The Wrong Understanding of Evidence-Based Research in Psychotherapy –

A Plea for Intensive Process-Outcome Research in Naturalistic Studies

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A Current EBM Practice in Psychotherapy Research

The predominant paradigm in evidence-based psychotherapy research is currently the *Medical Model*

The *Medical Model* is essentially based on

- double-blind studies
- randomized-controlled trials (RCT)
  - intervention group versus control group
  - intervention group receives the drug while the control group receives a placebo and no treatment or another treatment
  - basic assumption: only the content of the drug is responsible for the achieved effect(s)

Problems of the Medical Model in Psychotherapy

- double-blind studies are impossible in psychotherapy
  - thus essential basics of the RCT-design are violated
- a randomization of patients to intervention and control groups is neither reasonable nor possible:
  - patients are not homogeneous, even not with the same diagnosis
  - therapists are not homogeneous, even not the same therapist with another patient
  - diagnoses from DSM- and ICD-Glossaries are vot valid, they overlap to an extreme degree and are fuzzy
  - there are no 'pure' diagnostic groups of patients, nearly all patients suffer from comorbidities and multiple symptoms, thus attesting results from RCT-studies - which intend to test 'pure' diagnostic groups – an insufficient internal validity
  - there is no control in a 'controlled' study: man lives 168 hours a week and attends for 1 or 2 hours therapeutic treatment, thus leaving a patient uncontrolled in 166 hours (99%) – again no internal validity

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  - there is no control in a 'controlled' study: man lives 168 hours a week and attends for 1 or 2 hours therapeutic treatment, thus leaving a patient uncontrolled in 166 hours – again no internal validity
  - a manualized therapy is impossible: the reciprocal process in the therapeutic interaction between patient and therapist is not being considered
    - obscure: a therapist following his manual may be technically in session 36 and the patient is psychologically in session 5
  - a universe of intervening variables can not be controlled for – repeatedly no internal validity
  - and most of all: the importance of the treatment concept itself is marginal – there is a multiplicity of many other variables which are uncontrolled but account for more outcome variance such as the therapeutic alliance, the severity of patients' psychological problems, therapists' effectiveness, to mention a few (see the 'contextual' model in the following)
  - the explanation of outcome variance through the treatment concept itself is considered to vary between 1% and 15% (see *Generic Model of Psychotherapy*), and therapists even work to a vanishing small part with their learned treatment concept (see results in the following)
  - thus, RCT-studies in psychotherapy are solely based on a supposed ingredient which is of minor importance and is often not there

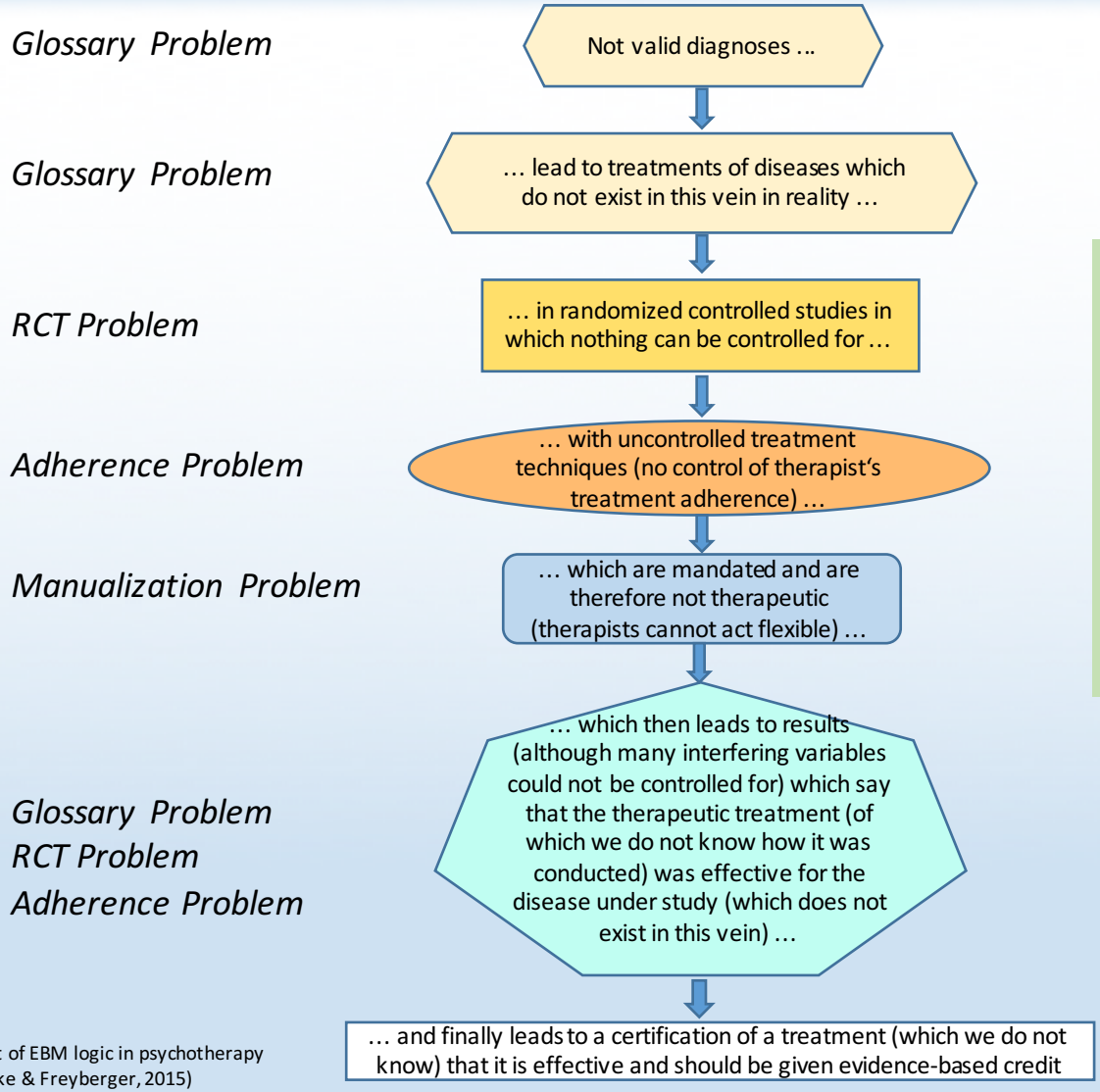


Figure 1: Flow chart of EBM logic in psychotherapy (Tschuschke & Freyberger, 2015)

The Absurdity of a Wrong Understanding of Evidence-Based Research in Psychotherapy

B The Alternative: Process-Outcome Research in Naturalistic Studies (Effectivenss Studies) (Contextual Model)

Generic Model of Psychotherapy

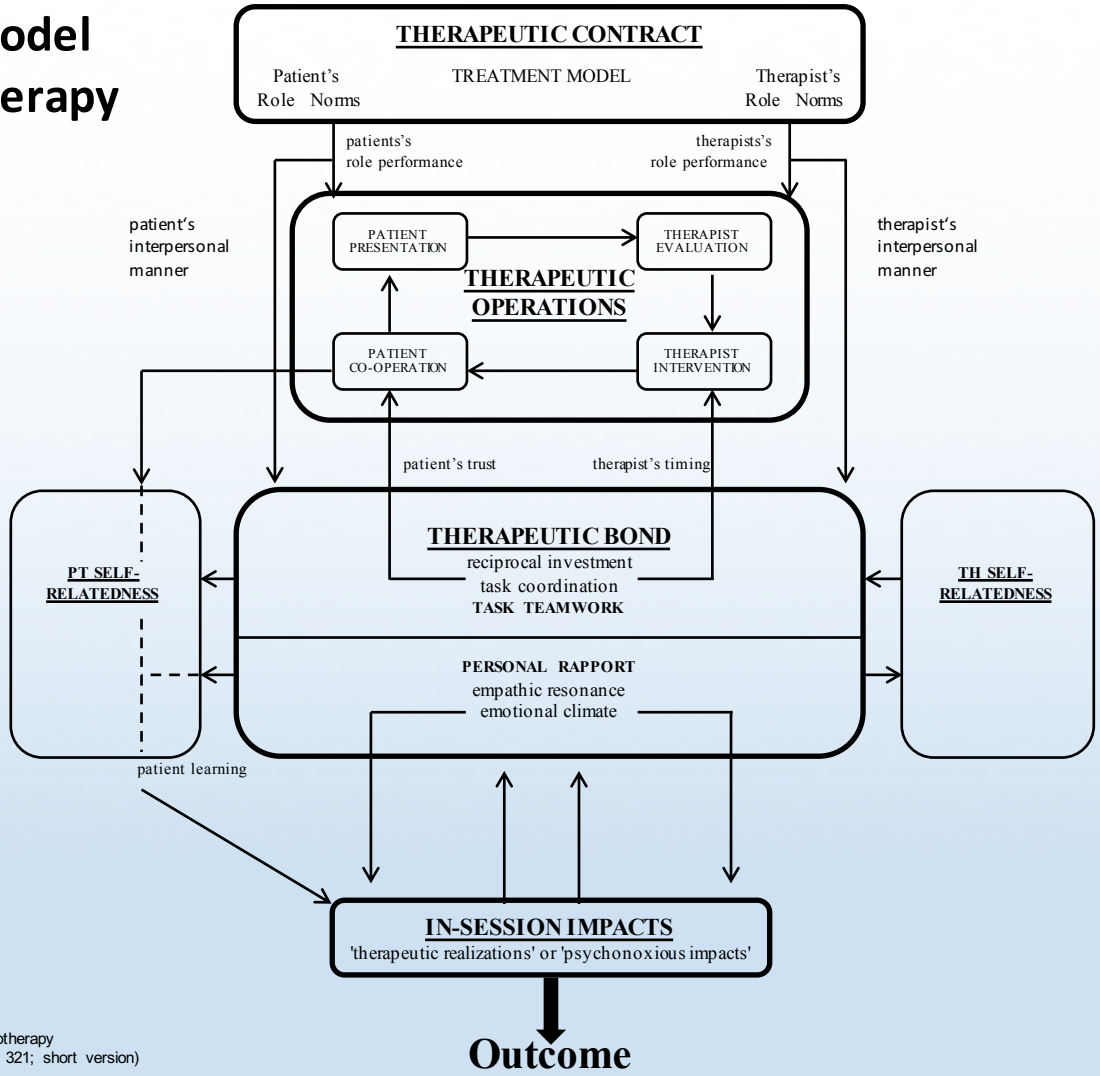
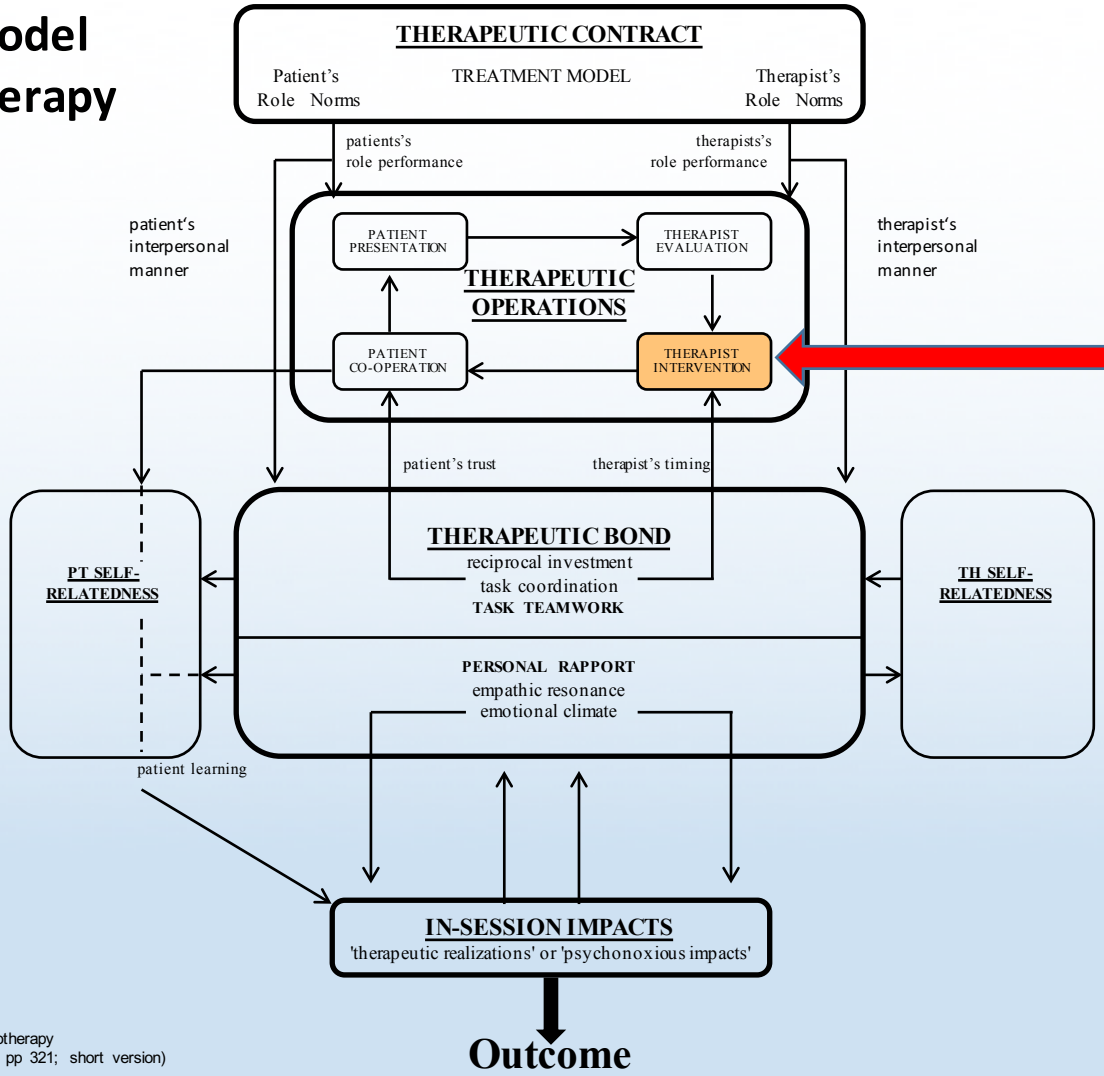


Figure 2: Generic model of psychotherapy (Orlinsky et al. 2004; pp 321; short version)

Generic Model of Psychotherapy



that's all what RCTs try to investigate !

Figure 3: Generic model of psychotherapy (ORLINSKY et al. 2004; pp 321; short version)

Wampold & Imel (2015)

Medical Model	Contextual Model
Absolute Efficacy	
1. Psychotherapy more effective than no treatment	1. Psychotherapy more effective than no treatment
2. Psychotherapy without specific ingredients will be less effective than psychotherapy with specific ingredients	2. Psychotherapy without specific ingredients will be less effective than psychotherapy with specific ingredients
	3. Psychotherapy without **specific ingredients** more effective than no treatment
Relative Efficacy	
1. Variability in efficacy of treatments (i.e. some treatments more effective than others)	1. Homogeneity of treatment effects: **All treatments** intended to be therapeutic will be **equally effective**
2. T x A is more effective than T x B for a particular disorder	
Therapist Effects	
1. Therapist effects are small, particularly when providing an evidence-based treatment and adhering to the model	1. **Therapist effects** will be relatively large, especially in comparison to effects of specific ingredients
	2. **Therapist differences** will be due to relationship factors
General Effects	
1. Relationship factors will not be critical factors in psychotherapy outcome	1. **Therapeutic alliance** will be associated with outcome
	2. Other **relationship factors** (e.g. empathy, goal consensus and collaboration, real relationship) will be associated with outcome
	3. **Expectations** are important for outcome
	4. Researcher **allegiance**, and particularly therapist allegiance, will be related to psychotherapy outcome
	5. **Cultural adaptations** will increase the effectiveness of treatments
Specific Effects	
1. Removing specific ingredients from a scientifically established treatment will attenuate the efficacy of the treatment	1. Removing **specific ingredients** from a scientifically established treatment will not attenuate the efficacy of the treatment
2. A treatment T 1 may be more efficacious than T 2 for treating symptoms S 1 but not for treating symptoms S 2	2. **Adherence** and **treatment specific competence** will not be related to outcome
3. Adherence and treatment specific competence related to outcome	

C The PAP-S Study – A Naturalistic Process-Outcome Study (Effectiveness Study)

Margit Koemeda-Lutz, Agnes von Wyl, Aureliano Crameri, Peter Schulthess, Volker Tschuschke

- 10 different theoretical concepts / schools participated
  - Analytical Psychology (SGAP) (psychodynamic)
  - Art and Expression Oriented Therapy (EGIS) (integrative)
  - Bioenergetic Therapy (SGBAT / DÖK) (body oriented)
  - Existential Analysis and Logotherapy (ILE) (humanistic)
  - Gestalt Therapy (SVG) (humanistic)
  - Integrative Body Psychotherapy (IBP) (body oriented)
  - Logotherapy and Existential Analysis (SGLE) (humanistic)
  - Process-Oriented Psychotherapy (IPA) (psychodynamic)
  - Psychoanalysis (psychodynamic)
  - Transaction Analysis (SGTA / ASAT) (humanistic)
- > 370 patients were enrolled in the study
- effect sizes vary between .69 and 1.22 du to the outcome measure; these effects were reached after a median of 43 therapy sessions
- > 80 psychotherapists from the 10 schools participated
- all or some sessions from more than 200 treatments were audiorecorded completely
- all ethical committees of the affected eight Swiss cantons (Basel, Berne, Graubünden, Lucerne, Neuenburg, St. Gallen, Waadt, Zurich) approved the research applications
- trained independent therapists in clinical assessment centers in nine Swiss cities (Basel, Berne, Chur, Lausanne, Lucerne, Neuchatel, St. Gallen, Winterthur, Zurich) tested patients at t 1 (treatment entry), t 2 (end of treatment), t 3 (follow-up 12 months after end of treatment) by using the following tests and methods:
  - Beck Depression Inventory II (BDI-II) (Hautzinger, Keller, & Kühner, 2006)
  - Brief Symptom Inventory (BSI) (Franke, 2000)
  - Outcome Questionnaire 45 (OQ-45.2) (Lambert, Hannöver, Nisslmüller, Richard, & Kordy, 2002)
  - Global Assessment Functioning Scale (GAF) (American Psychiatric Association, DSM-IV)
  - SKID I and II
- a new ratings system (PAP-S-RM) (Tschuschke, Schlegel, Koemeda-Lutz, 2014) for therapeutic interventions was developed for objective ratings of therapists' interventions during sessions for more than two years
- 5 independent raters (psychologists in postgraduate training) were intensively trained for more than two years to achieve a satisfactory interrater reliability
- the project was supported by a grant from an anonymous donor arranged by the Department of Health of the canton Zurich

Publications from the PAP-S Study

2015

- **Crameri, A., von Wyl, A., Koemeda, M., Schulthess, P., Tschuschke, V. (2015):** Sensitivity analysis in multiple imputation in effectiveness studies of psychotherapy. *Front. Psychol.,* 27 July 2015 http://dx.doi.org/10.3389/fpsyg.2015.01042

- **Koemeda-Lutz, M., Crameri, A., Schulthess, P., von Wyl, A. & Tschuschke, V. (2015):** Specificity and Pace Variability of Therapists' Interventions under Naturalistic Conditions. *International Journal for Psychotherapy*. Advanced publication online Dec. 2015 (will be published in vol 20, no 1, march 2016) (Download PDF/600KB)

- **Staczan, P., Schmuecker, R., Koehler, M., Berglar, J., Crameri, A., von Wyl, A., Koemeda-Lutz, M., Schulthess, P. & Tschuschke, V. (2015):** Effects of sex and gender in ten types of psychotherapy. Advance publication online August 2015 (will appear in April 2016 in *Psychotherapy Research*). DOI:10.1080/10503307.2015.1072285

- **Tschuschke, V., Crameri, A., Koehler, M., Berglar, J., Muth, K., Staczan, P., von Wyl, A., Schulthess, P. & Koemeda-Lutz, M. (2015)**. The role of therapists' treatment adherence, professional experience, therapeutic alliance, and clients' severity of psychological problems: Prediction of treatment outcome in eight different psychotherapy approaches. Preliminary results of a naturalistic study. *Psychotherapy Research 25 (4): 420-434* DOI: 10.1080/10503307.2014.896055 (Download PDF/1.1MB)

- **Tschuschke V., von Wyl, A., Koemeda-Lutz, M., Crameri A., Schlegel M., Schulthess P. (2015):** Bedeutung der psychotherapeutischen Schulen heute. Geschichte und Ausblick anhand einer empirischen Untersuchung. In: Psychotherapeut, Springer. S. 1-11. Advanced publication online November 2015. http://link.springer.com/article/10.1007/s00278-015-0067-y. *Psychotherapeut 61: 54-64*

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- **Tschuschke V., Crameri A., Koemeda-Lutz M., Schulthess P., von Wyl A. (2015)**: Abschlussbericht Praxisstudie Ambulante Psychotherapie Schweiz (PAP-S) der Institute der Schweizer Charta für Psychotherapie. Schriftenreihe Schweizer Charta für Psychotherapie, Band 4, ISSN: 1664-395X / ISBN: 978-3-9523782-3-6 (Download PDF/ 980KB)

2014

- **Aureliano Crameri, Margit Koemeda, Volker Tschuschke, Peter Schulthess, Agnes von Wyl:** Ergebnisqualität ambulanter Psychotherapie: Ergebnisse aus der Grundversorgung in der Schweiz: *Psychotherapie-Wissenschaft, Heft 2-2014, S. 96-107* (Download PDF /250KB)

- **Tschuschke V, Koemeda-Lutz M, Schlegel M (2014):** Rating Manual for the Objective Evaluation of Therapeutic Interventions of Psychotherapists based on Various Theoretical Concepts. Zürich, Schriftenreihe der Schweizer Charta für Psychotherapie, Bd. 3: ISSN: 1664-395X / ISBN: 978-3-9523782-2-9 (Download PDF/ 1.2M)

- **Tschuschke V, Koemeda-Lutz M, Schlegel M (2014):** PAP-S-Rating-Manual (PAP-S-RM), Rating-Manual zur objektiven Einschätzung therapeutischer Interventionen von Psychotherapeuten unterschiedlicher schultheoretischer Konzepte. Schriftenreihe der Schweizer Charta für Psychotherapie, Bd. 2, ISSN: 1664-395X (Download PDF/ 840KB)

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- **von Wyl A, Crameri A, Koemeda M, Tschuschke V, Schulthess P 2013:** Praxisstudie ambulante Psychotherapie Schweiz (PAP-S): Studiendesign und Machbarkeit. *Psychotherapie-Wissenschaft, 1-2013, S. 6-22* (Download PDF/270KB)

- **Von Wyl, A., Crameri, A., Koemeda, M. Tschuchke, V. & Schulthess, P. (2013).** The PAP-S (Practice of Ambulant Psycho-therapy-Study), Switzerland: Study Design and Feasibility. Zurich University of Applied Sciences, Zurich. (Download PDF/150KB)

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Fundamental Reflections on Psychotherapy Research and Initial Results of the Naturalistic Psychotherapy Study on Outpatient Treatment in Switzerland – PAP-S. International Journal for Psychotherapy: *Journal of the European Association for Psychotherapy (EAP) 14 (3) Nov 2010, 23 -35* (Download PDF/500KB)

Veigel, A. (2010). Untersuchung der Methodentreue von „Integrativen Körpertherapeuten". Bachelor-Arbeit an der Zürcher Hochschule für Angewandte Wissenschaften – Angewandte Psychologie (Referentin: A. von Wyl).

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Psychotherapieforschung – Grundlegende Überlegungen und erste Ergebnisse der naturalistischen Psychotherapie-Studie ambulanter Behandlungen in der Schweiz (PAP-S). In: *Psychotherapie Forum, Band 17, Heft 4, Wien, Springer* (Download PDF/560KB)

Tschuschke V., Crameri A., Koemeda M., Schulthess, P., von Wyl A., Weber R., 2009:
recherche en psychothérapie – réflexion fondamentale et premiers résultats de l'étude de la pratique ambulatoire en suisse (PaP-s). En: *Psychotherapie Forum, Band 17, Heft 4, 160-176, Wien, Springer* (Download PDF/560KB)

Treatment Adherence

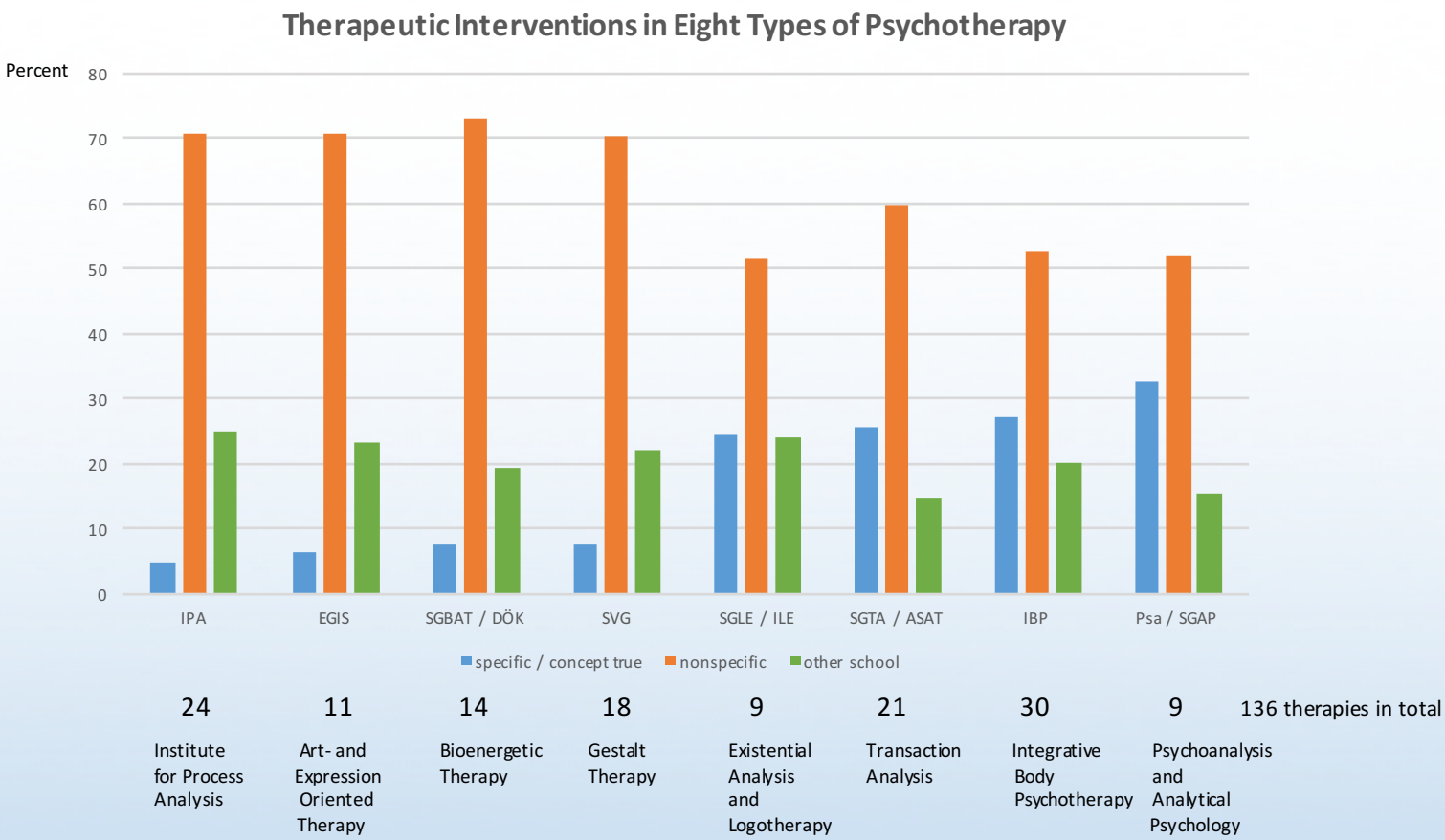


Figure 4: Eight types of psychotherapy: Specific (theory specific) interventions (treatment adherence; blue), nonspecific, common interventions (orange), and interventions from psychotherapy schools other than the therapists' own (green) (mean percentage across all rated sessions) and number of rated therapies in the bottom line

Tschuschke et al., 2016

The Importance of the Therapist

Effective-ness Groups	Age	N	Sex			Professional experience		Theoretical Orientations (N)			
	M		%	female	male	%	*M*	Body Oriented	Humanistic	Psychodynamic	Integrative
A more effective	54.5	43	63.2	30	13	70:30	12.9	20	13	8	2
B less effective	53.2	25	36.8	18	7	75:25	12.2	10	9	5	1
Total		68	100	48	20			30	22	13	3

Table 1: *Therapists' Grouping Characteristics (Age, Sex, Professional Experience, and Theoretical Orientation)*

Two Clusters of Differently Effective Therapists

	Responders *n (%)*	Non-responders *n (%)*	Dropouts *n (%)*	Non-responders and dropouts *n (%)*	*N*
BSI-GSI					
A more effective Th	99 (50.0)	58 (29.3)	41 (20.7)	99 (50.0)	198
B less effective Th	26 (26.3)	50 (50.5)	23 (23.2)	73 (73.7)	99
OQ-45-2					
A therapists	94 (47.5)	63 (31.8)	41 (20.7)	104 (52.5)	198
B therapists	20 (20.2)	56 (56.6)	23 (23.2)	79 (79.8)	99
BDI-II					
A therapists	122 (61.6)	35 (17.7)	41 (20.7)	76 (38.4)	198
B therapists	32 (32.3)	44 (44.4)	23 (23.2)	67 (67.7)	99

Patients of Group A therapists	*n*	*M*	*SD*	*t*	*df*	*p*	*Effect size (ES)*
BSI pre	157	.88	.55				
BSI post	157	.37	.36	13.075	156	.000	1.10
OQ-45 pre	157	64.53	22.04				
OQ-45 post	157	38.61	21.34	17.572	156	.000	1.20
BDI pre	157	15.62	9.57				
BDI post	157	5.88	6.86	14.388	156	.000	1.17
Mean ES							1.16
Patients of Group B therapists	*n*	*M*	*SD*	*t*	*df*	*p*	*Effect size (ES)*
BSI pre	78	.65	.40				
BSI post	78	.54	.54	2.293	77	.025	.23
OQ-45 pre	78	56.03	19.68				
OQ-45 post	78	47.82	23.07	4.017	77	.000	.38
BDI pre	78	12.12	9.05				
BDI post	78	9.29	10.14	2.7.02	77	.009	.29
Mean ES							.30

Table 2: *Treatment Effects in Patients Treated by Group A and Group B Therapists (Pre-Post Comparison)* (Berglar et al., 2016)

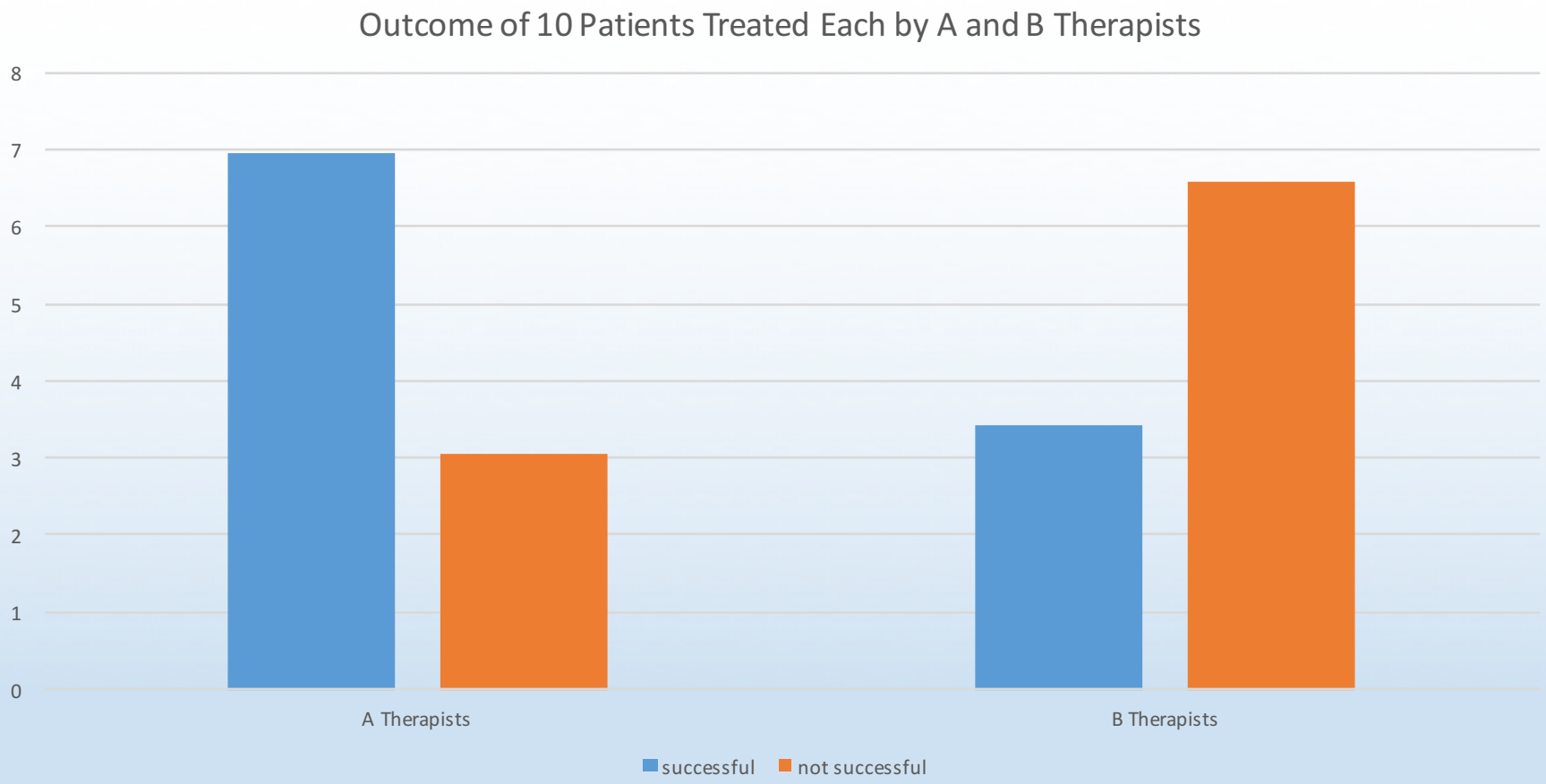


Figure 5: *Percentage of a favorable or unfavorable chance of treatment outcome*

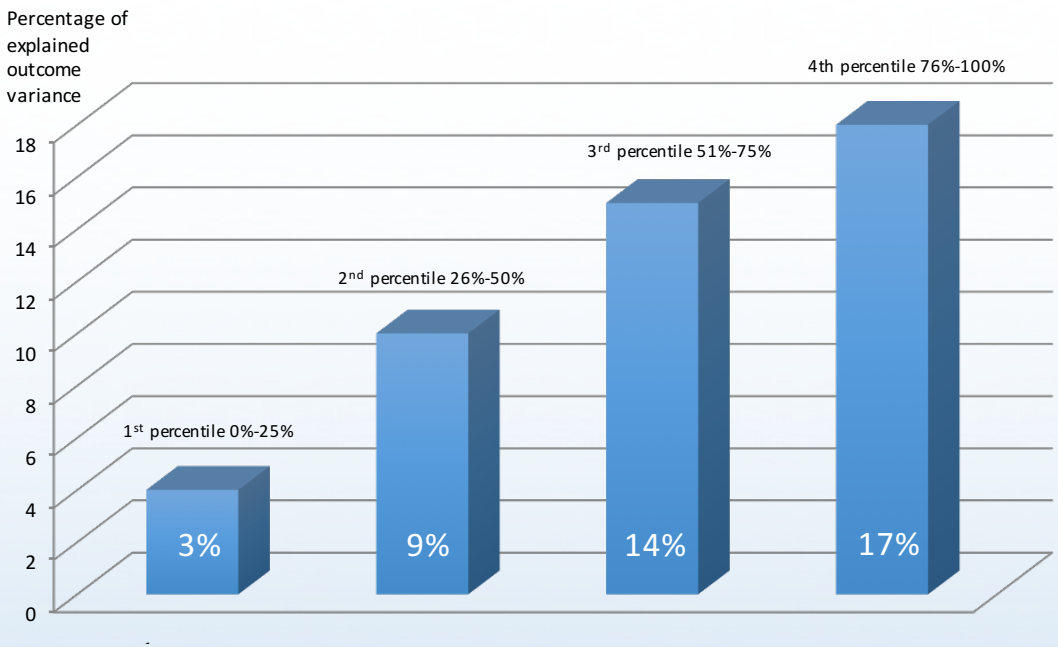


Figure 6: *Patients' severity of psychological problems and therapists' effects (percentiles of severity of psychological problems at treatment entry with the first percentile the lowest and the fourth percentile the highest severity level)*

Berglar et al. (2016)

Sex and Gender

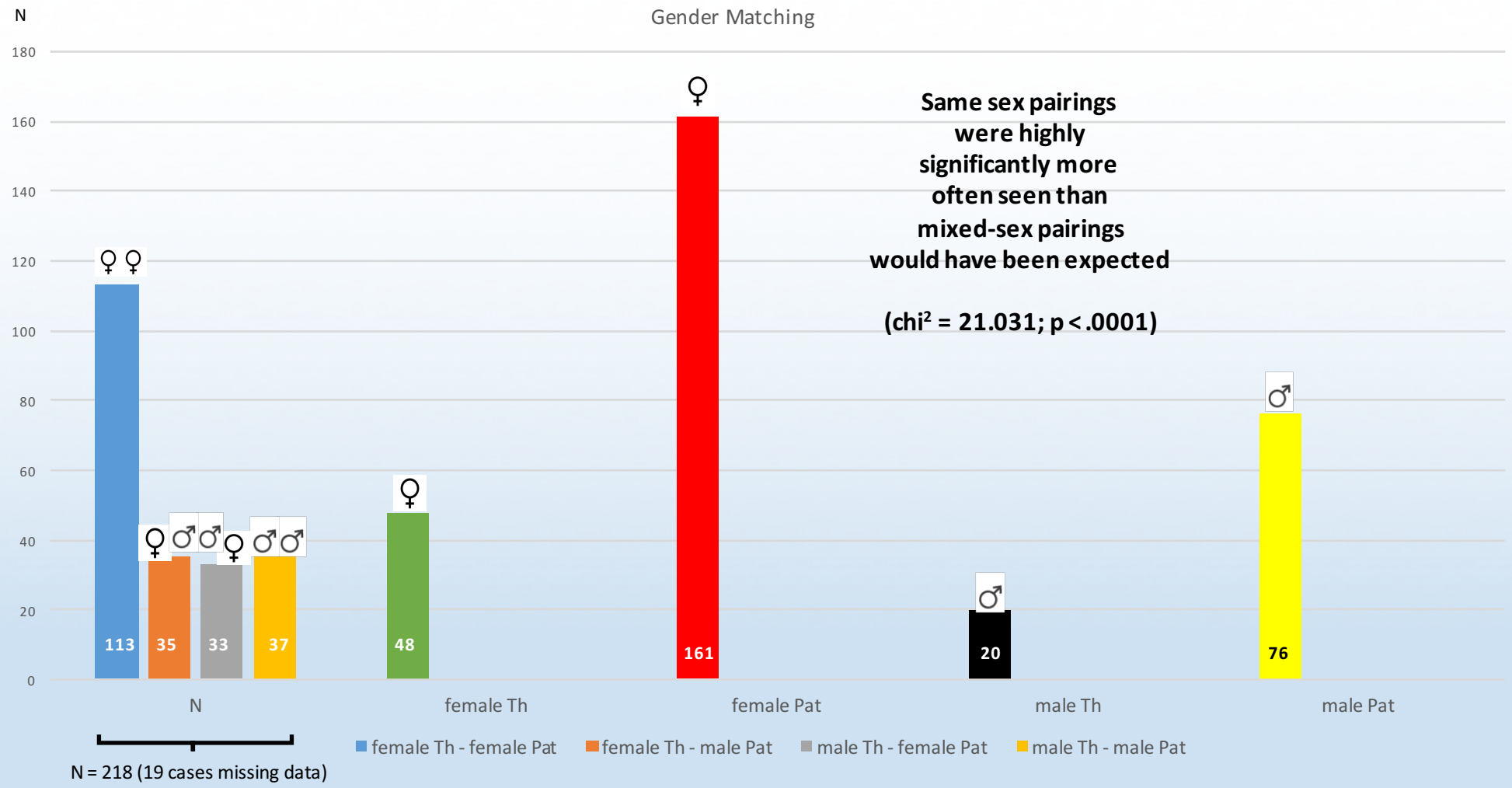


Figure 7: *Sex distributions ($patients_N = 237$; $therapists_N = 68$)*

Type III tests of fixed effects (SPSS)

Source	*Numerator df*	*F*	*p*
Intercept	1	57.109	.000
Type of psychotherapy	1	.858	.564
Sex of therapist	1	.699	.404
Sex of patient	1	.477	.491
Sex of therapist * sex of patient	1	.564	.453
Professional experience	1	2.747	.099
Therapeutic alliance	1	**10.890**	**.001***
Severity of psychological problems	1	**23.350**	**.000****

Test of random effects

Parameter	*Estimate*	*SE*	*Wald Z*	*p*
Residual	468.88	49.09	9.55	.000
Therapist	.57	23.78	.02	.981

Table 3: Prediction of Treatment Outcome (Total Sample)

Note. * $p < .001$ ** $p \leq .0001$

Dependent variable: Treatment outcome (mixed model analysis) with sex of patients, sex of therapists, type of psychotherapy, professional experience of therapists, therapeutic alliance as fixed effects, and therapists as random effects (total sample; N = 237)

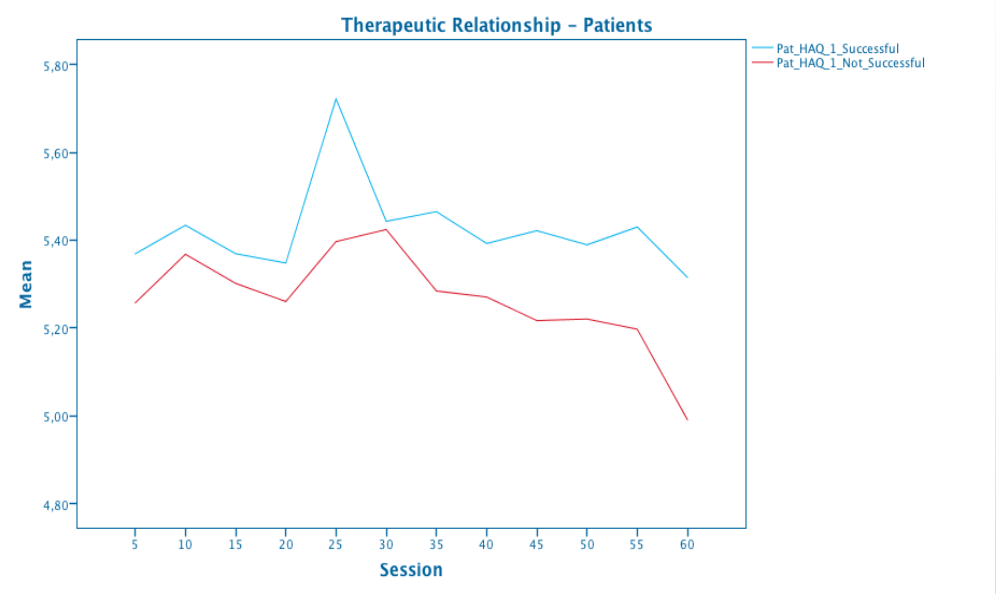
Staczan et al. (2015)

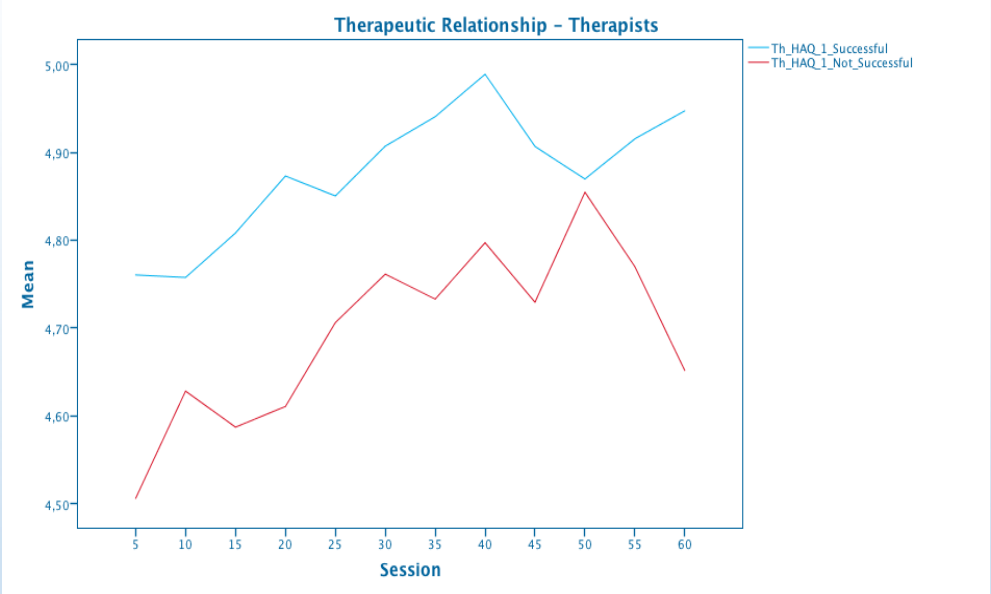
Gender Related Intervention Styles

- female therapists intervene significantly more often with **empathic** ($t = 1.990$; $df = 114$; $p < .040$) and **supportive** interventions ($t = 2.509$; $df = 114$; $p < .014$) compared to their male colleagues, no matter which sex the patient has
- empathic interventions alone tend to be negatively correlated with treatment outcome
- female therapists intervene highly significantly more with a **combination of empathic and supportive techniques** than their male colleagues ($t = 2.897$; $df = 114$; $p < .005$)
- male therapists intervene in tendency more with **confrontative** interventions compared to their female colleagues
- patients with a relatively low level of severity of psychological problems at the outset and treated by female therapists intervening on a higher level of empathy were significantly less successful compared to patients with a relatively higher severity of psychological problems and treated by male therapists who intervened with less empathy and with relatively more interpretations of defense and resistance ($t = -3.962$; $df = 16$; $p \leq .001$)
- thus, gender factors seem to play an important role in psychotherapists‘ technical intervention behavior

The Therapeutic Alliance

successful treatments = 89
not successful treatments = 51



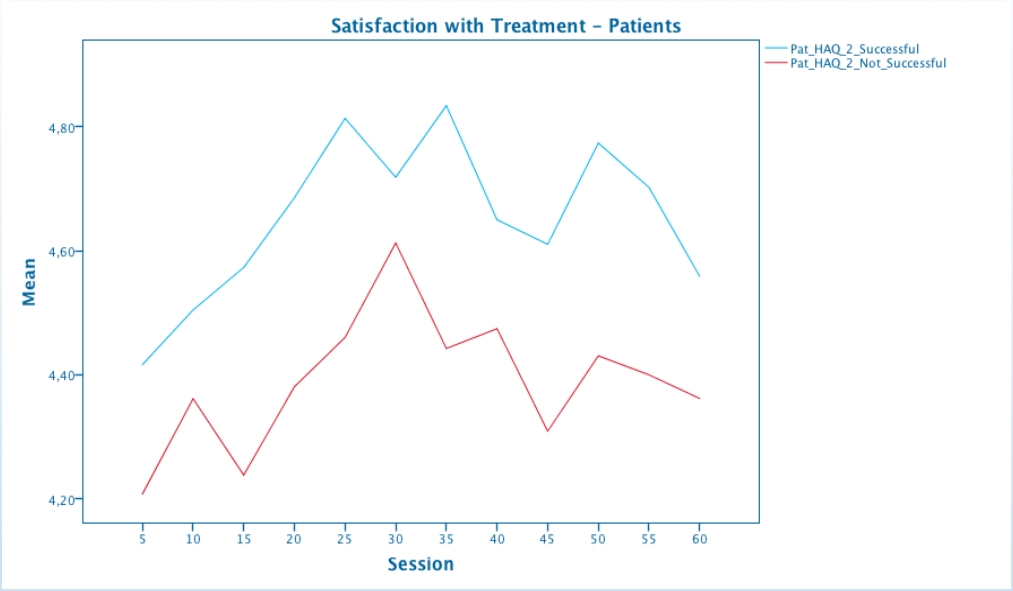


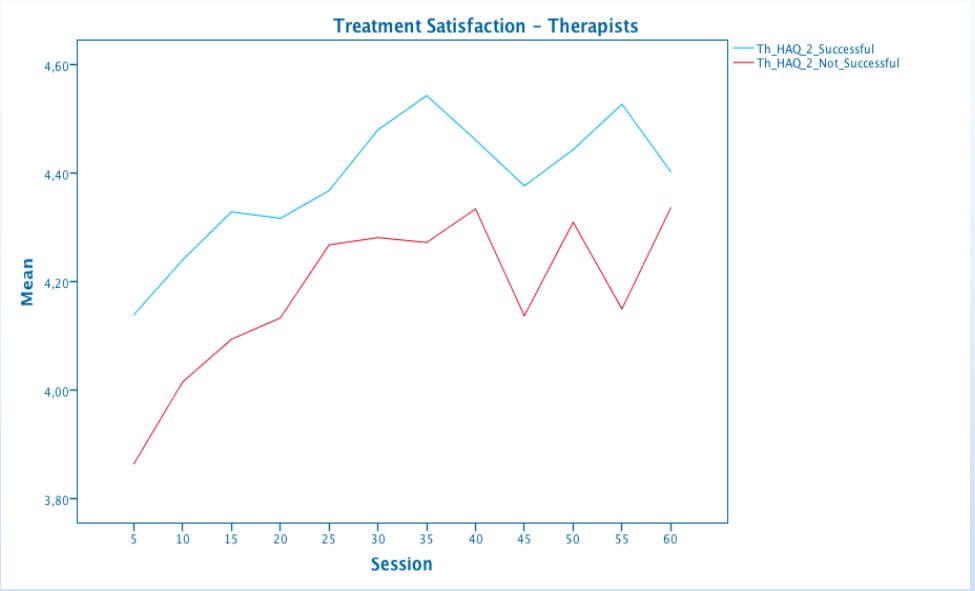
t-Test = 1.346; df = 139; p < .180

t-Test = 2.670; df = 139; p < .008

Figures 8 and 9: *Experiences of therapeutic relationship of successful versus not successful patients and therapists in successful and not successful treatments*

successful treatments = 89
not successful treatments = 51





t-Test = 2.618; df = 139; p < .010

t-Test = 2.403; df = 139; p < .018

Figures 10 and 11: *Experiences of satisfaction with treatment of successful versus not successful patients and therapists in successful and not successful treatments*

- later on successful patients (clinically significantly improved = 2 standard deviations and by the end of treatment under the cut-off score) experience a significantly better therapeutic relationship compared to not successful patients at session 5

- this holds true for sessions 10 and 15

(Schmücker, 2016)

Correlations – Number of Therapy Sessions and Therapeutic Relationship and Satisfaction with Treatment

		Session	Successful Pat_Relationship	Not Successful Pat Relationship	Successful Pat Satisfaction	Not Successful Pat Satisfaction
Session	**Pearson Correlation**	**1**	**-,199**	**-,562****	**-,715****	**-,777****
	Sig. (2-tailed)		**,211**	**,000**	**,000**	**,000**
	N	**42**	**41**	**42**	**42**	**42**
Pat_HAQ_1_Successful	Pearson Correlation	-,199	1	,234	,555**	,009
	Sig. (2-tailed)	,211		,141	,000	,954
	N	41	41	41	41	41
Pat_HAQ_1_Not_Successful	Pearson Correlation	-,562**	,234	1	,540**	,657**
	Sig. (2-tailed)	,000	,141		,000	,000
	N	42	41	42	42	42
Pat_HAQ_2_Successful	Pearson Correlation	-,715**	,555**	,540**	1	,650**
	Sig. (2-tailed)	,000	,000	,000		,000
	N	42	41	42	42	42
Pat_HAQ_2_Not_Successful	Pearson Correlation	-,777**	,009	,657**	,650**	1
	Sig. (2-tailed)	,000	,954	,000	,000	
	N	42	41	42	42	42

Table 4: Treatment length and therapeutic alliance and treatment satisfaction

C Complex Interrelationships

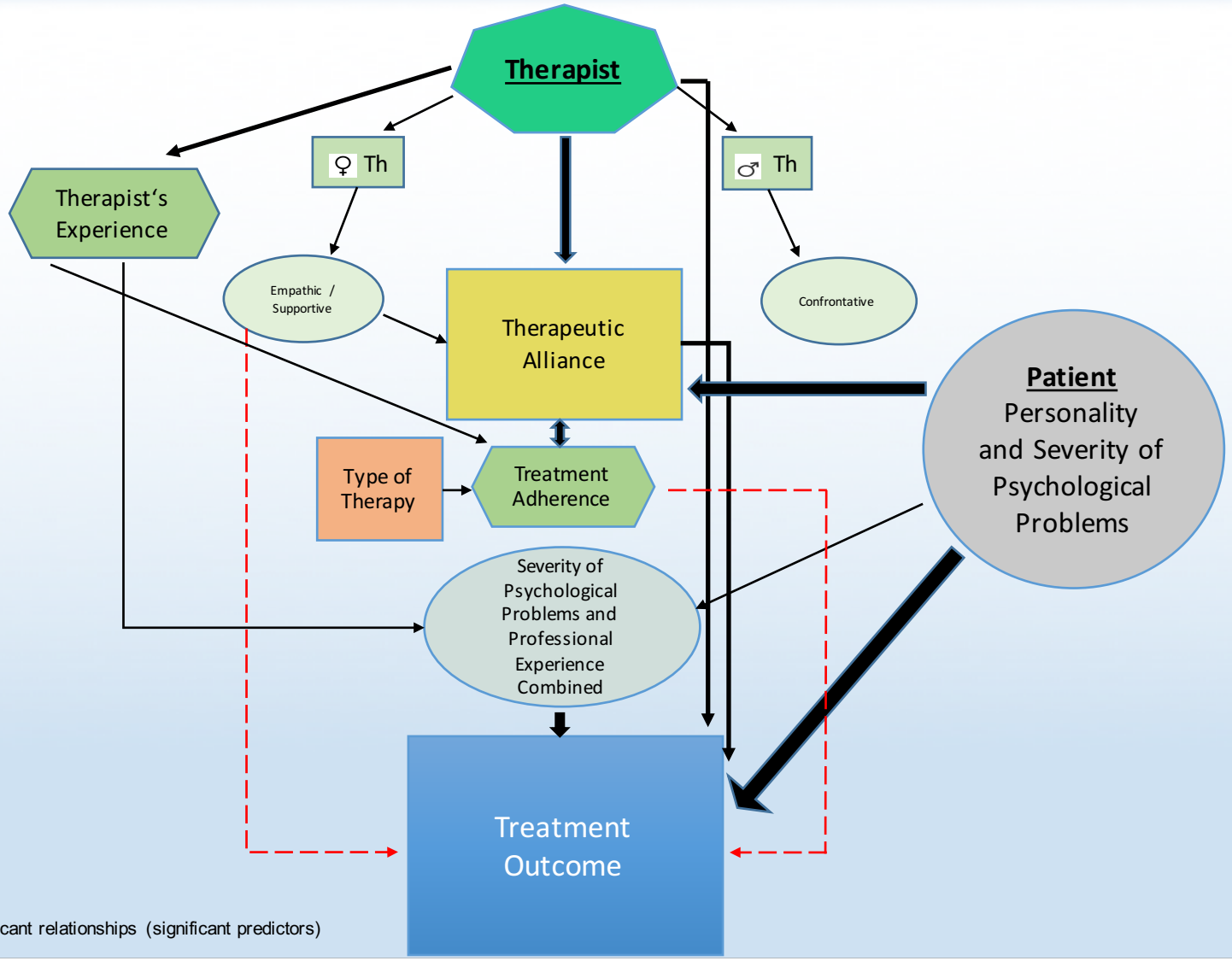


Figure 12: Significant relationships (significant predictors)

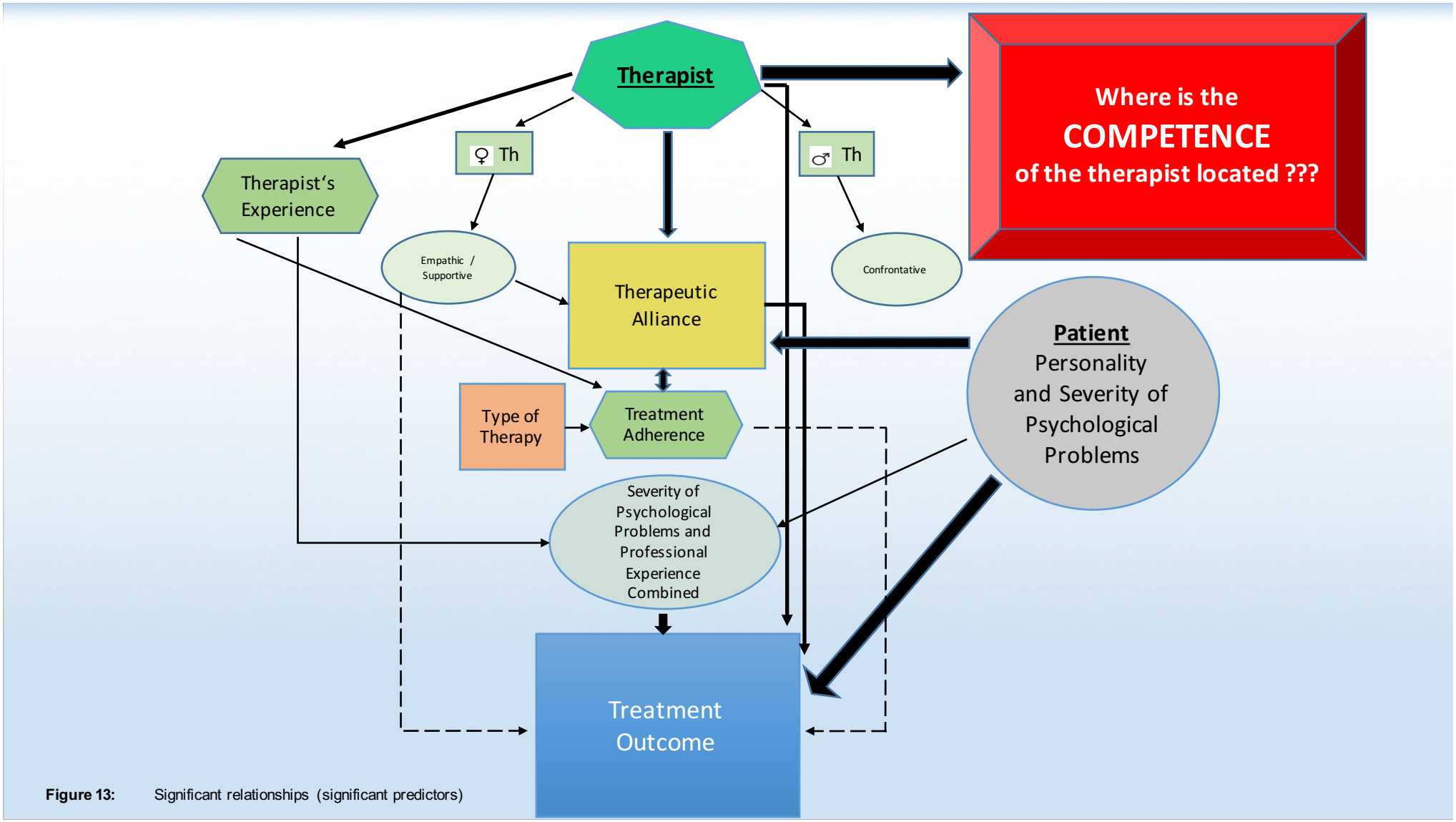


Figure 13: Significant relationships (significant predictors)

D Conclusions

- many factors play a more or less important role in psychotherapy which are not controllable in a RCT trial or are simply considered by medical model apologists
- the medical model and RCTs aim at so-called specific factors and neglect nonspecific factors completely
- specific factors seem to play a minor role in psychotherapy; this is confirmed by all major meta-analyses
- RCTs necessarily fade out these nonspecific factors
- there is a whole slew of nonspecific fators which are essential for making psychotherapy work
- RCTs are “undercomplex“ for psychotherapy and hold a blurred view of psychotherapy
- detailled and extensive process-outcome studies only do justice to the complex interrelationships
- our research results suggest that the person of the patient and the person of the therapist are the central agents of the change process
- between these two actors a universum of variables unfolds an highly complex interrelationship of therapeutic agents
- these agents or ingedients of the change process comprise interpersonal issues, the fitting of two individuals, motivational aspects and compliance, appropriate working with defenses, the development of trust, communicative skills, the intelligent and empathic timing of interventions, emotional and cognitive learning, emotional realizations, opportunities and the time for working through anger and mourning, the trial and error with new behavior as well as the reflection of the new behavior, and much more
- psychotherapy is not the simple and pure applying of a technique from a learned treatment approach or concept in a way that each given situation would have its one best answer or action from the therapist (sic: manualization does also not apply in psychotherapy), but rather a sophisticated use of once learned techniques at the right moment – or the non-usage of theoretically prescribed interventions in favor of a better handling of the patients or clients actual situation
- a successful psychotherapist seems to be a person that works on the basis of a once learned treatment concept with its inherent theoretical assumptions and its technical interventions and integrates continuously technical modifications of interpersonally helpful communication skills and techniques from other concepts which fit his / her personality and add to his / her authenticity as a competent person and psychotherapist
- we must offensively stand up for another scientific stance towards the scientific community, the public and the politicians, in favor of the highly more complex process of psychotherapeutic change compared to the medical model which is completely inappropriate for our profession
- thus, we have to make clear that science in psychotherapy is way more complex than suggested by RCTs and that we, nevertheless, can investigate psychotherapeutic processes on evidence-based grounds – but adequately

Thank you very much for your interest !

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