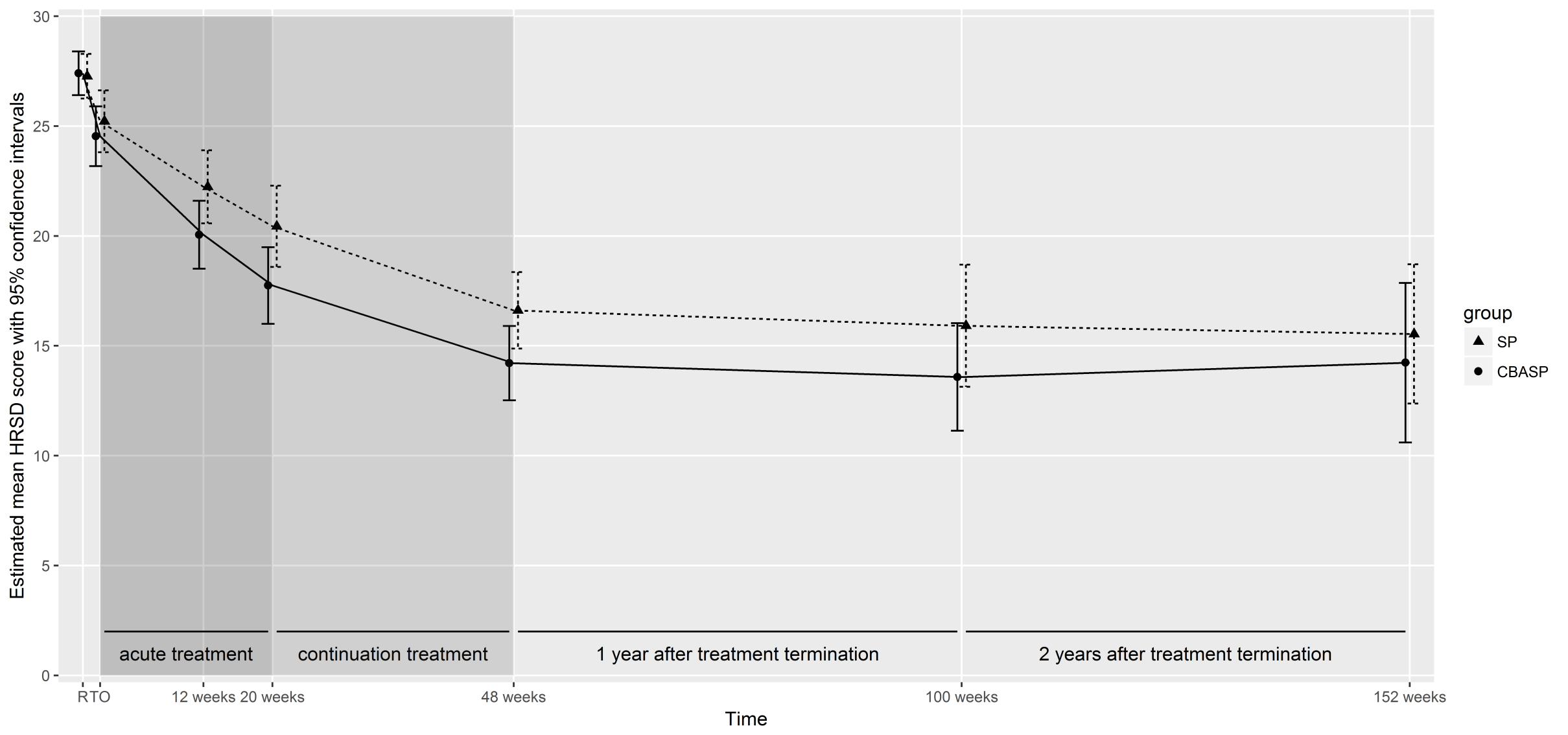
	Observed data						Per-protocol effect estimate			
	CBASP			SP						
	n	events	(%)	n	events	(%)	odds ratio	(95% CI)	p	d
Suicidal behavior										
1 year after treatment	89	0	(0.0)	62	1	(1.6)	--			
2 years after treatment	83	0	(0.0)	56	0	(0.0)	--			
Response with regard to clinician-rated depressive symptom severity (HRSD)										
End of treatment	99	53	(53.5)	72	29	(40.3)	--			
1 year after treatment	85	49	(57.6)	59	32	(54.2)	1.00	(0.81 to 1.23)	.98	0.00
2 years after treatment	82	48	(58.5)	56	31	(55.4)	1.04	(0.84 to 1.29)	.73	0.02
Remission with regard to clinician-rated depressive symptom severity (HRSD)										
End of treatment	99	36	(36.4)	72	20	(27.8)	--			
1 year after treatment	85	34	(40.0)	59	22	(37.3)	0.98	(0.78 to 1.22)	.84	-0.01
2 years after treatment	82	32	(39.0)	56	23	(41.1)	0.94	(0.73 to 1.20)	.61	-0.03
Response with regard to self-rated depressive symptom severity (IDS-SR)										
End of treatment	85	37	(43.5)	62	17	(27.4)	--			
1 year after treatment	77	30	(39.0)	59	17	(28.8)	1.81	(0.96 to 1.45)	.11	0.33
2 years after treatment	78	25	(32.1)	55	18	(32.7)	1.02	(0.83 to 1.26)	.83	0.01
Remission with regard to self-rated depressive symptom severity (IDS-SR)										
End of treatment	90	30	(33.3)	62	8	(12.9)	--			
1 year after treatment	82	23	(28.0)	59	13	(22.0)	1.11	(0.94 to 1.32)	.21	0.06
2 years after treatment	82	22	(26.8)	55	10	(18.2)	1.13	(0.99 to 1.30)	.067	0.07

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; HRSD, Hamilton Rating Scale for Depression; IDS-SR, Self-Rated Inventory of Depressive Symptomatology; SP, supportive psychotherapy

eTable 7. Observed data and results of the per-protocol analysis for the life event outcomes

	Observed data						Per-protocol effect estimate			
	CBASP			SP						
	n	events	(%)	n	events	(%)	odds ratio	(95% CI)	p	d
Education and training										
1 year after treatment	82	24	(29.3)	58	18	(31.0)	0.98	(0.93 to 1.04)	.52	-0.01
2 years after treatment	78	23	(29.5)	53	15	(28.3)	1.01	(0.96 to 1.06)	.69	0.00
Parents and family										
1 year after treatment	82	51	(62.2)	58	35	(60.3)	1.01	(0.85 to 1.21)	.88	0.01
2 years after treatment	78	42	(53.8)	53	27	(50.9)	1.03	(0.83 to 1.28)	.78	0.02
Social contacts and spare time activities										
1 year after treatment	81	77	(95.1)	58	53	(91.4)	1.00	(1.00 to 1.00)	.24	0.00
2 years after treatment	78	72	(92.3)	53	50	(94.3)	1.00	(1.00 to 1.00)	.67	0.00
Partnership and love affairs										
1 year after treatment	82	68	(82.9)	58	53	(91.4)	0.99	(0.98 to 1.00)	.18	0.00
2 years after treatment	78	67	(85.9)	53	46	(86.8)	1.00	(0.99 to 1.02)	.54	0.00
Pregnancy and children										
1 year after treatment	82	32	(39.0)	58	20	(34.5)	1.18	(1.01 to 1.37)	.039	0.09
2 years after treatment	78	33	(42.3)	53	17	(32.1)	1.19	(1.01 to 1.39)	.037	0.09
Death of relatives										
1 year after treatment	82	16	(19.5)	58	9	(15.5)	1.01	(1.00 to 1.01)	.32	0.00
2 years after treatment	78	18	(23.1)	53	3	(5.7)	1.01	(1.00 to 1.02)	.082	0.01
Job and housekeeping										
1 year after treatment	82	70	(85.4)	58	48	(82.8)	1.00	(1.00 to 1.00)	.72	0.00
2 years after treatment	78	63	(80.8)	53	45	(84.9)	1.00	(1.00 to 1.00)	.77	0.00
Financial issues										
1 year after treatment	82	39	(47.6)	58	28	(48.3)	1.02	(0.85 to 1.21)	.85	0.01
2 years after treatment	78	34	(43.6)	53	32	(60.4)	0.85	(0.71 to 1.01)	.070	-0.09
Habitation										
1 year after treatment	82	61	(74.4)	58	43	(74.1)	1.00	(0.93 to 1.06)	.89	0.00
2 years after treatment	78	54	(69.2)	53	41	(77.4)	0.94	(0.83 to 1.06)	.15	-0.03
Court and conflict with law										
1 year after treatment	82	8	(9.8)	57	5	(8.8)	1.00	(1.00 to 1.00)	.99	0.00
2 years after treatment	78	5	(6.4)	53	6	(11.3)	1.00	(1.00 to 1.00)	.46	0.00
Health										
1 year after treatment	82	43	(52.4)	57	28	(49.1)	1.03	(0.87 to 1.24)	.71	0.02
2 years after treatment	78	41	(52.6)	53	21	(39.6)	1.12	(0.93 to 1.34)	.24	0.06
Any life event										
1 year after treatment	82	82	(100.0)	58	58	(100.0)	--			
2 years after treatment	78	78	(100.0)	53	53	(100.0)	--			

CBASP, Cognitive Behavioral Analysis System of Psychotherapy; CI, confidence interval; d, Cohen's d; SP, supportive psychotherapy


Estimated mean HRSD score with 95% confidence intervals
30
25
20
15
10
5
0
acute treatment
continuation treatment
1 year after treatment termination
2 years after treatment termination
RTO
12 weeks
20 weeks
48 weeks
100 weeks
152 weeks
Time
group
SP
CBASP