

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



**Gemeinsamer  
Bundesausschuss**

# 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)**



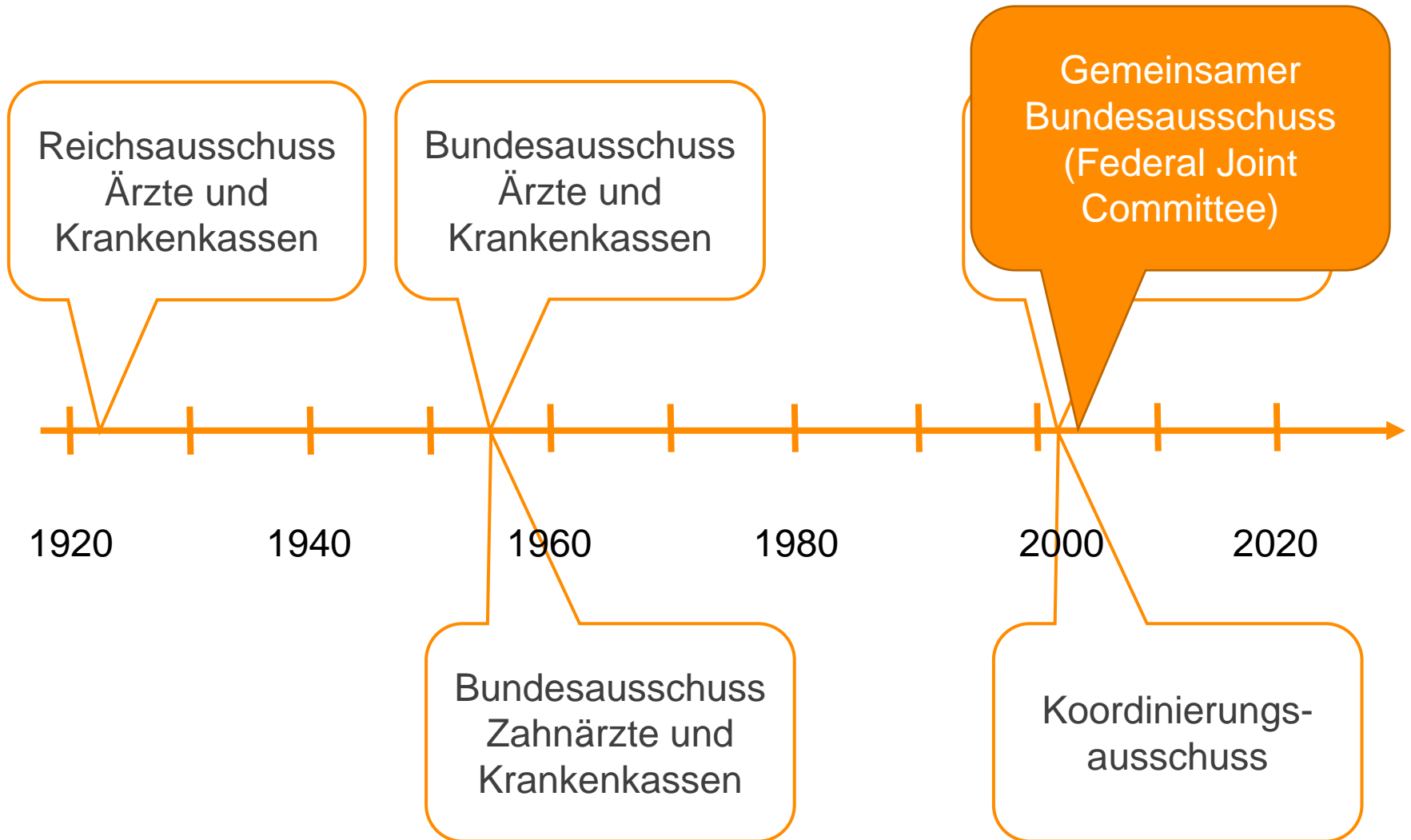
# **Self-governing health care system - Federal Joint Committee (G-BA)**

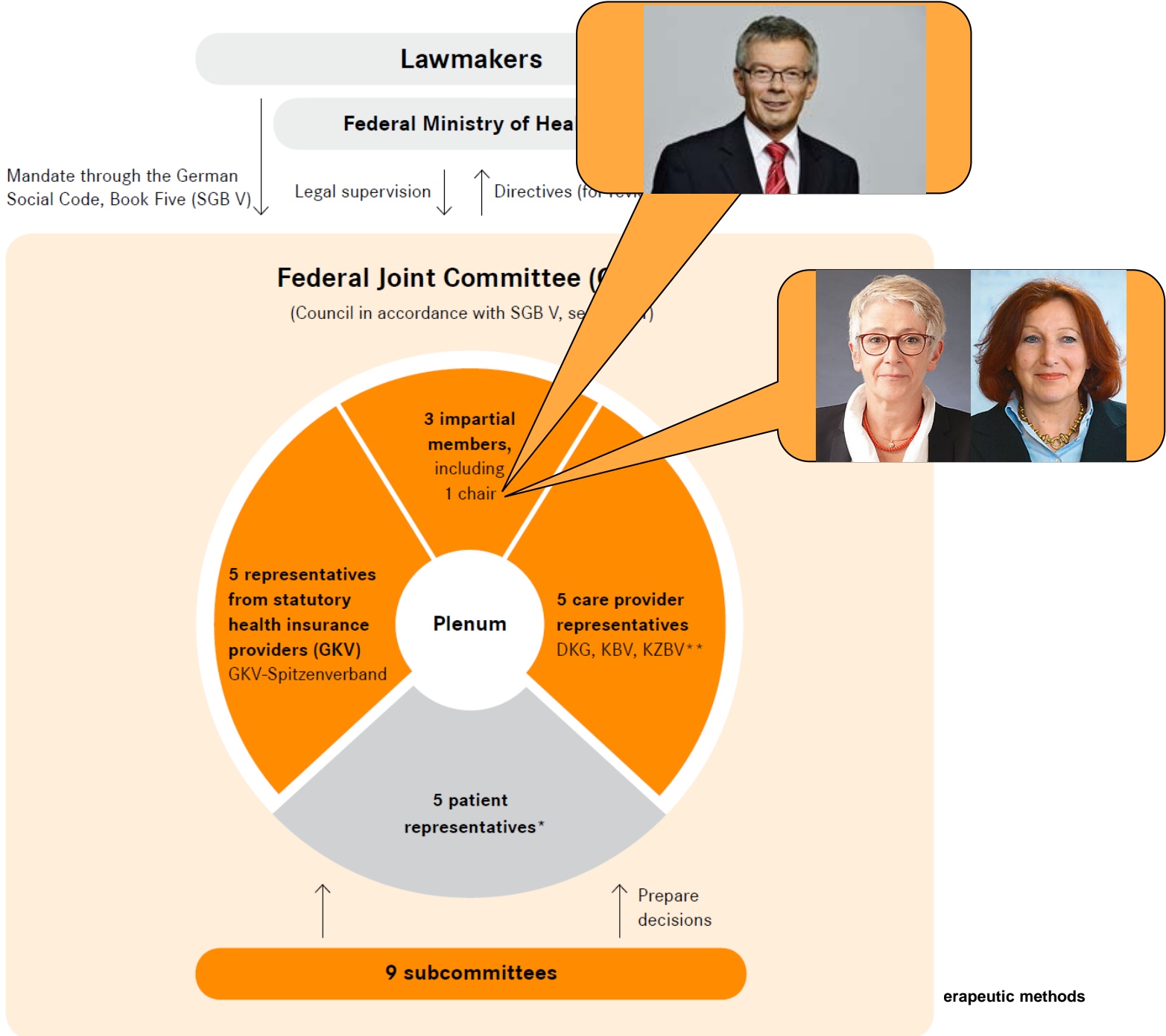
**is...**

- **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...

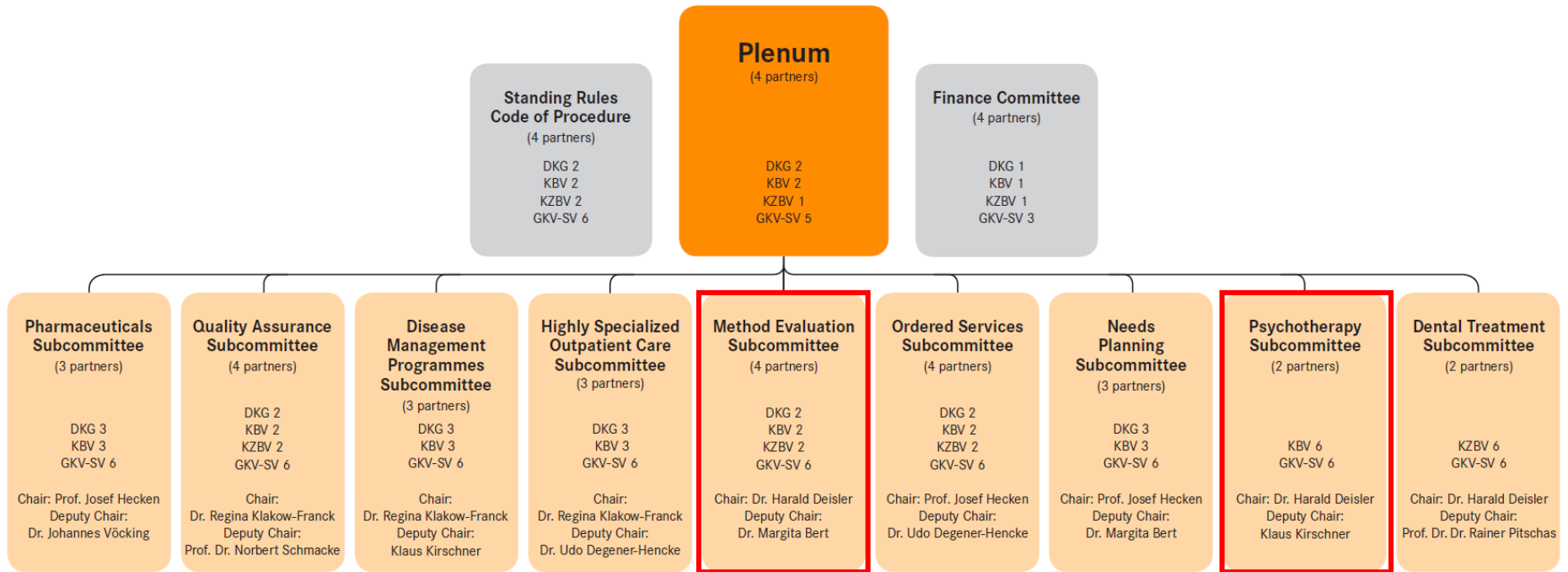








# G-BA: structure and committees



Abbreviations: DKG = German Hospital Federation; KBV = National Association of Statutory Health Insurance Physicians; KZBV = National Association of Statutory Health Insurance Dentists; GKV-SV = Federal Association of Statutory Health Insurance Funds

**managed by office of the G-BA with 6 departments and about 200 employees**



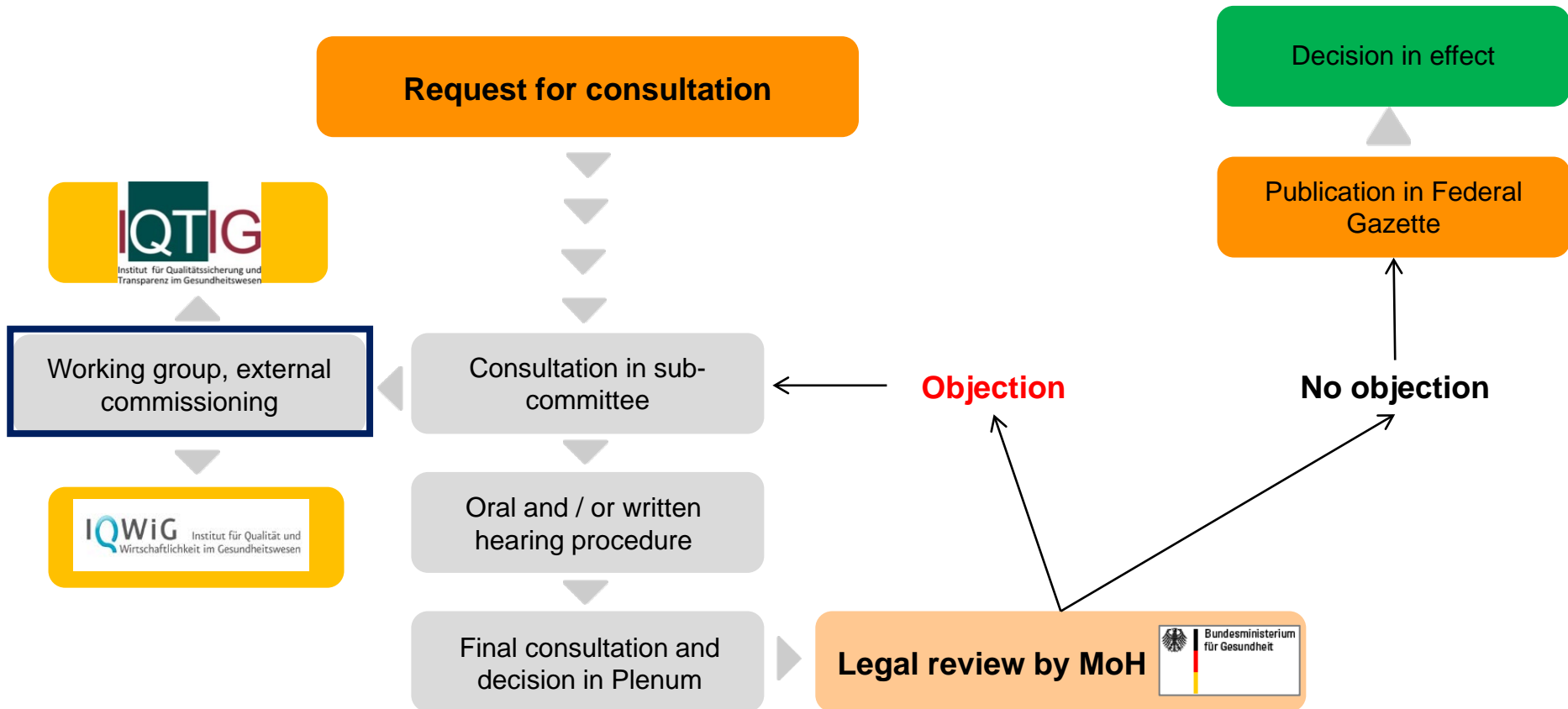


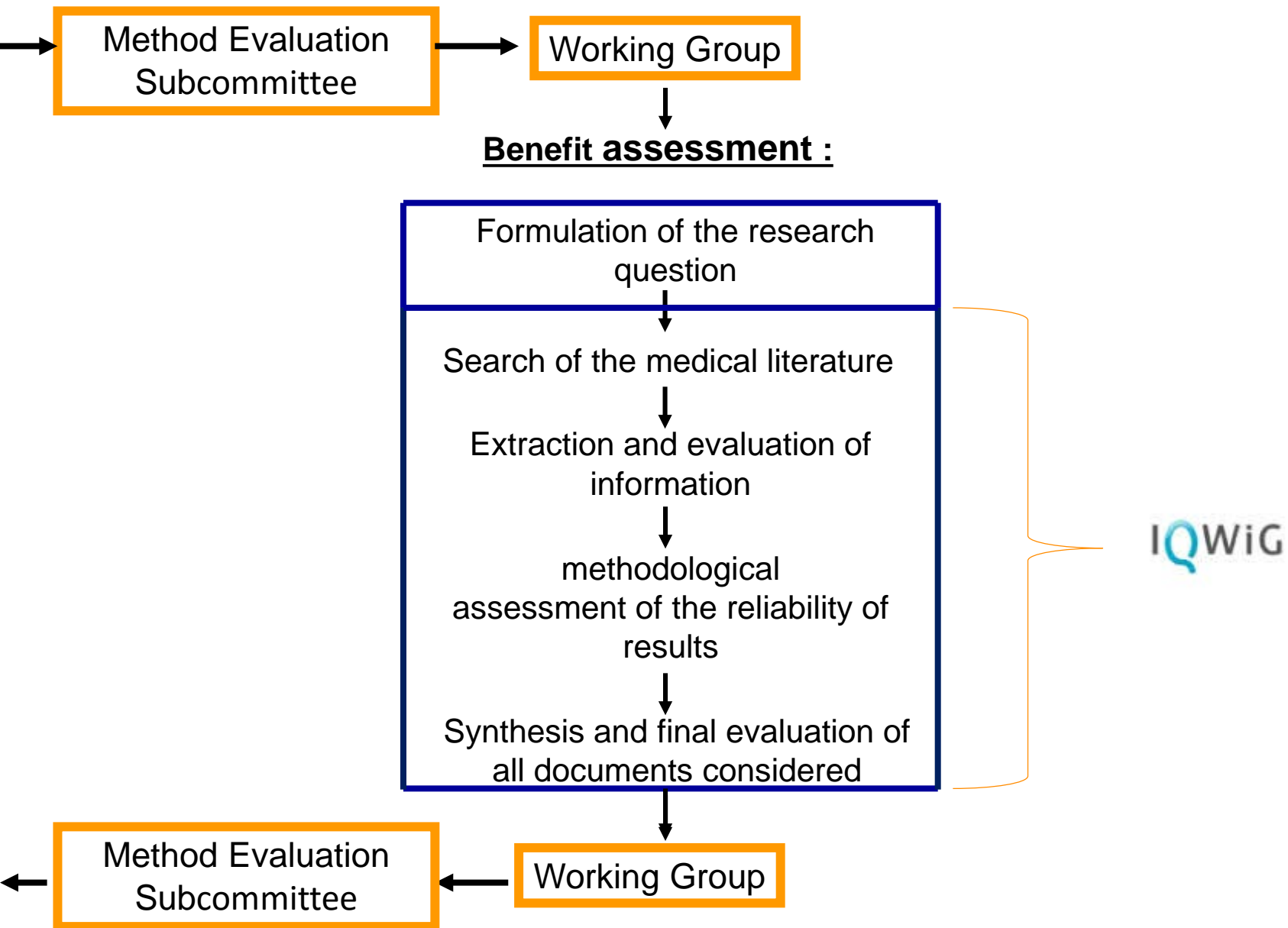
# Examples of non-drug interventions

- **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**



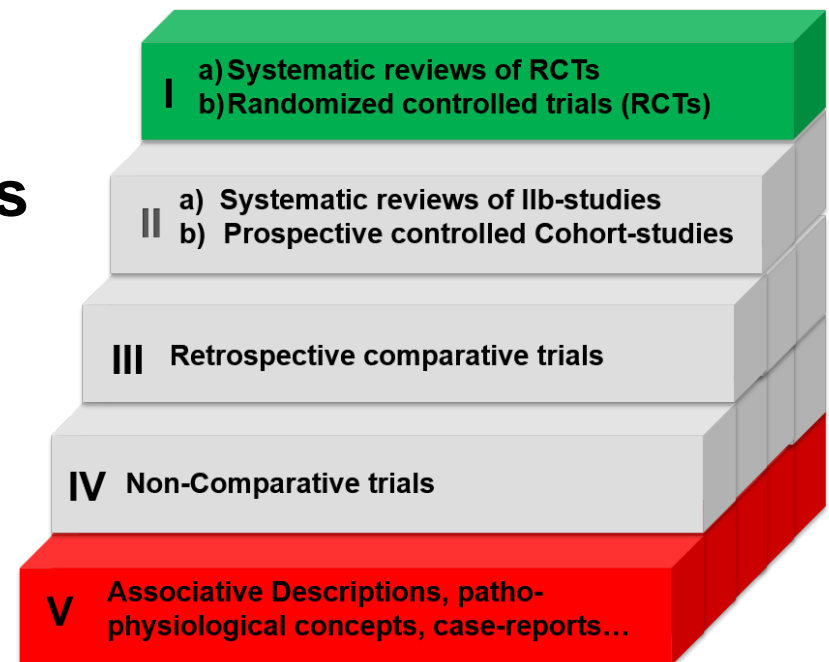
# Assessment pathways & decision making



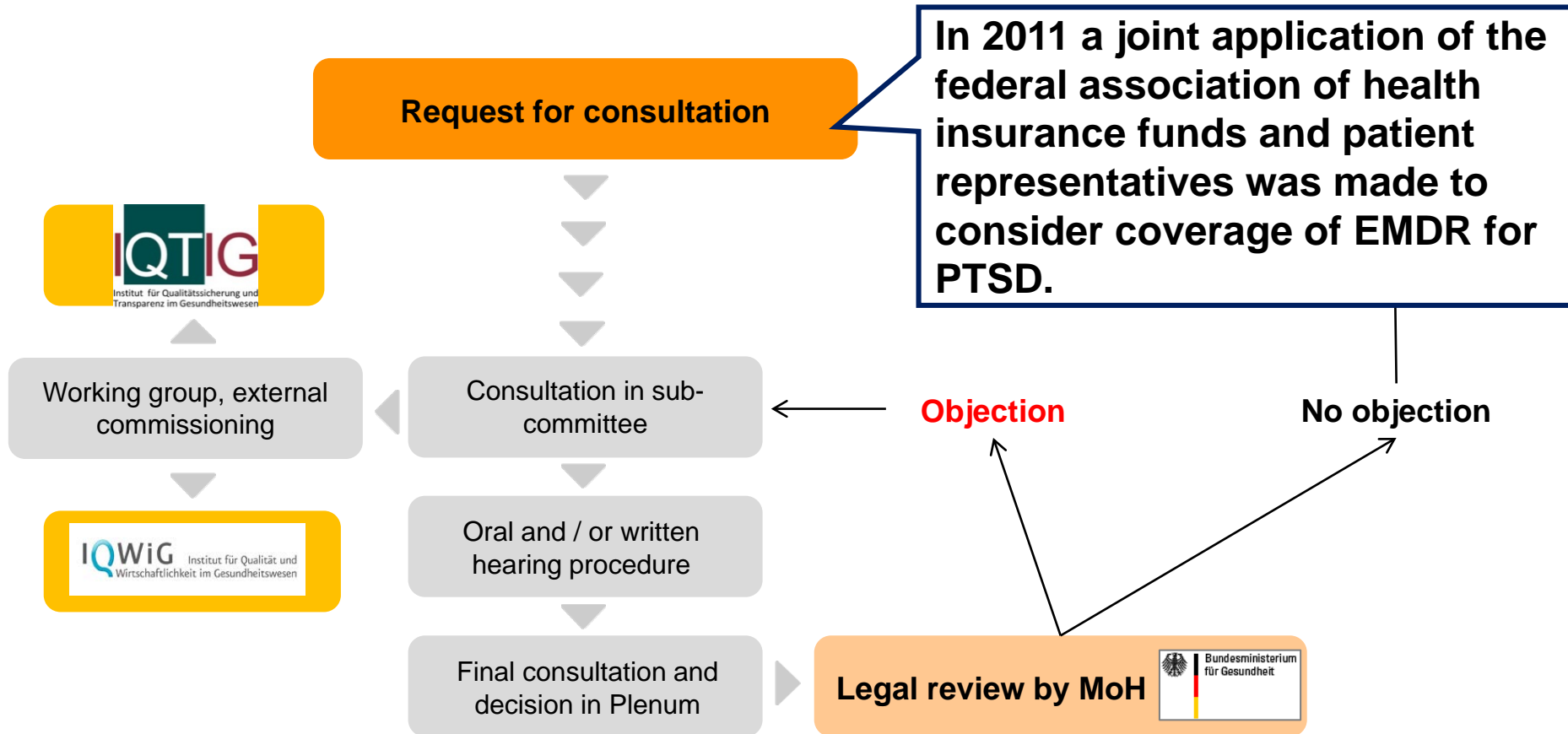


# Assessment of new services / Principles of benefit assessment

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



# Request for consultation



# 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

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



# Screening - Selection criteria

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



# 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

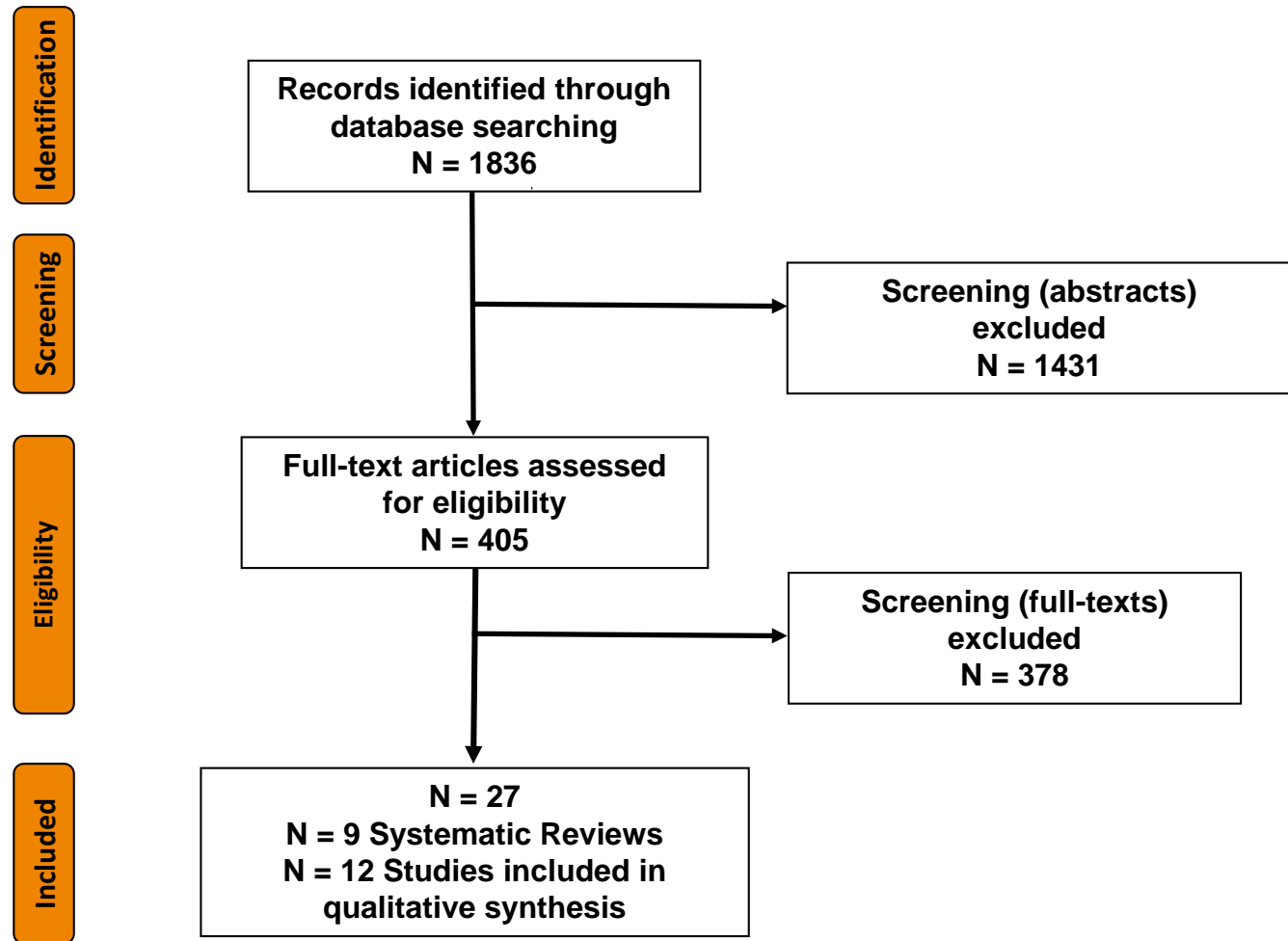
$I^2$  statistic,  $I^2 < 70\%$  FEM,  $I^2 \geq 70\%$  REM

## Software

Comprehensive Meta-Analysis  
Biostat, Inc. 2006-2013



# Flowchart of literature review process



# Overview – Systematic Reviews



## Critical appraisal



# Results – Systematic Reviews

SR  
1

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.”

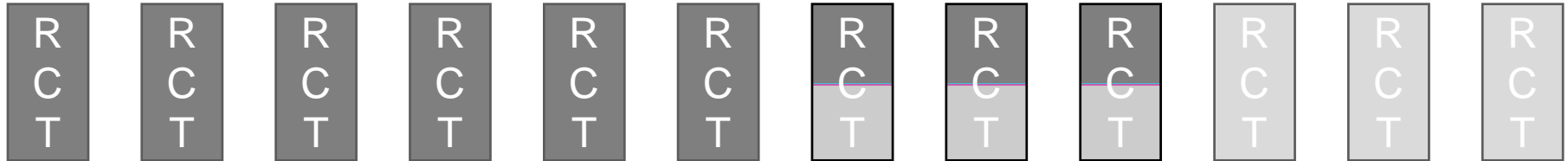
**Open question: does these reviews reflect the current state of research due to the date of their last searches?**

SR  
2

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)**

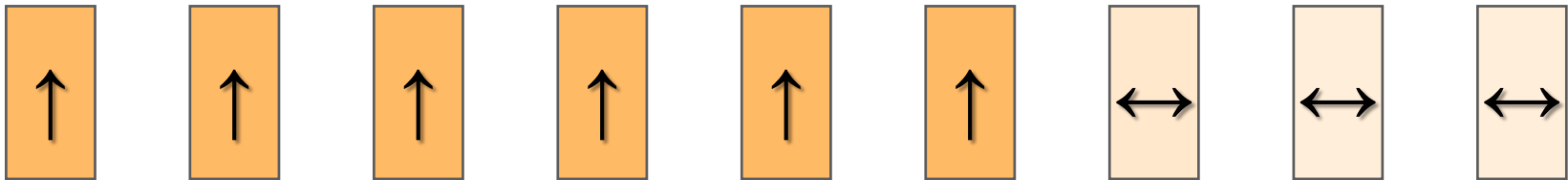


# Critical appraisal – Primary studies

	Random sequence generation	Allocation concealment	Blinding of participants / personnel	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other bias
Jensen 1992/1994	?	?	⊖	⊖	?	?	?
Marcus 1997/2004*	?	?	⊖	⊕	?	?	?
Rothbaum 1997	?	?	⊖	⊖	⊕	⊕	⊕
Carlson 1998	?	?	⊖	⊕	?	?	?
Rogers 1999	?	?	⊖	⊕	?	?	?
Ironson 2002	?	?	⊖	⊖	?	?	?
Power 2002	⊕	⊕	⊖	⊕	?	⊕	?
Taylor 2003*	?	?	⊖	⊕	?	?	?
Rothbaum 2005*	?	?	⊖	⊕	⊕	⊖	?
Johnson 2006	?	?	⊖	⊕	?	?	?
Högberg 2007	?	?	⊖	⊕	?	?	?
Van der Kolk 2007	⊕	?	⊖	⊕	⊖	⊕	⊕



# EMDR vs. „unspecific“ interventions



## Interventions

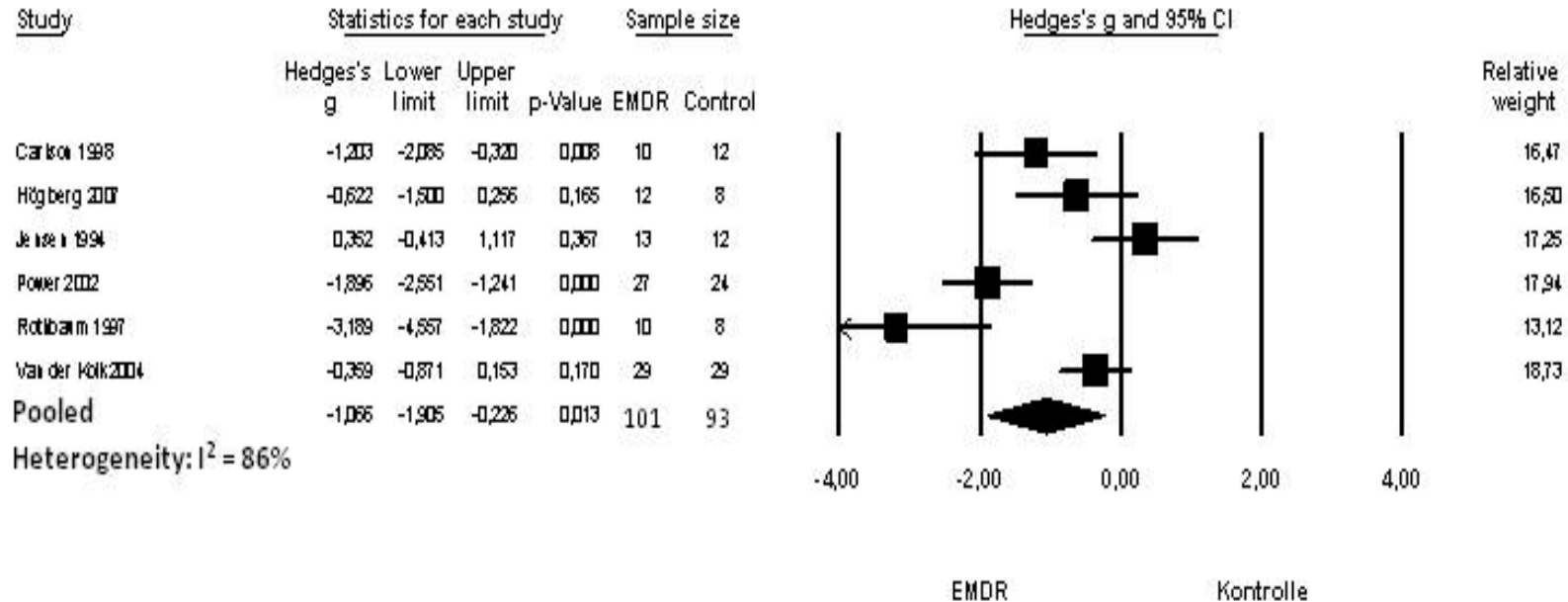
- Waiting list
- Relaxation
- Treatment as usual
- Pill placebo

## Outcomes

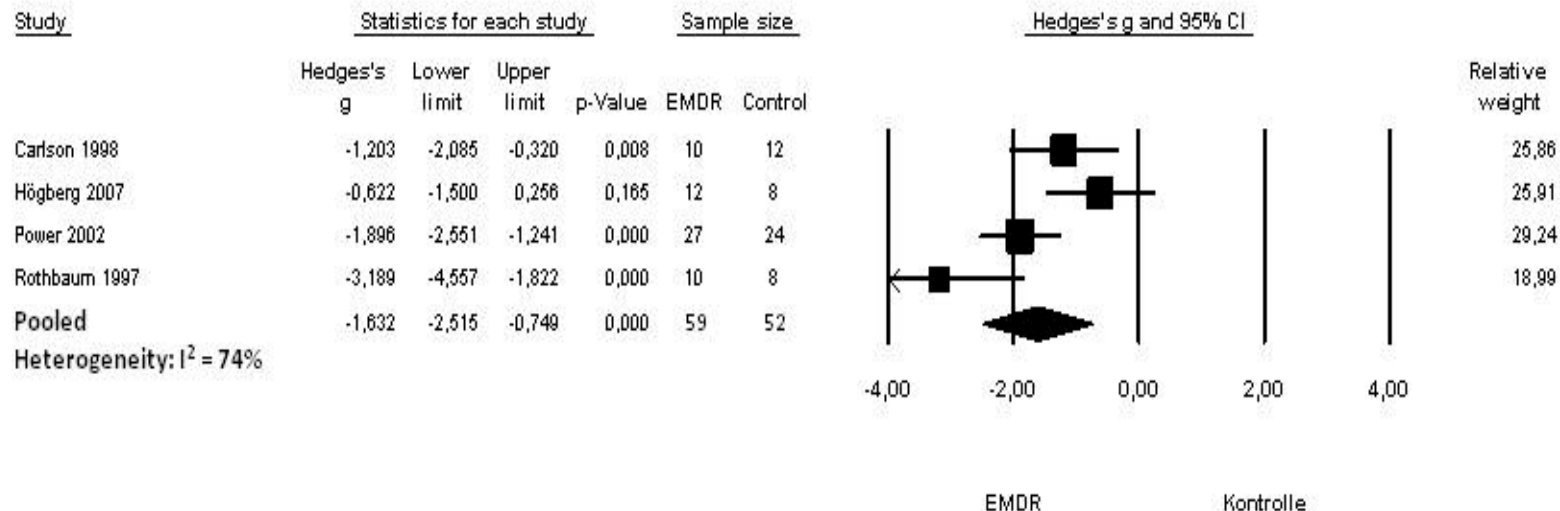
- Clinician rated traumatic stress symptoms or
- Self-reported PTSD symptom severity



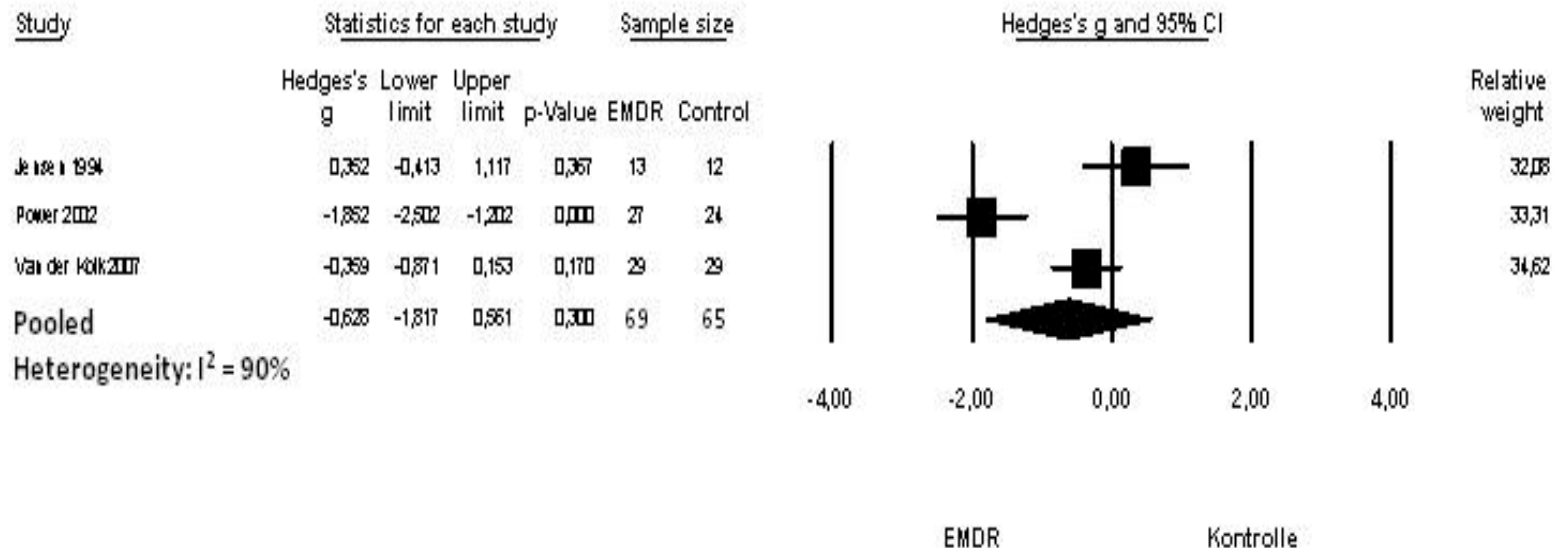
# EMDR vs. „unspecific“ interventions, PTSD symptoms



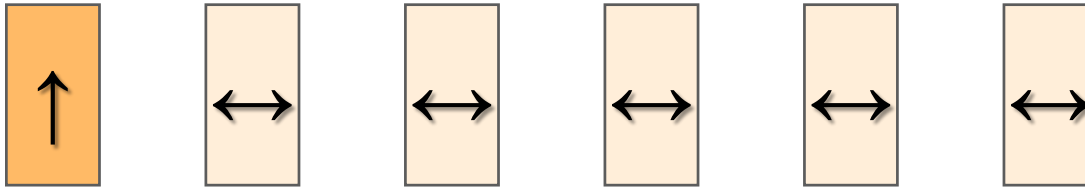
# EMDR vs. „unspecific“ interventions, self-rated PTSD symptoms



# EMDR vs. „unspecific“ interventions, observer-rated PTSD symptoms



# EMDR vs. „specific“ interventions



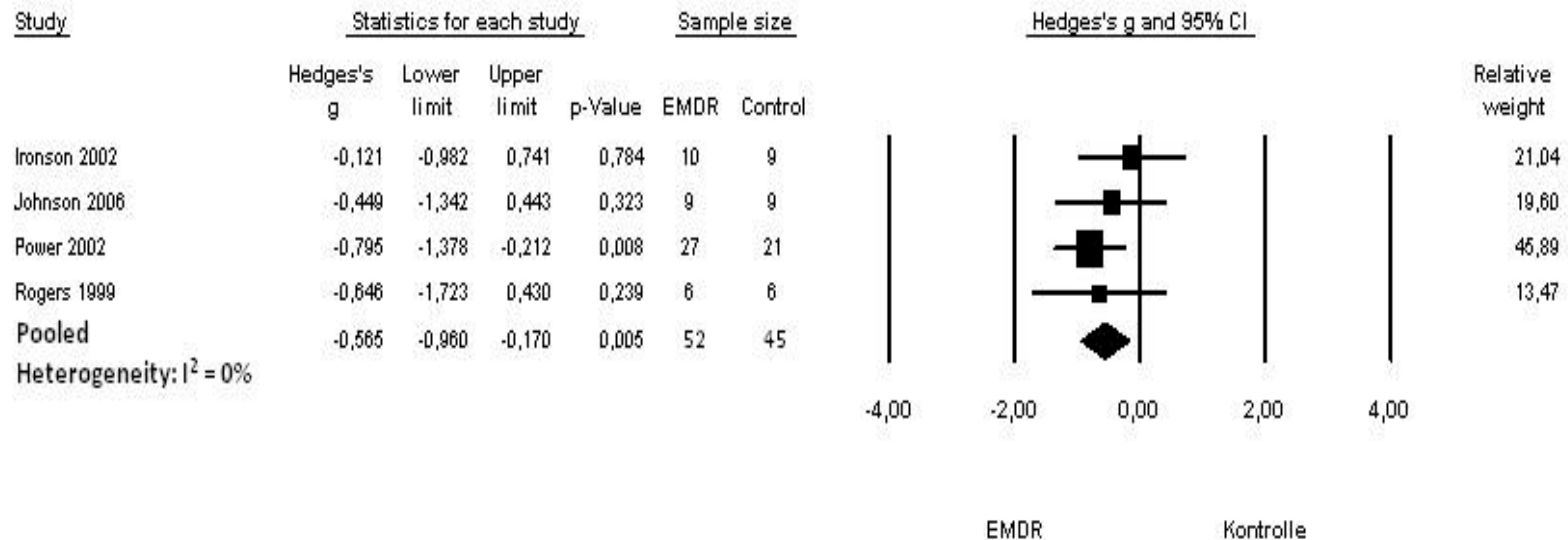
## Interventions

- 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



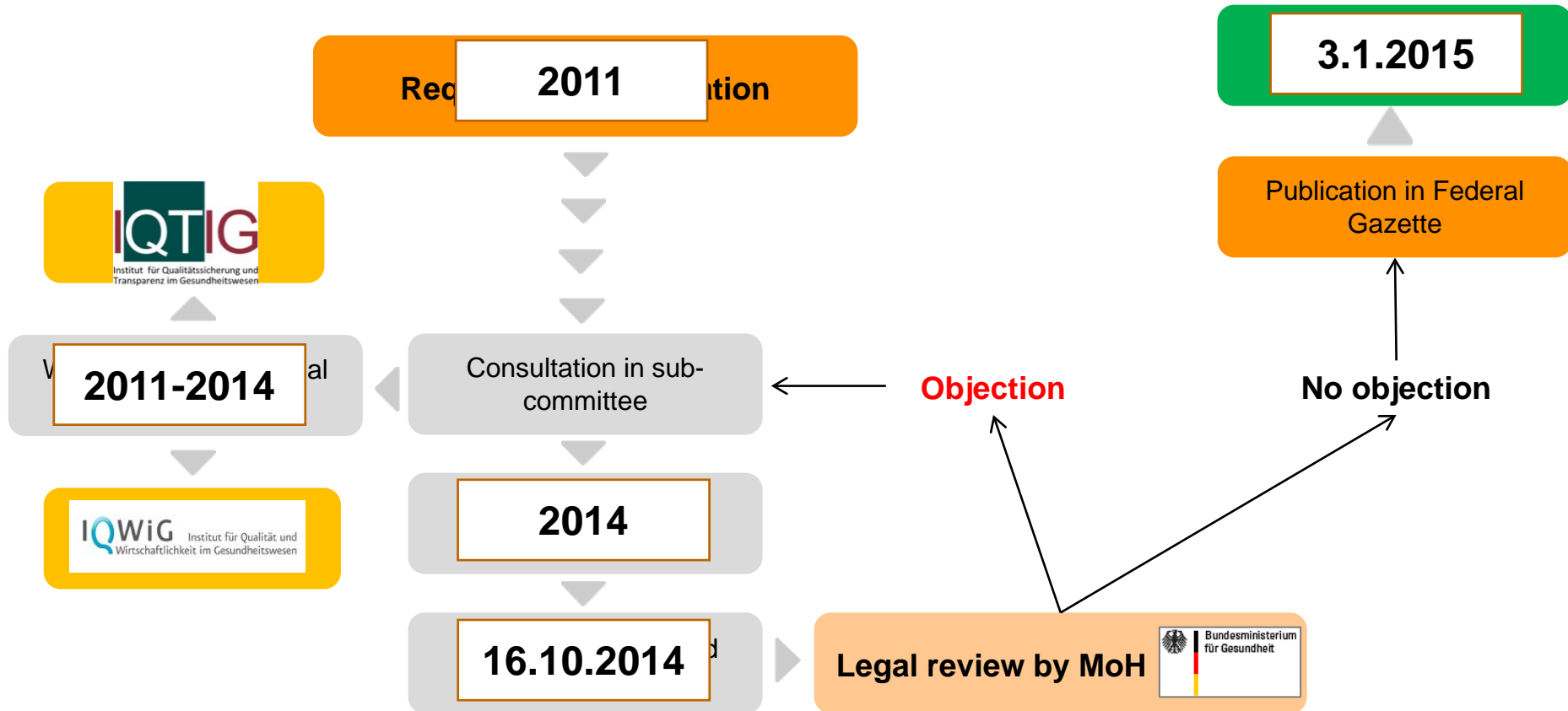


# Conclusion of the G-BA

- **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



# 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!

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