Science meets Reality - systematic reviews for health policy decisions according to new psychotherapeutic methods in Germany
Agenda

- Introduction Federal Joint Committee (G-BA)
  - Structure, committees, responsibilities
- Assessment of non-drug interventions
  - General procedures
- Assessment of EMDR
  - Research question
  - Methods
  - Findings
  - Coverage decision
- Conclusions and implications
German Health Care System

- Bismarck Model of Health Care
- Decentralized and self-governing system
- Compulsory health insurance
- Financed mainly through payroll deductions
- Federal Ministry of Health sets up legal framework
- Inpatient and ambulatory sectors
- Health expenditure 11.3% of gross domestic product (OECD 2017)
Self-governing health care system - Federal Joint Committee (G-BA)

is...

• main decision-making body in German health care
• mandated by law (Social Code Book V) to issue legally binding directives

• consists of payers and care providers and (non-voting) patient representatives and three impartial members (one chairman)
• determines benefits schedule for statutory health insurance
• legal supervision by Ministry of Health (MoH)
A short trip to History…

1920 Reichsausschuss Ärzte und Krankenkassen
1940 Sachverständigenrat für die Begutachtung der Krebsursachen
1960 Bundesausschuss Ärzte und Krankenkassen
1980 Gemeinsamer Bundesausschuss (Federal Joint Committee)
2000 Gremium Krankenhausauschuss
2020 Koordinierungs-ausschuss
Science meets Reality - systematic reviews for health policy decisions according to new psychotherapeutic methods in Germany.

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G-BA: structure and committees

managed by office of the G-BA with 6 departments and about 200 employees
Examples of non-drug interventions

• Biomarker Tests in Breast Cancer
• Fluoride Varnish in the Prevention of Dental Caries
• Screening for Depression
• Proton Therapy for Tumors
• Methods of Artificial Fertilization
• Tonsillotomie (surgery of the tonsils)
• Photodynamic Therapy with Verteporfin
• Continuous Active Motion Therapy (knee ligament rupture)
• Eye Movement Desensitization and Reprocessing
Assessment pathways & decision making

Request for consultation

Working group, external commissioning

Consultation in sub-committee

Oral and/or written hearing procedure

Final consultation and decision in Plenum

Objection

Legal review by MoH

No objection

Decision in effect

Publication in Federal Gazette
Method Evaluation Subcommittee → Working Group → Benefit assessment:

- Formulation of the research question
- Search of the medical literature
- Extraction and evaluation of information
- Methodological assessment of the reliability of results
- Synthesis and final evaluation of all documents considered

Method Evaluation Subcommittee → Working Group
Assessment of new services / Principles of benefit assessment

- Evidence based medicine
- G-BA Rules of Procedure (Verfahrensordnung, VerfO)
- Benefits & harms
- Patient-relevant outcomes
- Principle of causality
- Risk of bias
- Generalisability

Diagram:

I
a) Systematic reviews of RCTs
b) Randomized controlled trials (RCTs)

II
a) Systematic reviews of IIb-studies
b) Prospective controlled Cohort-studies

III
- Retrospective comparative trials

IV
- Non-Comparative trials

V
- Associative Descriptions, pathophysiological concepts, case-reports...
In 2011 a joint application of the federal association of health insurance funds and patient representatives was made to consider coverage of EMDR for PTSD.
Case study - EMDR in PTSD

• Eye Movement Desensitization and Reprocessing (EMDR)
  ➢ standardized psychotherapeutic treatment method
  ➢ aimed at the processing of events and experiences that have been traumatic

• Posttraumatic stress disorder (PTSD)
  ➢ mental disorder with characteristic and high symptom exposure
  ➢ high co-morbidity to other mental illnesses
  ➢ prevalence of PTSD in trauma patients can reach up to 50% depending on the type of trauma
Research question

Efficacy of EMDR in comparison with „unspecific“ treatment interventions for PTSD or „specific“ interventions using the change of PTSD symptoms by means of standardized instruments as the main outcome measure.
### Methods / Part 1

<table>
<thead>
<tr>
<th>Search methods</th>
<th>Cochrane Library, PubMed (Medline), EMBASE, PsycInfo and Psyndex (2011/2013), Reference lists, studies received in hearing procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>a priori selection criteria (PICO)</td>
</tr>
<tr>
<td>Data collection and analysis</td>
<td>Two or more members of the working group independently identified studies, assessed trial or review quality and extracted data. Discrepancies were solved by discussion.</td>
</tr>
<tr>
<td>Assessment of risk of bias in included primary studies</td>
<td>Cochrane Collaboration’s ’Risk of bias’ tool (Higgins 2008)</td>
</tr>
</tbody>
</table>
### Screening - Selection criteria

<table>
<thead>
<tr>
<th>Types of studies</th>
<th>Systematic Review (SR), HTA, Guideline or Randomised Controlled Trial (RCT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Types of participants</td>
<td>Adults with PTSD (according DSM-III, DSM-III-R, DSM-IV or ICD-10)</td>
</tr>
<tr>
<td>Type of intervention</td>
<td>EMDR</td>
</tr>
<tr>
<td>Types of control interventions</td>
<td><strong>Unspecific</strong> (e.g. waiting list, treatment as usual or relaxation methods) or <strong>specific interventions</strong> (e.g. other psychological treatments already covered by statutory health insurance)</td>
</tr>
<tr>
<td>Types of outcomes</td>
<td>Severity of clinician rated or self-reported traumatic stress symptoms</td>
</tr>
</tbody>
</table>
## Methods / Part 2

| Measures of treatment effect | Continuous outcomes: calculating standardised mean difference (SMD) and 95% confidence intervals (95% CIs). Effect size: Hedges'g
|                           | Dichotomous outcomes: calculating risk ratios
| Subgroup analysis          | Self-reported or clinician-rated PTSD symptoms
| Assessment of heterogeneity| $I^2$ statistic, $I^2 < 70\%$ FEM, $I^2 \geq 70\%$ REM
| Software                   | Comprehensive Meta-Analysis
|                           | Biostat, Inc. 2006-2013
Flowchart of literature review process

Records identified through database searching
N = 1836

Screening (abstracts) excluded
N = 1431

Full-text articles assessed for eligibility
N = 405

Screening (full-texts) excluded
N = 378

N = 27
N = 9 Systematic Reviews
N = 12 Studies included in qualitative synthesis
Overview – Systematic Reviews

Critical appraisal
Results – Systematic Reviews

Committee on Treatment of posttraumatic Stress disorder 2008
“The committee concludes that the evidence is inadequate to determine the efficacy of EMDR in the treatment of PTSD.”

Open question: does these reviews reflect the current state of research due to the date of their last searches?

Bisson & Andrew 2007 (Cochrane Review)
“Trauma focused cognitive behavioural therapy and eye movement desensitisation and reprocessing have the best evidence for efficacy at present and should be made available to PTSD sufferers.”… “The considerable unexplained heterogeneity observed in these comparisons, and the potential impact of publication bias on these data, suggest the need for caution in interpreting the results of this review.”
Overview – Primary studies

- 9 studies with unspecific interventions
- 6 studies with specific interventions
- 531 patients included (small sample sizes)
- Great variability between studies (e.g. number of EMDR session - range from 1 to 12)
## Critical appraisal – Primary studies

<table>
<thead>
<tr>
<th></th>
<th>Random sequence generation</th>
<th>Allocation concealment</th>
<th>Blinding of participants / personnel</th>
<th>Blinding of outcome assessors</th>
<th>Incomplete outcome data</th>
<th>Selective reporting</th>
<th>Other bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power 2002</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>?</td>
<td>Θ</td>
<td>?</td>
</tr>
<tr>
<td>Rothbaum 2005*</td>
<td>?</td>
<td>?</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>?</td>
</tr>
<tr>
<td>Van der Kolk 2007</td>
<td>Θ</td>
<td>?</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
<td>Θ</td>
</tr>
</tbody>
</table>
EMDR vs. „unspecific“ interventions

Interventions
- Waiting list
- Relaxation
- Treatment as usual
- Pill placebo

Outcomes
- Clinician rated traumatic stress symptoms or
- Self-reported PTSD symptom severity
EMDR vs. „unspecific“ interventions, PTSD symptoms

<table>
<thead>
<tr>
<th>Study</th>
<th>Statistics for each study</th>
<th>Sample size</th>
<th>Hedges’s g and 95% CI</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hedges’s g</td>
<td>Lower limit</td>
<td>Upper limit</td>
<td>p-Value</td>
</tr>
<tr>
<td>Carlson 1989</td>
<td>-1.203</td>
<td>-2.085</td>
<td>-0.320</td>
<td>0.008</td>
</tr>
<tr>
<td>Höglberg 2001</td>
<td>-0.622</td>
<td>-1.500</td>
<td>0.286</td>
<td>0.166</td>
</tr>
<tr>
<td>Je Lee 1994</td>
<td>0.252</td>
<td>-0.413</td>
<td>1.117</td>
<td>0.367</td>
</tr>
<tr>
<td>Power 2002</td>
<td>-1.896</td>
<td>-2.551</td>
<td>-1.241</td>
<td>0.000</td>
</tr>
<tr>
<td>Rottbaum 1997</td>
<td>-3.189</td>
<td>-4.557</td>
<td>-1.822</td>
<td>0.000</td>
</tr>
<tr>
<td>Van der Kolk 2004</td>
<td>-0.369</td>
<td>-0.811</td>
<td>0.163</td>
<td>0.170</td>
</tr>
<tr>
<td>Pooled</td>
<td>-1.066</td>
<td>-1.905</td>
<td>-0.226</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Heterogeneity: $I^2 = 86\%$
EMDR vs. „unspecific“ interventions, self-rated PTSD symptoms

<table>
<thead>
<tr>
<th>Study</th>
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<td>Carlson 1998</td>
<td>-1,203</td>
<td>-2,085</td>
<td>-0,320</td>
<td>0,008</td>
</tr>
<tr>
<td>Högborg 2007</td>
<td>-0,822</td>
<td>-1,500</td>
<td>0,256</td>
<td>0,185</td>
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<tr>
<td>Power 2002</td>
<td>-1,896</td>
<td>-2,561</td>
<td>-1,241</td>
<td>0,000</td>
</tr>
<tr>
<td>Rothbaum 1997</td>
<td>-3,189</td>
<td>-4,557</td>
<td>-1,822</td>
<td>0,000</td>
</tr>
<tr>
<td>Pooled</td>
<td>-1,632</td>
<td>-2,515</td>
<td>-0,749</td>
<td>0,000</td>
</tr>
</tbody>
</table>

Heterogeneity: $I^2 = 74\%$

![Graph showing comparison between EMDR and control groups]
EMDR vs. „unspecific“ interventions, observer-rated PTSD symptoms

<table>
<thead>
<tr>
<th>Study</th>
<th>Hedges's g</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>p-Value</th>
<th>Sample size</th>
<th>Hedges's g and 95% CI</th>
<th>Relative weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Je 1994</td>
<td>0.352</td>
<td>-0.413</td>
<td>1.117</td>
<td>0.367</td>
<td>13</td>
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<td>32.08</td>
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<tr>
<td>Power 2002</td>
<td>-1.882</td>
<td>-2.802</td>
<td>-1.202</td>
<td>0.000</td>
<td>21</td>
<td>-1.882 - -1.202</td>
<td>30.31</td>
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<tr>
<td>Van der Kolk 2007</td>
<td>-0.389</td>
<td>-0.671</td>
<td>0.153</td>
<td>0.170</td>
<td>29</td>
<td>-0.389 - 0.153</td>
<td>34.62</td>
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<tr>
<td>Pooled</td>
<td>-0.628</td>
<td>-1.817</td>
<td>0.561</td>
<td>0.300</td>
<td>69</td>
<td>-0.628 - 0.561</td>
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</tr>
</tbody>
</table>

Heterogeneity: $I^2 = 90\%$

-4.00  -2.00  0.00  2.00  4.00

EMDR  Kontrolle
EMDR vs. „specific“ interventions

Interventions
- Prolonged exposure therapy
- Exposure therapy
- Exposure plus cognitive restructuring
- Counting method

Outcomes
- Clinician rated traumatic stress symptoms or
- Self-reported PTSD symptom severity
## EMDR vs. „specific“ interventions, PTSD symptoms

<table>
<thead>
<tr>
<th>Study</th>
<th>Statistics for each study</th>
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<td>Hedges's g</td>
<td>Lower limit</td>
<td>Upper limit</td>
<td>p-Value</td>
</tr>
<tr>
<td>Ironson 2002</td>
<td>-0.121</td>
<td>-0.982</td>
<td>0.741</td>
<td>0.784</td>
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<tr>
<td>Johnson 2006</td>
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<td>0.443</td>
<td>0.323</td>
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<tr>
<td>Power 2002</td>
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<td>-1.378</td>
<td>-0.212</td>
<td>0.008</td>
</tr>
<tr>
<td>Rogers 1999</td>
<td>-0.646</td>
<td>-1.723</td>
<td>0.430</td>
<td>0.239</td>
</tr>
<tr>
<td>Pooled</td>
<td>-0.565</td>
<td>-0.960</td>
<td>-0.170</td>
<td>0.005</td>
</tr>
</tbody>
</table>

**Heterogeneity:** $I^2 = 0\%$

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**EMDR vs. Kontrolle**
Conclusion of the G-BA

• methodological limitations of the majority of the studies
• no studies formally considered adverse effects
• clear indication of the effectiveness for EMDR in PTSD post-treatment in comparison to “unspecific” and „specific“ treatment interventions
• medical necessity is seen in addition to the existing treatment alternatives in the outpatient area
Timeline EMDR

1. Request for consultation
2. Consultation in sub-committee
3. Final consultation and decision in Plenum
4. Legal review by MoH
5. Decision in effect
6. Publication in Federal Gazette

- IQTIG
- IQWiG

2011-2014

2014

16.10.2014

3.1.2015

Objection

No objection
Conclusions

• The use of systematic reviews for comparative benefit assessment in the German health care system has been established for many years and contributes to the efficiency of the statutory health care system.

• The quality of systematic reviews has to be further improved to enable fast health policy decisions.
Thank you for your attention!

katja.matthias@g-ba.de