

Do mentalisation-based interventions work for patients with borderline personality disorder and chronic depression?

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Registration date 08/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/09/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness of mentalisation-based interventions and their influence on the therapeutic alliance for patients with borderline personality disorder and chronic depression: a single case study of three psychoanalytic long-term therapies based on the plan formulation method (Control Mastery Theory)

Study objectives

The concept of mentalisation-based treatment is a sophisticated approach to the pathology of mental disorders from the perspective of mentalisation, attachment theory and human development. The Control Mastery Theory provides an empirically supported model for psychoanalytic and psychodynamic treatment techniques. The purpose of this study is to investigate the process and efficiency of therapeutic interventions under the perspective of both theories with reference to the ability to mentalise. Three patients will be investigated. One with borderline disorder, one with chronic depression and one with both. The research is based on the work of the Single Case Psychotherapy Research Group Frankfurt (SCPRGF). The degree of structural/mentalisation-deficits and conflict-pathology is checked with the Operationalised Psychodynamic Diagnostic (OPD-2).

1. Hypotheses on pathogenic beliefs:

- 1.1. Therapy sessions with a high amount of interventions disproving pathogenic beliefs lead to a better results of those sessions by the patient than the ones with a lower amount
- 1.2. Therapy sessions with interventions disproving pathogenic beliefs lead to a better judging of the therapeutic alliance/bound (assessed by the patient) than the ones with a lower amount
- 1.3. Therapy sessions with a high amount of interventions disproving pathogenic beliefs lead to positive immediate effects with a higher emotional involvement ('experiencing') than the ones with a lower amount

2. Hypotheses on mentalisation:

- 2.1. Therapy sessions with a high amount of interventions promoting mentalisation lead to a better results of those sessions by the patient than the ones with a lower amount
- 2.2. Therapy sessions with a high amount of interventions promoting mentalisation lead to a better judging of the therapeutic alliance/bound (accessed by the patient) than the ones with a lower amount
- 2.3. Therapy sessions with a high amount of interventions promoting mentalisation lead to positive immediate effects with a higher emotional involvement ('experiencing') than the ones with a lower amount

3. Hypothesis on associations between pathogenic beliefs and failures of mentalisation:

- 3.1. There is a significant correlation between pathogenic beliefs and failures of mentalisation to be found in therapy sessions
- 3.2. Therapy sessions with a high amount of interventions disproving the pathogenic beliefs, also promote mentalisation
- 3.3. Therapy sessions with a high amount of interventions promoting mentalisation disprove also pathogenic beliefs

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Observational longitudinal case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Major depression recurrent, dysthymia, borderline

Interventions

Specific interventions are studied in an observational trial. Due to psychodynamic /psychoanalytic treatment, it is not possible to control the interventions actively without distortion of the therapeutic alliance and uncontrolled effects on the dependent variables. For the analysis of the therapeutic process we will evaluate the effects of interventions disproving pathogenic beliefs (Control Mastery Theory) and mentalisation-based interventions. We will rate the sessions 1 - 10, 20 - 30, 50 - 60 and 90 - 100. In these intervals the patients have questionnaires (process and therapeutic alliance) every session. Audiotapes are made in every session of the treatment.

1. The raters will rate each of the sessions in 5 minute sections:

- 1.1. Two raters will rate pro-plan versus anti-plan therapist-interventions in each of the 5 minute sections
- 1.2. Two raters will rate promoting of mentalisation of the therapist-interventions in each of the 5 minute sections
- 1.3. Two raters will rate the patients verbatim in each of the 5 minute sections with the experiencing-scale

2. Two clinical experts identify P1-TI-P2 episodes in each of the investigated sessions (P1: patient's remark 1; TI: therapist intervention; P2: patient remark 2)

- 2.1. Two raters will rate sections P1-TI for pro-plan/anti-plan and two raters will rate sections P1-TI for mentalisation promotion
- 2.2. Two raters will rate each section P1 and P2 with the "experiencing scale" without knowing where P1 or P2 had been located

With this data we will be able:

1. To correlate the therapists intervention scores (1.1. and 1.2.) with the experiencing scores of

the patient (1.3.)

2. To correlate the mean of the intervention scores of every session (1.1. and 1.2.) with the outcome of every session, assessed by the patient in the special intervals (1 - 10, 20 - 30, 50 - 60 and 90 - 100)

3. To correlate the intervention-scores TI with the residualised experiencing-scores P2-P1

4. To correlate P1-TI-P2 episodes, that are both highly relevant for "testing" pathogenic beliefs and mentalisation failures

5. To evaluate with techniques like time-series analysis

Due to the natural design the end of the analytic treatments will be expected within 100 - 200 sessions. A one year follow up interview will be taken by an independent interviewer.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Therapists Interventions (pro-plan, mentalisation promotion) and Experiencing Scale: assessment by trained clinical experts in 5-minute sections and in identified episodes

2. Therapeutic Alliance-Revised (STA-R) and The Bern post session reports: assessment by the patient after each session within the special intervals (sessions 0 - 10, 20 - 30, 50 - 60 and 90 - 100)

Secondary outcome measures

1. Symptom Check List (SCL-90-R) and Interpersonal Problems (IIP): assessment by the patient at the beginning and end of each special interval, at the end of the therapy and 1 year follow up

2. Beck Depression Inventory (BDI) and Borderline Personality Inventory (BPI): assessment by the patient at the beginning and the end of the therapy and 1 year follow up

Overall study start date

01/09/2009

Completion date

31/01/2011

Eligibility

Key inclusion criteria

1. Patients with a psychoanalytic treatment longer than 100 sessions

2. Aged 18 - 60 years, either sex

3. Diagnosis: major depression recurrent (DSM 296.3) or dysthymia (DSM 300.40) or borderline (DSM 301.83). Diagnosis Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) proved by an independent interviewer with the semi-structured interview Structured Clinical Interview for DSM-IV (SCID) I and II.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Three patients

Key exclusion criteria

1. Psychosis
2. Drug or alcohol addiction
3. Organic brain diseases

Date of first enrolment

01/09/2009

Date of final enrolment

31/01/2011

Locations

Countries of recruitment

Germany

Study participating centre

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Sponsor information

Organisation

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Sponsor type

Research organisation

Funder(s)**Funder type**

Research organisation

Funder Name

Lotte Köhler Foundation (Lotte Köhler Stiftung) (Germany) - German Foundation Centre (Deutsches Stiftungszentrum [DSZ]) (ref: S112/10081/07)

Funder Name

Annemarie Wolff Fund/German Society for Individual Psychology (Annemarie Wolff Fond /Deutsche Gesellschaft für Individualpsychologie [DGIP]) (Germany)

Funder Name

A. Adler Institute Mainz e.V. (Germany)

Funder Name

Friends of the A. Adler Institute Mainz e.V. (Germany)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration