Running Title: Helping Alliance and Unmet Needs

Helping alliance and unmet needs in routine care of people with severe mental illness across Europe: a prospective longitudinal multicenter study

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Appendix: The CEDAR study group

The study "Clinical decision making and outcome in routine care for people with severe mental illness" (CEDAR) is a multicenter collaboration between the Section Process-Outcome Research at Department of Psychiatry II, Ulm University, Germany (Bernd Puschner); the Section for Recovery at Institute of Psychiatry, King's College London, U.K. (Mike Slade); the Department of Psychiatry at Second University of Naples, Italy (Mario Maj); the Department of Psychiatry at Debrecen University, Hungary (Anikó Égerházi); the Unit for Psychiatric Research at Aalborg Psychiatric Hospital, Denmark (Povl Munk-Jørgensen); and the Department of General and Social Psychiatry at University of Zurich, Switzerland (Wulf Rössler).

The CEDAR study group includes the following members: Bernd Puschner (chief investigator), Katrin Arnold, Esra Ay, Thomas Becker, Jana Konrad, Petra Neumann, Sabine Loos, Nadja Zentner (Ulm); Mike Slade, Elly Clarke, Harriet Jordan (London); Mario Maj, Andrea Fiorillo, Domenico Giacco, Mario Luciano, Corrado De Rosa, Gaia Sampogna, Valeria Del Vecchio, Pasquale Cozzolino, Heide Gret Del Vecchio, Antonio Salzano (Naples); Anikó Égerházi, Tibor Ivánka, Marietta Nagy, Roland Berecz, Theodóra Glaub, Ágnes Süveges, Attila Kovács, Erzsébet Magyar (Debrecen); Povl Munk-Jørgensen, Malene Krogsgaard Bording, Helle Østermark Sørensen, Jens-Ivar Larsen (Aalborg); Wolfram Kawohl, Arlette Bär, Wulf Rössler, Susanne Krömer, Jochen Mutschler, Caitriona Obermann (Zurich).

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Conflict of interest: None declared.

ABSTRACT

The helping alliance (HA) refers to the collaborative bond between patient and therapist including shared goals and tasks. People with severe mental illness have a complex mixture of clinical and social needs. Using mixed-effects regression, this study examined in 588 people with severe mental illness whether an increase in the HA is associated with fewer unmet needs over time, and whether change in the HA precedes change in unmet needs. It was found that a reduction of unmet needs was slower in patients with higher HA (B=0.04, p<.0001) only for patient-rated measures. Improvement in both patient-rated and staff-rated HA over time was associated with fewer subsequent patient- (B=-0.10, p<0.0001) and staff-rated (B=-0.08, p=0.0175) unmet needs. With positive changes in the HA preceding fewer unmet needs, findings provide further evidence for a causal relationship between alliance and outcome in the treatment of people with severe mental illness.

Keywords: Helping alliance; unmet needs; severe mental illness; prospective observational study

INTRODUCTION

Helping alliance (HA) refers to the collaborative bond between patient and therapist including shared goals and tasks (Ardito and Rabellino, 2011; Bordin, 1979) and has been consistently found to predict outcome of psychotherapy (Horvath et al., 2011; Horvath and Symonds, 1991; Martin et al., 2000). Over the last years, evidence has been accumulated testifying to the importance of the alliance-outcome relation also in psychiatric treatment settings (Johansson and Jansson, 2010; Priebe et al., 2011) where treatment differs from psychotherapy in an number of aspects. E.g. the role of the therapist, being "merely" a member of a multiprofessional team, is less clearly defined, and treatment is provided to patients with higher levels of severity and chronicity (Priebe and McCabe, 2006).

The large majority of studies investigating the alliance-outcome relation used cross-sectional or two time-point data only, limiting causal inferences. An exception is a study which reported that patient- and staff-rated HA predicted subsequent clinical improvement when controlling for prior symptom change (De Bolle et al., 2010). Another study, using a multilevel model controlled for confounders, showed that a reduction in outcome (unmet needs) preceded an increase of the patient-, but not of the staff-rated HA (Junghan et al., 2007).

Aim of the present study is to add to the scarce knowledge about the temporal relationship between the helping alliance and outcome in psychiatric treatment taking into account the perspectives of both patients and staff by examining the following research questions:

(1) Is an increase in the patient- vs. staff-rated helping alliance associated with fewer patient- vs. staff-rated unmet needs over time?

(2) Do changes in the patient- vs. staff-rated helping alliance precede changes in patient- vs. staff-rated unmet needs?

METHODS

Design and Recruitment

Participants of the naturalistic prospective longitudinal multicenter study "Clinical decision-making and outcome in routine care for people with severe mental illness" (CEDAR, ISRCTN75841675) were recruited between November 2009 and December 2010 at six European centers: Ulm (Germany), London (UK), Naples (Italy), Debrecen (Hungary), Aalborg (Denmark), and Zurich (Switzerland). Apart from expected contact with mental health services (excluding inpatient services) during the time of study participation, inclusion criteria were: (a) adult age (18-60 years) at intake, (b) mental disorder of any kind as main diagnosis established by case notes or staff communication using SCID criteria (First et al., 1997), (c) presence of severe mental illness (illness duration $\geq$ 2 years and Threshold Assessment Grid $\geq$ 5 points; Slade et al., 2000), (d) sufficient knowledge of the host country's language, and (e) capable of giving informed consent. Exclusion criteria were: (a) main diagnosis of mental retardation, dementia, substance use or organic brain disorder, (b) cognitive impairment too severe to provide meaningful information on study instruments, and (c) treatment by forensic psychiatric services. A paired member of staff was identified by the service user. Assessments at baseline, 2, 4, 6, 8, 10 and 12 months (T0-T6) were completed online or on paper-and-pencil-forms. The study was approved by the Ethics Committees of all participating centers. 588 patients were recruited for whom 213 staff members provided 574 assessments. All participants received routine care. More details on design, procedures, participant flow and mental health services at study sites are given elsewhere (Puschner et al., 2010; Puschner et al., 2016).

Measures

HA was measured from T0 to T6 via the *Helping Alliance Scale* (HAS; Priebe and Gruyters, 1993), with versions rated by patients (HAS-P, six items) and staff (HAS-S, five items). The scale for each item ranges from 0 (worst) to 10 (best), except for item six of the patient-rated version which can only be rated 0, 5 or 10. The HAS total score is the mean over all items, also ranging from 0 (low helping alliance) to 10.

Unmet need was assessed from T0 to T6 by using the *Camberwell Assessment of Need Short Appraisal Scale* (CANSAS). The CANSAS measures needs in 22 health and social domains, with versions rated by patients (CANSAS-P; Trauer et al., 2008) and staff (CANSAS-S; Slade et al., 1999). Each domain is rated as either an unmet need (current serious problem, regardless of any help given), met need (no or moderate problem because of help given), no need or not known. The summary unmet need score is the total number of unmet need ratings, ranging from 0 to 22, with a higher score being worse.

The *Threshold Assessment Grid* (TAG; Slade et al., 2000) which is a staff-rated seven-item measure of severity of mental illness was included as a baseline control variable. The items are rated 0 (none) to 3 (severe) or 4 and above (very severe), and the total score is the sum, ranging from 0 (low severity) to 24. Further control variables were patient characteristics including age, gender, education (years in school), diagnostic group (psychotic, mood or other), and duration of illness.

Statistical analysis

To investigate the impact of the HA on outcome, two mixed-effects regression models were fitted with patient- and staff-rated number of unmet needs at each measurement point as the dependent variables. Independent variables included mean-centered HA at each measurement point, months since baseline, and mean-centered HAS x time. To test whether changes in the HA precede changes in unmet needs, again two mixed-effects regression models were computed for patient- and staff-rated measures, with number of unmet needs at each measurement point as the dependent variables. Independent variables were mean HAS over all assessments (to assess the effect of the general level of the HA on unmet need), change of the HA from the previous to the current time point, and months since baseline. Control variables in all models were age, gender, education, illness severity (TAG), diagnostic group and duration of illness. Random effects were

observations within subjects over time, and fixed effects were effects of time, HA and covariates on unmet needs. Analyses were carried out using SAS version 9.2 for Windows.

RESULTS

Table 1 shows sample characteristics.

insert Tab. 1 about here

Staff participants were M = 46.0 (SD = 10.5) years old, with on average 15 years (SD = 9.6) of work experience in mental health services. Professions were psychiatrists (36.4%), psychologists (9.2%), social workers (5.3%), or other professions including nurses, psychiatric trainees or support time and recovery workers (49.0%). HAS ratings were generally high and relatively stable over time, with patient ratings higher than staff ratings. Unmet needs decreased over time, with patients indicating fewer unmet needs than staff (Fig. 1).

insert Fig. 1 about here

As shown in Table 2 (upper part), at baseline patients with an average HAS-P score reported 3.13 unmet needs which decreased by 0.36 points with each unit that participants scored above the average HAS-P score. Overall, unmet needs decreased by 0.16 points every two months. As indicated by the significant positive interaction effect of time and HA, each unit that participants scored above the average HA was associated with a deceleration of the slope by 0.04 points. Results of the staff model were similar to the patient model. However, there was no significant interaction between HA and time.

insert Tab. 2 about here

As shown in the lower part of Table 2, higher levels of patient-rated HA were associated with fewer patient-rated unmet needs at each single time point (*B*= -0.58). An increase of the HA was associated with fewer unmet needs at the next assessment point (*B*=-0.10), and there was a significant improvement in patient-rated unmet needs over time (*B*=-0.13). Again, effects were

similar in the model using staff-rates measures, with the exception that the level of staff-rated HA averaged over all time points was not predictive of staff-rated unmet needs at each time point.

DISCUSSION

Using repeated standardized assessments over one year of the helping alliance (HA) and unmet needs from a large European sample of people with severe mental illness and paired staff, helping alliance was tested as a predictor of unmet needs over time from both patient and staff perspectives. Beyond examining these longitudinal associations, temporal precedence between the HA and unmet needs was analyzed.

Does alliance predict unmet needs over time?

For patient-rated measures, patients with higher HA ratings reported fewer unmet needs at baseline, but also a less pronounced decrease of unmet needs over time. For staff-rated measures, the HA only affected unmet needs at baseline. This confirms evidence from psychotherapy research of a stronger alliance-outcome relation when using patient-rated measures (Horvath and Symonds, 1991). In contrast, our finding that the rate of reduction of patient-rated unmet needs *decelerated* with higher patient-rated HA ratings was rather surprising at first, as previous research suggests that a better alliance is related to faster (De Bolle et al., 2010) or no change (Puschner et al., 2008) in subsequent clinical improvement. However, these studies used different alliance and outcome measures, and analyses applied absolute rather than mean-centered alliance scores. Against the background of our finding that patients with a higher HA across time points (i.e. above mean) already had fewer unmet needs at baseline, there might have been less room to improve. It should be borne in mind, though, that the effect size for the deceleration of the main effect of time due to the alliance, albeit significant, was small (B=0.04). Furthermore, as the patient-rated HA overall was high and stable, a one point increase may be regarded as highly unrealistic. Thus, the finding that staff-rated HA across time points did not exert a significant

effect on the change rate of staff-rated unmet needs can may be regarded merely as a statistical difference in comparison to the results of the patient models, but hardly qualifies for a clinically relevant difference. Taken together, findings suggest a limited association of the alliance with change in unmet needs over time, especially for staff-rated measures. This could also be interpreted as a hint towards an "optimal dose", i.e. once a good enough helping alliance has been established, further significant improvement is unlikely (Loos et al., 2015). Other factors, for example effectively addressing major problem areas of the patient during therapy, might play a more important role for a reduction of unmet needs.

Does change in alliance precede change in unmet needs?

At each time point, fewer unmet needs were predicted by an increase in the HA during the preceding two months in both patient and staff models, supporting the view that an increase in the helping alliance *leads* to improved outcome. This finding is in line with several studies from psychotherapy settings (Barber et al., 2000; Klein et al., 2003; Zuroff and Blatt, 2006). However, it contradicts the result of Junghan and colleagues (2007), who, having used the same instruments (HAS and CANSAS) and comparable analysis methods (regression models), reported that a change in unmet needs preceded a change in the HA, but not vice versa. The shorter intervals between repeated measurements (1 month) and the shorter observation period (7 months) in the study of Junghan and colleagues may contribute to an explanation of these divergent findings. Also, complex interdependencies or reciprocal effects between HA and outcome may occur (Barber et al., 2000) and therefore logically explain why evidence for both directions of the effect can be found. A further reason could be that there are other important determinants of unmet needs or HA, respectively, which were neither controlled for in the study of Junghan and colleagues nor in our study. In both studies, remaining unexplained variance of the dependent variable was considerable, pointing to the possibility of underlying covariate effects not

accounted for. Further repeated-measures studies using comparable methods and controlling for the effect of other potential covariates (e.g. perceived support by family and friends, medication adherence) and studies applying cross-lagged panel designs are needed to draw more firm conclusions on the direction of the effect between HA and unmet needs in complex mental health care settings.

Limitations

This study has a number of limitations: participating patients may have been more likely to nominate a staff member with whom they have a good HA; there was a vast variety of mental health care providers and ingredients of routine mental health care among study sites; staff changes, especially of the staff member nominated by the patient to participate with him/her in the study, might have affected the HA as well as outcome; repeated measurement itself might have had an effect; and analyses were not controlled for clustering of patients in staff members, i.e. idiosyncratic rating patterns of staff participants cannot be ruled out.

Conclusions

This study extends previous research on the alliance-outcome relation in psychiatric settings, which rarely employed repeated measures designs and – apart from one exception (Junghan et al., 2007) – did not investigate the effect of the HA on unmet needs. Results confirm the importance of a good HA for treatment outcome in people with severe mental illness, with positive changes in the HA preceding a reduction of unmet needs. Overall, this study supports the presence of a causal influence of the HA on unmet needs, especially when both variables are assessed by patients. A clinical implication is that a strong focus on the HA is indicated. Clinicians need enough time during the assessment and ongoing treatment phases to build and maintain a positive relationship with their clients, which is likely to be more than the time needed solely for decision making.

References

Ardito RB, Rabellino D (2011) Therapeutic alliance and outcome of psychotherapy: historical excursus, measurements, and prospects for research. *Front Psychol* 2:270.

Barber JP, Connolly MB, Crits-Christoph P, Gladis L, Siqueland L (2000) Alliance predicts patients' outcome beyond in-treatment change in symptoms. *J Consult Clin Psychol* 68:1027–1032.

Bordin ES (1979) The generalizability of the psychoanalytic concept of the working alliance. *Psychother Theor Res Pract Train* 16:252–260.

De Bolle M, Johnson JG, De Fruyt F (2010) Patient and clinician perceptions of therapeutic alliance as predictors of improvement in depression. *Psychother Psychosom* 79:378–385.

First MB, Spitzer RL, Gibbon M, Williams JBW (1997) *Structured Clinical Interviews for DSM-IV Axis I Disorders - Clinical Version (SCID-CV)*. Washington, DC: American Psychiatric Press.

Horvath AO, Del RAC, Fluckiger C, Symonds D (2011) Alliance in individual psychotherapy. *Psychotherapy* 48:9–16.

Horvath AO, Symonds BD (1991) Relation between working alliance and outcome in psychotherapy: A meta-analysis. *J Counsel Psychol* 38:139–149.

Johansson H, Jansson JA (2010) Therapeutic alliance and outcome in routine psychiatric out-patient treatment: patient factors and outcome. *Psychol Psychother* 83:193–206.

Junghan UM, Leese M, Priebe S, Slade M (2007) Staff and patient perspectives on unmet need and therapeutic alliance in community mental health services. *Br J Psychiatry* 191:543–547.

Klein DN, Schwartz JE, Santiago NJ, Vivian D, Vocisano C, Castonguay LG, Arnow B, Blalock JA, Manber R, Markowitz JC, Riso LP, Rothbaum B, McCullough JP, Thase ME, Borian FE, Miller IW, Keller MB (2003) Therapeutic alliance in depression treatment: controlling for prior change and patient characteristics. *J Consult Clin Psychol* 71:997–1006.

Loos S, Arnold K, Slade M, Jordan H, Vecchio V, Sampogna G, Süveges Á, Nagy M, Krogsgaard Bording M, Østermark Sørensen H, Rössler W, Kawohl W, Puschner B, the CEDAR study group (2015) Courses of helping alliance in the treatment of people with severe mental illness in Europe: a latent class analytic approach. *Soc Psychiatry Psychiatr Epidemiol* 50:363–370.

Martin DJ, Garske JP, Davis MK (2000) Relation of the therapeutic alliance with outcome and other variables: A meta-analytic review. *J Consult Clin Psychol* 68:438–450.

Priebe S, Gruyters T (1993) The role of the helping alliance in psychiatric community care. A prospective study. *J Nerv Ment Dis* 181:552–557.

Priebe S, McCabe R (2006) The therapeutic relationship in psychiatric settings. *Acta Psychiatr Scand*:69–72.

Priebe S, Richardson M, Cooney M, Adedeji O, McCabe R (2011) Does the therapeutic relationship predict outcomes of psychiatric treatment in patients with psychosis? A systematic review. *Psychother Psychosom* 80:70–77.

Puschner B, Becker T, Mayer B, Jordan H, Maj M, Fiorillo A, Égerházi A, Ivánka T, Munk-Jørgensen P, Krogsgaard Bording M, Rössler W, Kawohl W, Slade M, for the CEDAR study group (2016) Clinical decision making and outcome in the routine care of people with severe mental illness across Europe (CEDAR). *Epidemiol Psychiatr Sci* 25:69–79.

Puschner B, Steffen S, Slade M, Kaliniecka H, Maj M, Fiorillo A, Munk-Jorgensen P, Larsen JI, Egerhazi A, Nemes Z, Rössler W, Kawohl W, Becker T (2010) Clinical decision making and outcome in routine care for people with severe mental illness (CEDAR): study protocol. *BMC Psychiatr* 10:90.

Puschner B, Wolf M, Kraft S (2008) Helping alliance and outcome in psychotherapy: what predicts what in routine outpatient treatment? *Psychother Res* 18:167–178.

Slade M, Loftus L, Thornicroft G, Wykes T (1999) *Camberwell Assessment of Need*. London: Gaskell.

Slade M, Powell R, Rosen A, Strathdee G (2000) Threshold Assessment Grid (TAG): the development of a valid and brief scale to assess the severity of mental illness. *Soc Psychiatry Psychiatr Epidemiol.* 35:78–85.

Trauer T, Tobias G, Slade M (2008) Development and evaluation of a patient-rated version of the Camberwell Assessment of Need Short Appraisal Schedule (CANSAS-P). *Community Ment Health J* 44:113–124.

Zuroff DC, Blatt SJ (2006) The therapeutic relationship in the brief treatment of depression: contributions to clinical improvement and enhanced adaptive capacities. *J Consult Clin Psychol* 74:130–140.

FIGURE CAPTIONS

FIGURE 1. Patient- and staff-rated helping alliance and unmet needs over time
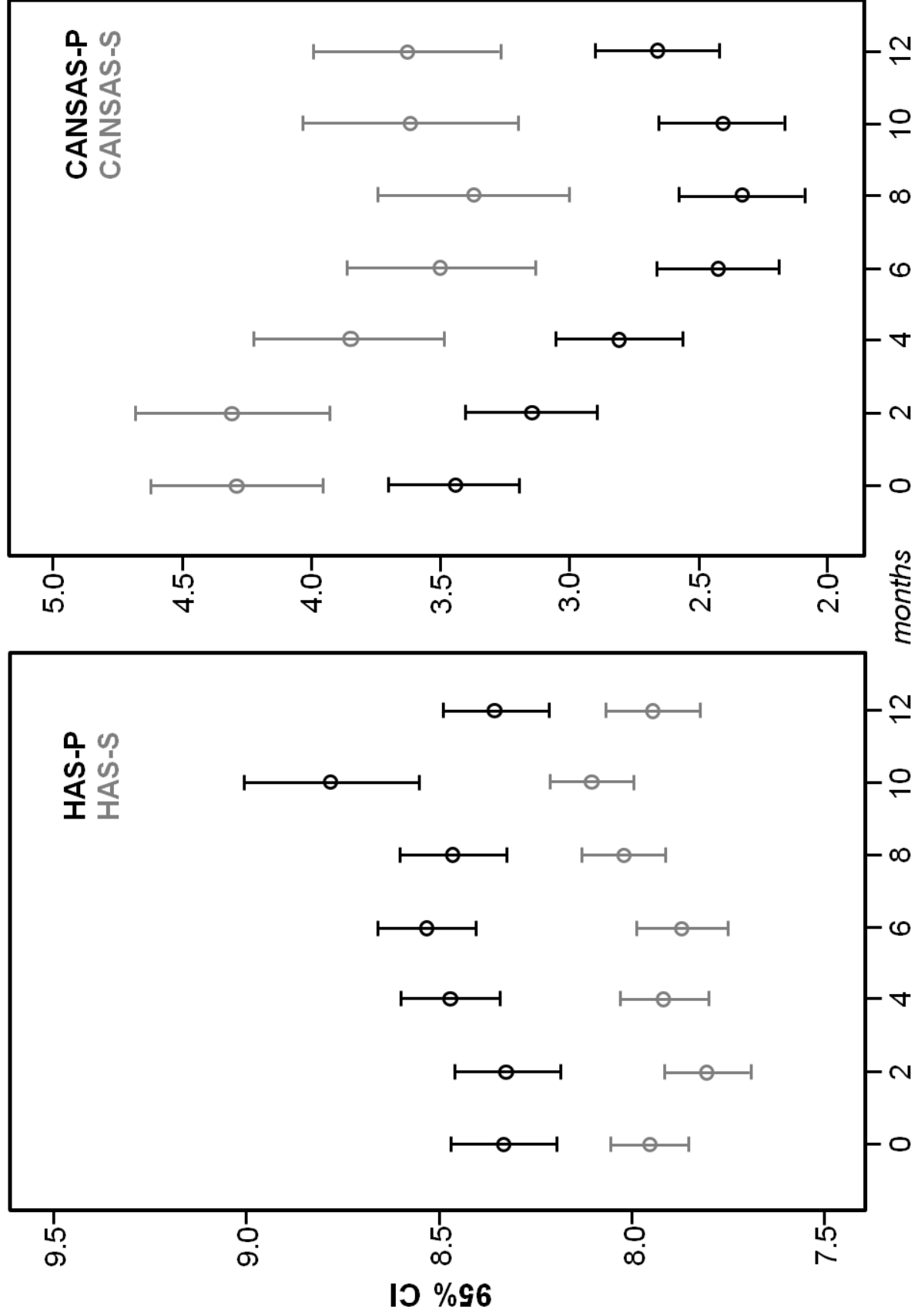
Figure 1

Table 1

TABLE 1. Participant characteristics

Study centre: Ulm, *n (%)*	112 (19.05)
London, *n (%)*	85 (14.46)
Naples, *n (%)*	101 (17.18)
Debrecen, *n (%)*	97 (16.49)
Aalborg, *n (%)*	98 (16.67)
Zurich, *n (%)*	95 (16.16)
Gender; female, *n (%)*	307 (52.21)
Age; years, *Mean (SD)*	41.69 (10.74)
Married; *n (%)*	149 (25.38)
Ethnic group; Caucasian; *n (%)*	552 (94.04)
Years in school; *Mean (SD)*	10.43 (1.88)
Living alone; *n (%)*	231 (39.55)
Paid or self employed; *n (%)*	110 (18.74)
Receiving state benefits; *n (%)*	425 (72.40)
Illness duration; years, *Mean (SD)*	12.51 (9.27)
Diagnosis: Psychotic disorder, *n (%)*	269 (45.75)
Mood disorder, *n (%)*	200 (34.01)
Other, *n (%)*	119 (20.24)
TAG; *Mean (SD)*	7.54 (2.24)

Notes. TAG=Threshold Assessment Grid; missing values: N=1 (married, ethnic group, work, benefits), N=4 (living),

N = 11 (school).

Table 2

TABLE 2. Effect of helping alliance on current and subsequent unmet needs (mixed-effects regression models)

	B	*SE*	*df*	*t*	*p*
Current patient-rated[1]					
Intercept	3.13	0.81	567	3.85	**.0001**
Mean-centered HAS-P	-0.36	0.04	2403	-8.04	**<.0001**
Months (linear trend)	-0.16	0.02	562	-9.20	**<.0001**
Mean-centered HAS-P x months	0.04	0.01	2403	4.12	**<.0001**
Current staff-rated[2]					
Intercept	7.66	1.41	554	5.45	**<.0001**
Mean-centered HAS-S	-0.19	0.06	2164	-3.01	**.0026**
Months (linear trend)	-0.13	0.02	549	-5.71	**<.0001**
Mean-centered HAS-S x months	0.02	0.02	2164	1.27	.2048
Subsequent patient-rated[3]					
Intercept	7.80	1.06	555	7.36	**<.0001**
Mean HAS-P over all assessments	-0.58	0.08	1800	-7.66	**<.0001**
Prior change in HAS-P	-0.10	0.02	1800	-5.38	**<.0001**
Months (linear trend)	-0.13	0.02	542	-6.44	**<.0001**
Subsequent staff-rated[4]					
Intercept	8.00	2.21	524	3.61	**.0003**
Mean HAS-S over all assessments	-0.11	0.17	1578	-0.66	.5066
Prior change in HAS-S	-0.08	0.03	1578	-2.38	**.0175**
Months (linear trend)	-0.12	0.03	492	-4.21	**<.0001**

Notes. HAS-P=Helping Alliance Scale, patient-rated; HAS-S=Helping Alliance Scale, staff-rated. [1]577 participants and 3543 observations; goodness of fit: AIC=15531.0, AICC=15531.0, BIC=15548.5; [2]566 staff ratings and 3278 observations; goodness of fit: AIC=15266.1, AICC=15266.1, BIC=15283.4. [3]564 participants and 2908 observations; goodness of fit: AIC=12667.3, AICC=12667.3, BIC=12684.7; [4]535 staff ratings and 2605 observations; goodness of fit: AIC=12221.9, AICC=12221.9, BIC=12239.0. All models controlled for age, gender, years in school, illness severity (TAG), diagnosis and illness duration (years), coefficients not shown.