Alkoholabhängigkeit: Krankheitslast und neue Therapieoptionen

State of the art Symposium
DGPPN 2012

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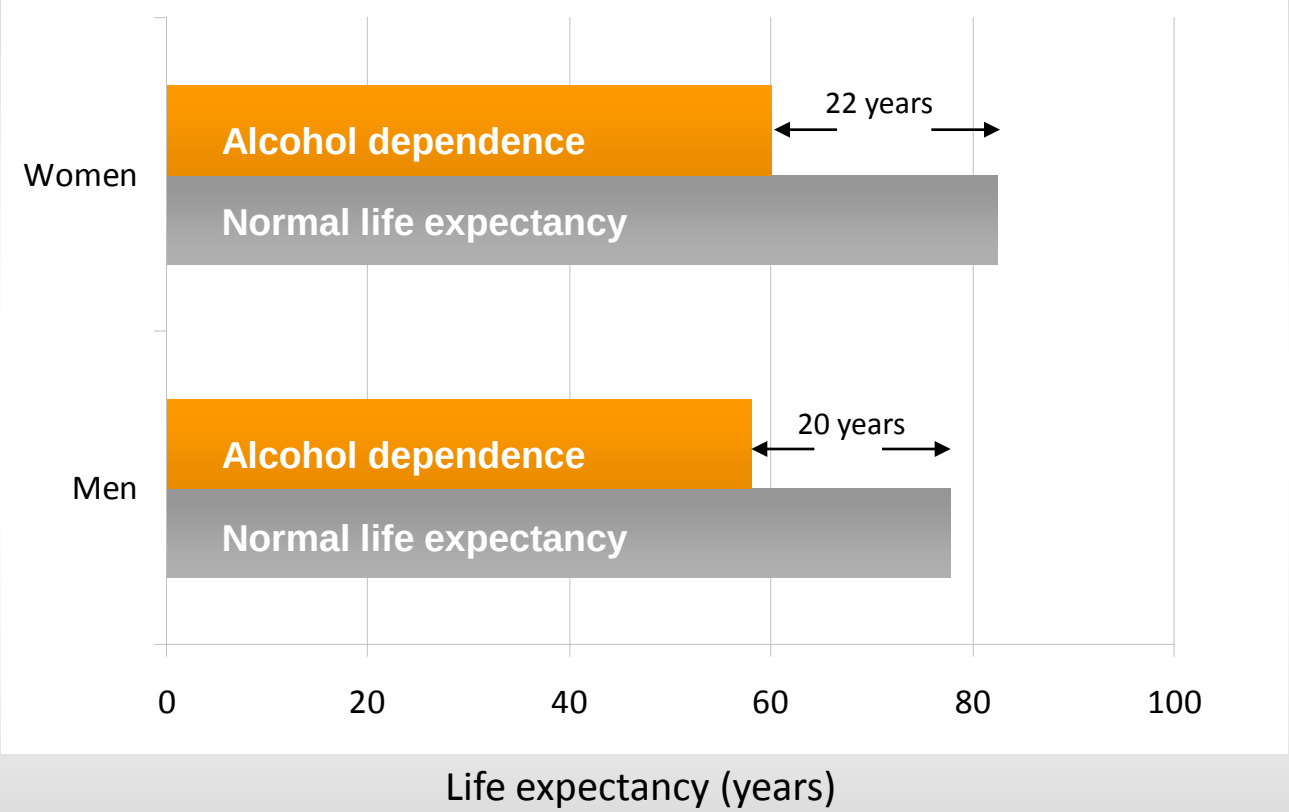
Zentralinstitut für Seelische Gesundheit
Landesstiftung des öffentlichen Rechts

Lebenserwartung bei Alkoholikern reduziert



To improve life expectancy in Alcohol Dependence, it is essential to reach more alcohol dependent patients at an earlier stage in their lives

John et al. Alcoholism Clin Exp Res 2012; in print
CIA World FactBook (2011 life expectancy estimates, Germany)

Potentielle Interessenkonflikte

Unterstützung für Studien:

Alkermes, MSD, Lundbeck,

Mundipharma, McNeill

Advisory Board:

Alkermes, Desitin, Lundbeck, McNeill, Pfizer

Gliederung:

1. “Krankheitslast” und Kosten

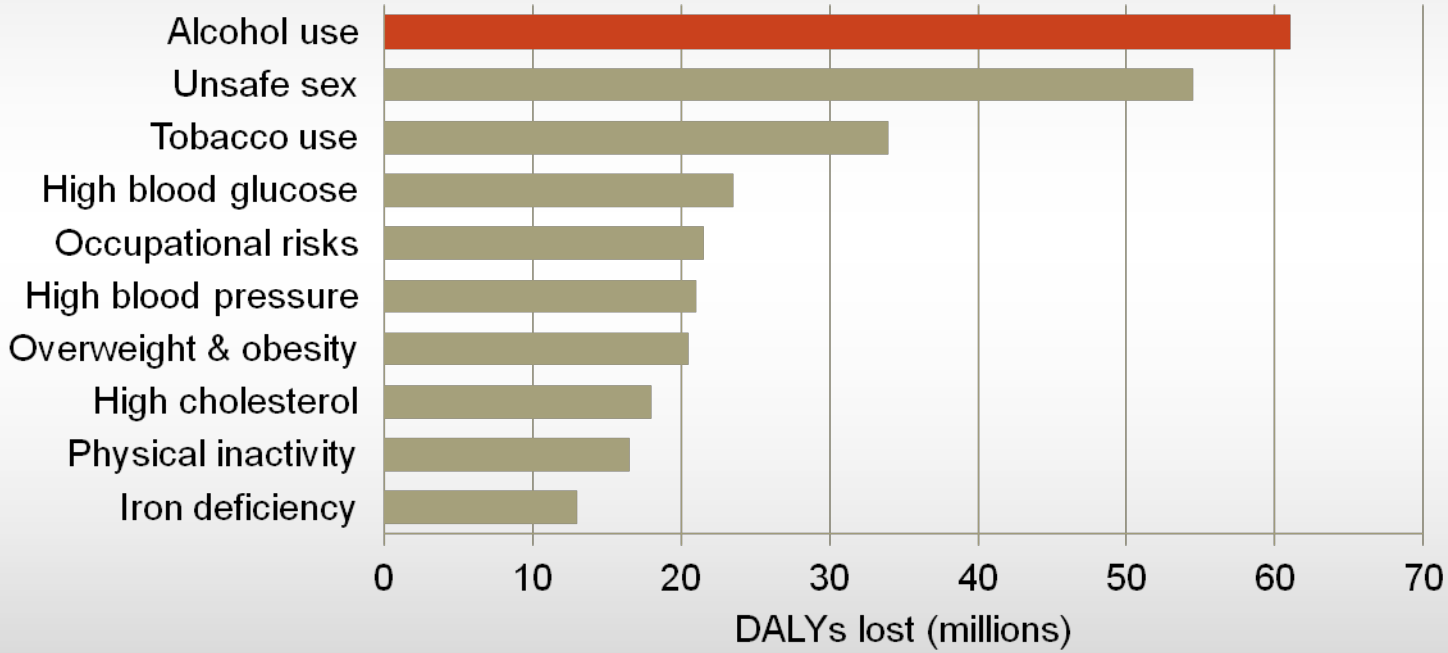
2. Hilfesystem, Psycho- und Pharmakotherapie

3. Aktuelle Entwicklungen
   - Individualisierte Therapie
   - Therapieziele

   (Abstinenz; Kontrolliertes Trinken; Risikoarmes Trinken)

Alcohol is the worlds leading risk factor for overall burden of disease among men aged 15–59

Disability-adjusted life year (DALYs) lost attributable to 10 leading risk factors, for the age group 15–59 years (2004)



In 2004, 4.5% of the global burden of disease and injury was attributable to alcohol: 7.4% for men and 1.4% for women

DALY=disability-adjusted life year

WHO. Global status report on alcohol and health, 2011

Europa ist Spitzenreiter - weltweit

- The WHO European Region is the heaviest drinking region in the world
  - Over one fifth of the European population aged ≥15 years report heavy episodic drinking* at least once a week
  - Heavy episodic drinking is widespread across all age ranges
  - Heavy episodic drinking is widespread across all parts of Europe

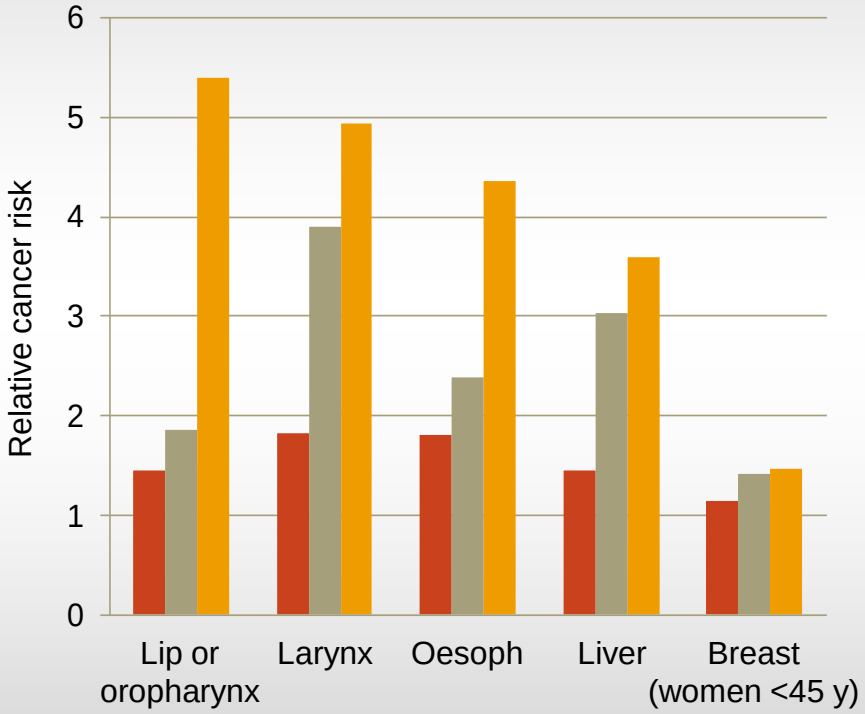
*Defined as ≥5 drinks (≥50 g alcohol) on one occasion; definitions of drink units vary across European countries

WHO=World Health Organization

WHO. European status report on alcohol, 2010

Health risks increase in proportion to the amount of alcohol consumed

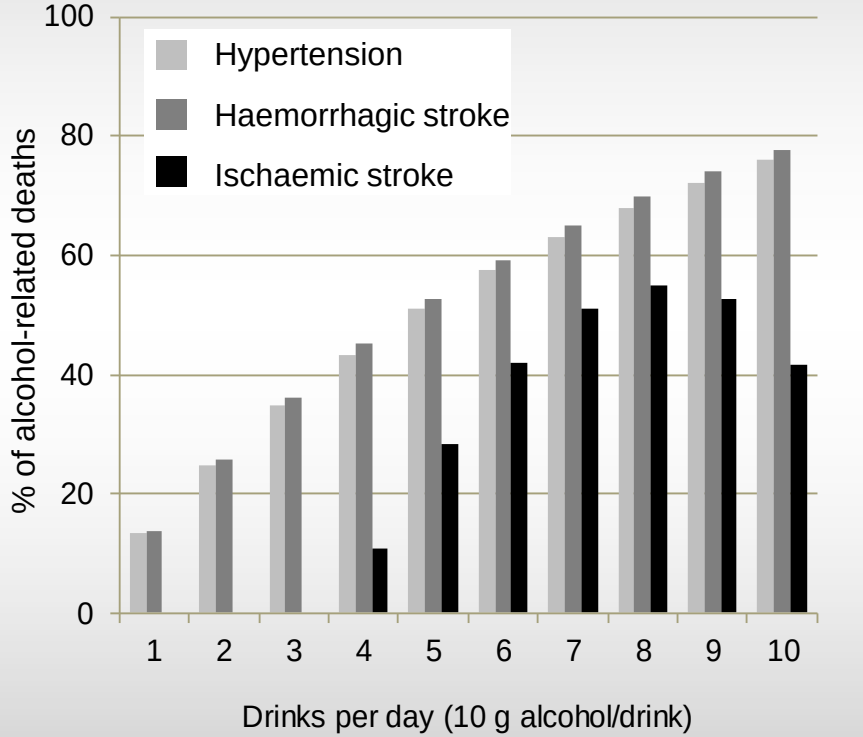
Cancer



Drinking category:

Low-risk Moderate-risk High-risk

Cardiovascular disease



WHO DRL:
High-risk drinking=>40 g women/>60 g men;
Moderate-risk drinking=20–40 g women/40–60 g men;
Low-risk drinking=0–20 g women/0–40 g men

WHO. International guide for monitoring alcohol consumption, 2000;
Rehm et al. Int J Methods Psychiatr Res 2008;17(3):141–151;
Rehm et al. In: Comparative quantification of health risks, WHO 2004;
Ridolfo & Stevenson. AIHW 2001:PHE 29

European Neuropsychopharmacology (2011) 21, 655–679

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ECNP/EBC REPORT 2011

The size and burden of mental disorders and other disorders of the brain in Europe 2010

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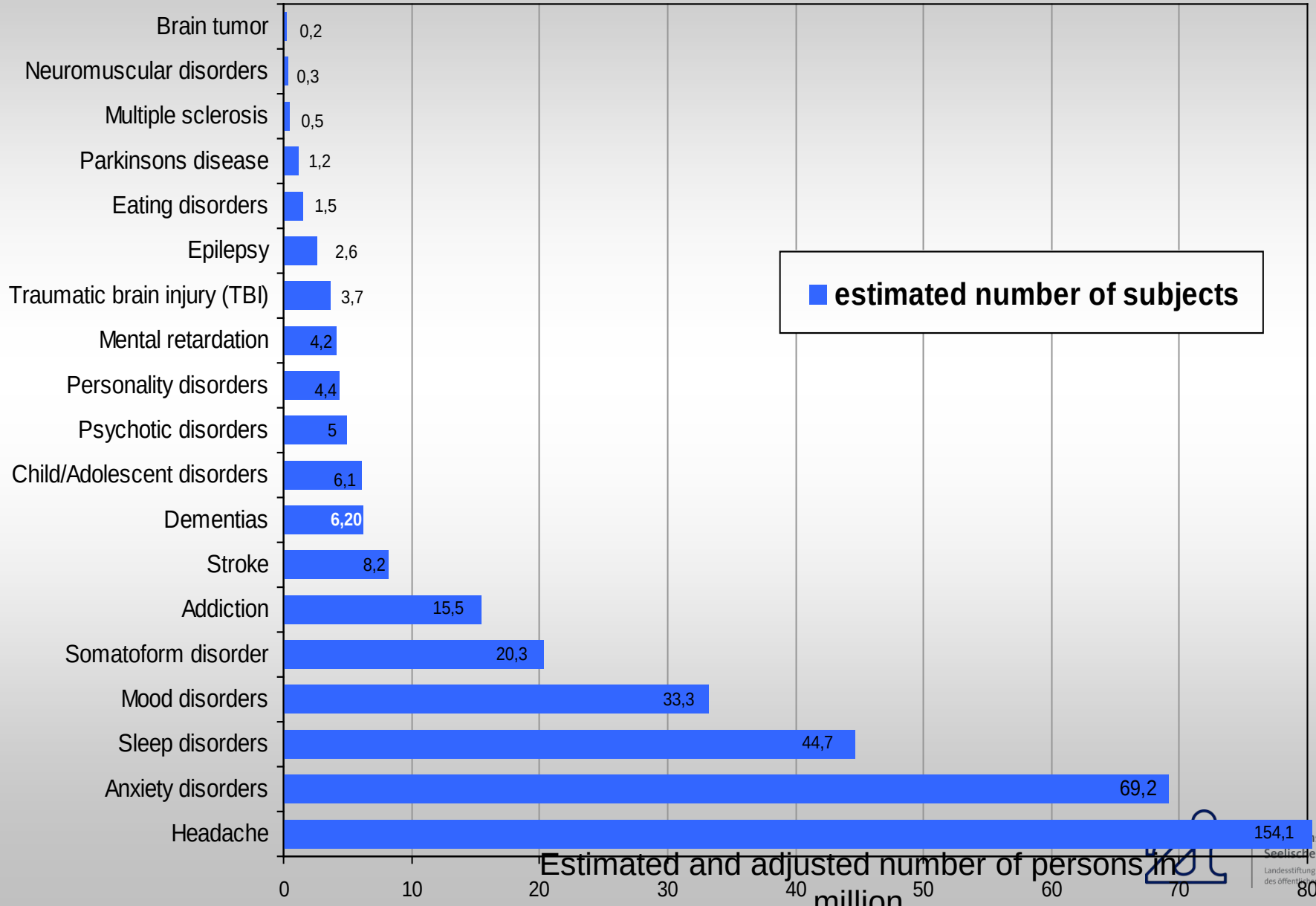
doi:10.1016/j.euroneuro.2011.07.018

Mental disorders affect 38% of the total EU-population



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European Neuropsychopharmacology (2011) xx, xxx–xxx

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Cost of disorders of the brain in Europe 2010

Anders Gustavsson[a], Mikael Svensson[b], Frank Jacobi[c], Christer Allgulander[d], Jordi Alonso[e], Ettore Beghi[f], Richard Dodel[g], Mattias Ekman[a], Carlo Faravelli[h], Laura Fratiglioni[i], Brenda Gannon[j], David Hilton Jones[k], Poul Jennum[l], Albena Jordanova[m,n,o], Linus Jönsson[a], Korinna Karampampa[a], Martin Knapp[p,q], Gisela Kobelt[r,s], Tobias Kurth[t], Roselind Lieb[u], Mattias Linde[v,w], Christina Ljungcrantz[a], Andreas Maercker[x], Beatrice Melin[y], Massimo Moscarelli[z,aa], Amir Musayev[a], Fiona Norwood[ab], Martin Preisig[ac], Maura Pugliatti[ad], Juergen Rehm[ae,af], Luis Salvador-Carulla[ag,ah], Brigitte Schlehofer[ai], Roland Simon[aj], Hans-Christoph Steinhausen[ak,al,am], Lars Jacob Stovner[an], Jean-Michel Vallat[ao], Peter Van den Bergh[ap], Jim van Os[aq,ar], Pieter Vos[as], Weili Xu[i], Hans-Ulrich Wittchen[at], Bengt Jönsson[au], Jes Olesen[av,*]

on behalf of the CDBE2010 study group[1]

Cost of brain disorders in Europe 2010

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European Neuropsychopharmacology (■■■) ■, ■■–■■

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The burden and cost of disorders of the brain in Europe with the inclusion of harmful alcohol use and nicotine addiction

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KEYWORDS
Substance use disorders;
Alcohol;
Tobacco;
Cost of illness;
DALY;
Burden of disease

Abstract
Recent publications calculated an annual prevalence of 38% of the population within the European Union having a "disorder of the brain" including substance use disorders (SUD) (Wittchen et al., 2011). The overall economic burden was estimated at 789 billion € (Gustavsson et al., 2011). While these calculations included alcohol dependence, harmful use of alcohol, a common ICD-10 diagnosis, was not considered appropriately. Tobacco related figures were completely left out. We hence estimated burden and costs of these diagnoses for the European Union by extrapolating basic figures from Germany, which have average proportions of alcohol and tobacco related consumption and prevalence rates. Several German Data sets were used to estimate prevalence, disability adjusted life years (DALYs) and Cost-of-illness for alcohol and tobacco use disorders in Germany. Results were obtained by focussing on the burden of SUD including well-known comorbidities. Results were then extrapolated to the European level. Compared with the earlier estimations DALYs increased from 2.8 million to over 6.6 million for SUDs. Costs augmented from 65.68 billion € PPP to about 350 billion € PPP. We discuss the robustness and validity of our findings under different assumptions and with regard to methodology. We further took into account that in the new DSM 5 alcohol abuse and alcohol dependence - and similar tobacco - will be collapsed into one category of "alcohol related disorder". If added to the burden and cost calculations the substance use disorders rank on top of all disorders of the brain in Europe. Regardless of the calculation procedure our figures represent lower estimates and have to be regarded as conservative approaches.

1. Introduction

Alcohol and tobacco consumption are among the most dangerous threats to health in the world (WHO, 2009). From a psychiatric point of view alcohol and tobacco products bear the risk of dependence and harmful use,

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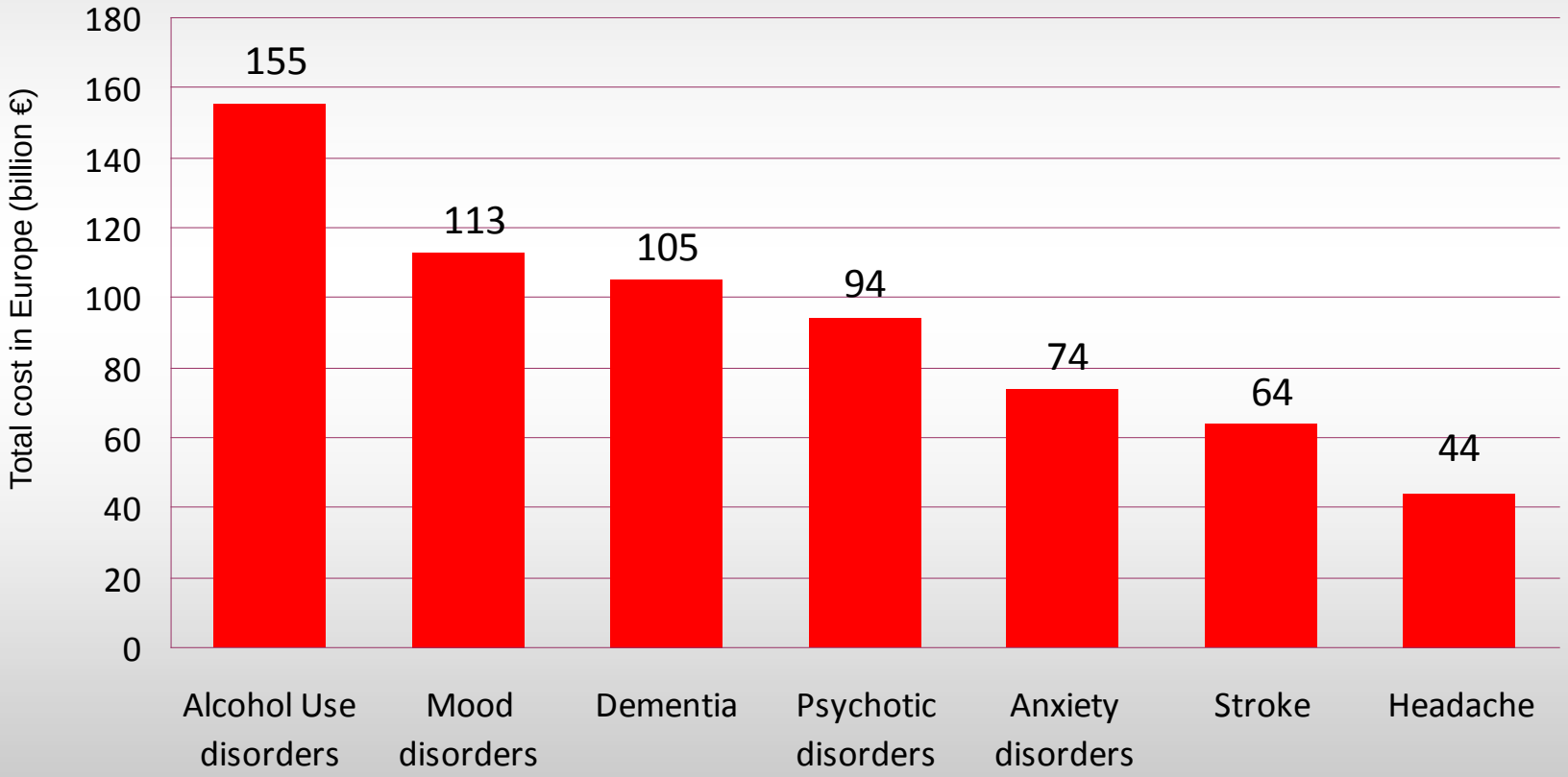
Alcohol and nicotine use disorders bear the most severe burden and costs



Effertz & Mann. Eur Neuropsychopharmacol 2012; epub ahead of print

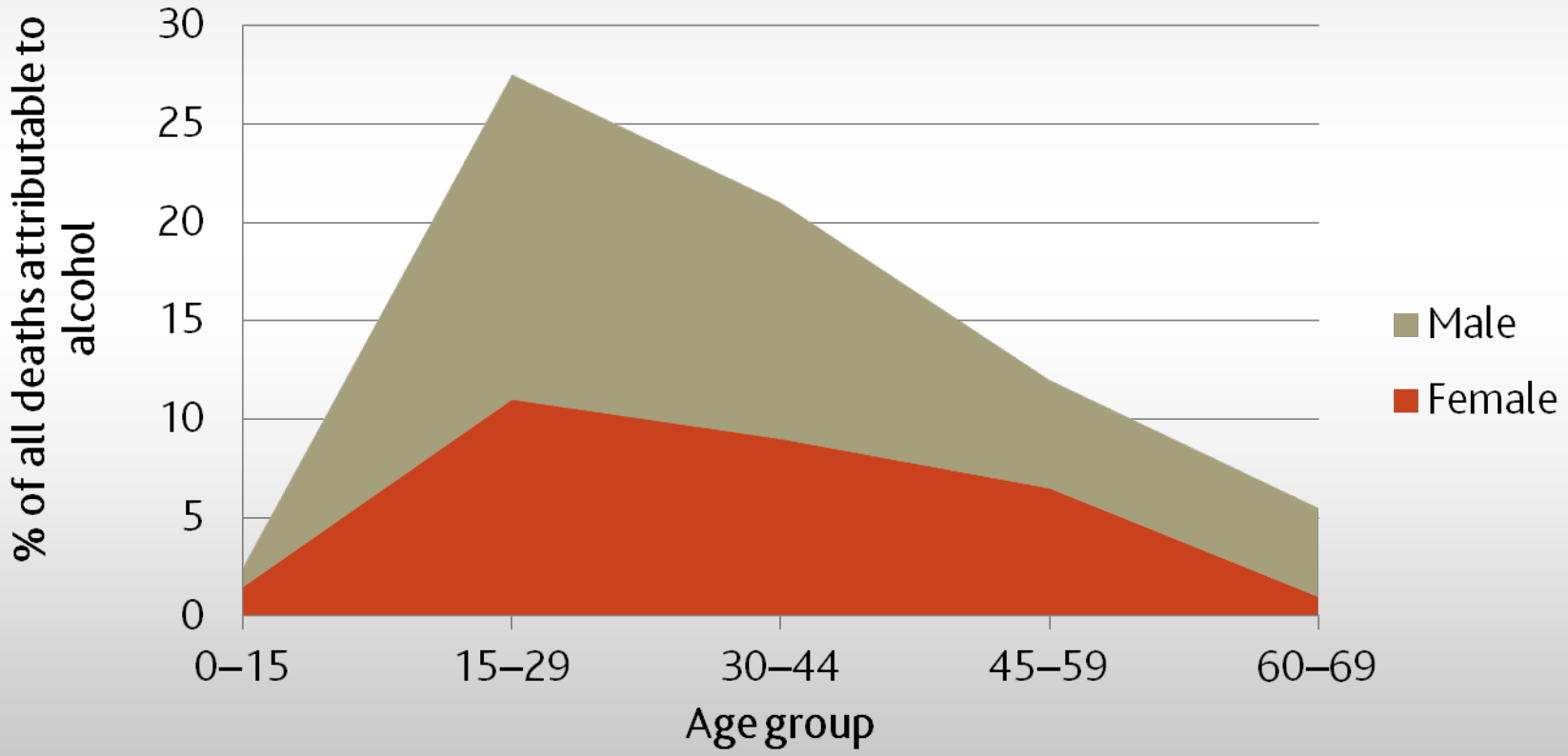
Anderson & Baumberg. Alcohol in Europe, 2006

Alcohol consumption leads to a high annual mortality burden in the EU

Neuropsychiatric conditions	– 17,000 deaths – 200,000 episodes of depression
Gastrointestinal conditions	– 45,000 deaths due to liver cirrhosis
Cancers	– 50,000 deaths – 11,000 of these are due to breast cancer
Intentional injuries	– 2,000 homicides (4 in 10 of all homicides) – 10,000 suicides (1 in 6 of all suicides)
Unintentional injuries	– 17,000 deaths due to drink-driving (1 in 3 of all driving deaths) – 27,000 accidental deaths

Anderson & Baumberg. Alcohol in Europe, 2006

Deaths attributable to alcohol in the EU, by age



Anderson & Baumberg. Alcohol in Europe, 2006;
European Commission. Factsheet, 2006

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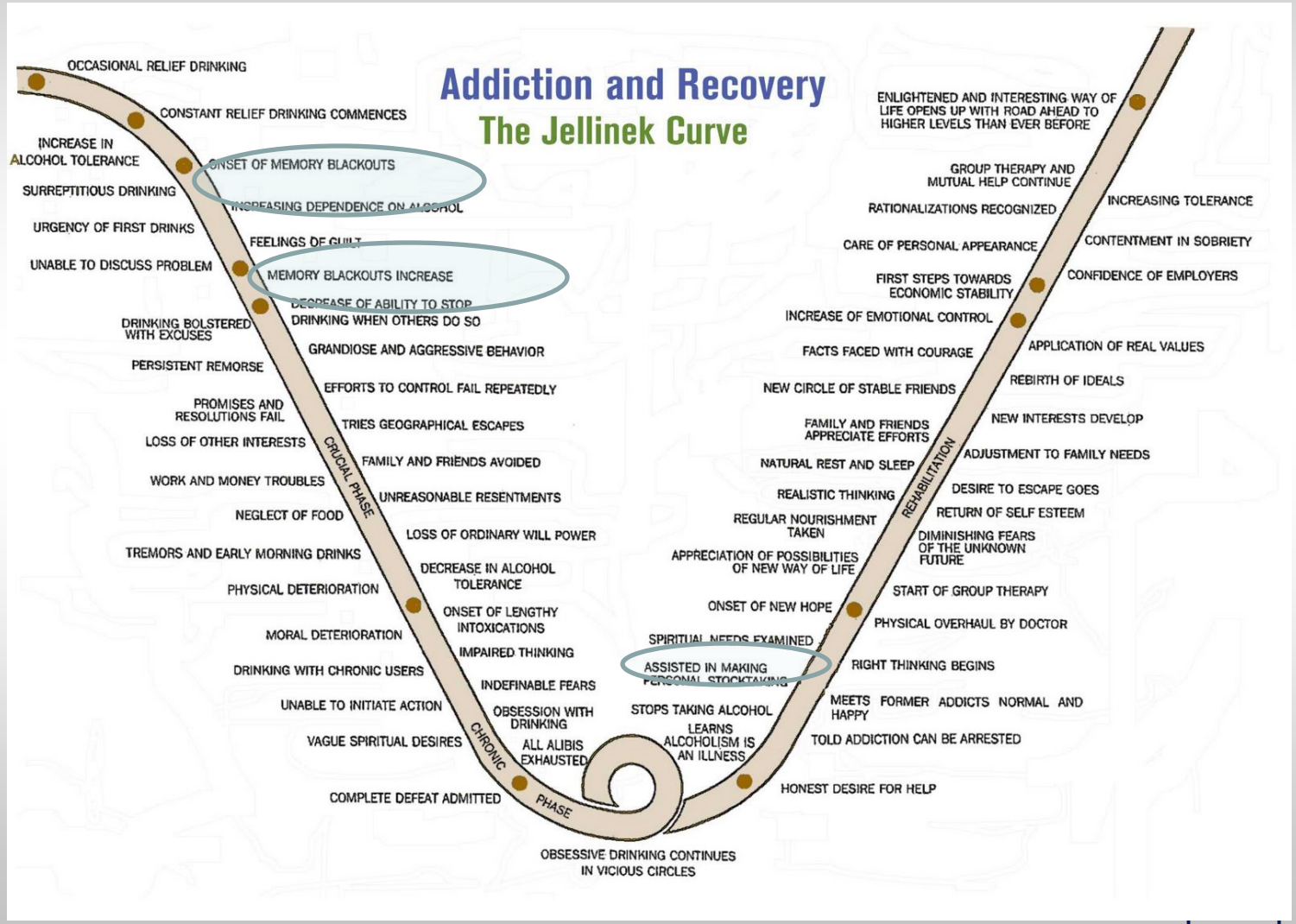
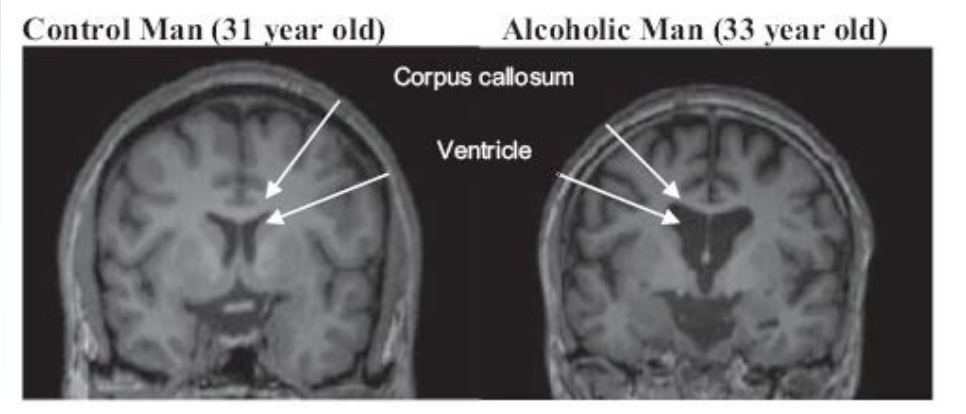


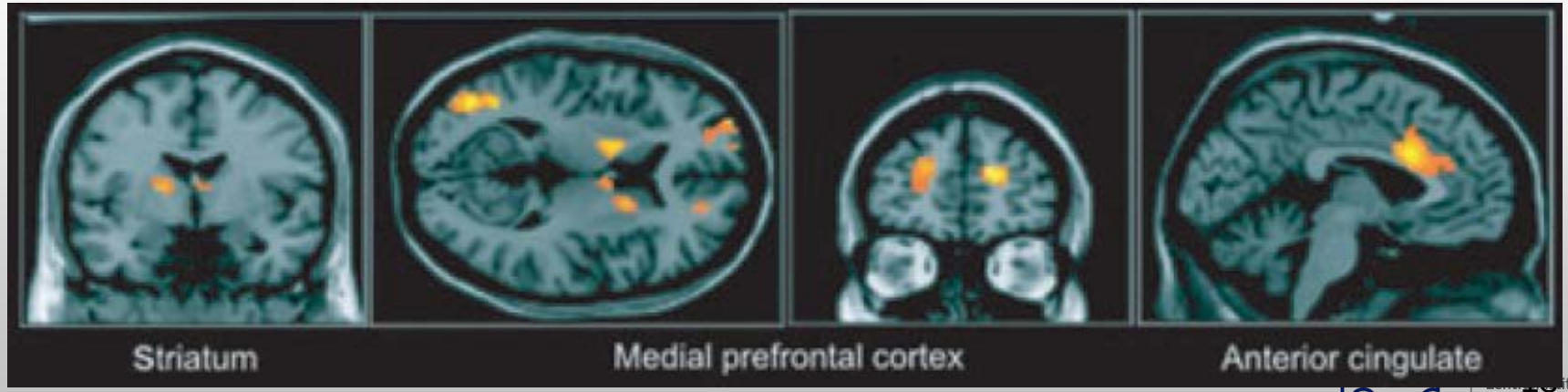
Jellinek, E. M., The Disease Concept of Alcoholism, Hillhouse, (New Haven), 1960.

Alcohol dependence as brain disease

Structural brain damage



Brain function (fMRI)



Buhler / Mann, Alcoholism: Clin & Exp Res, 2011, 35:10)1771-1793

Das Suchthilfesystem

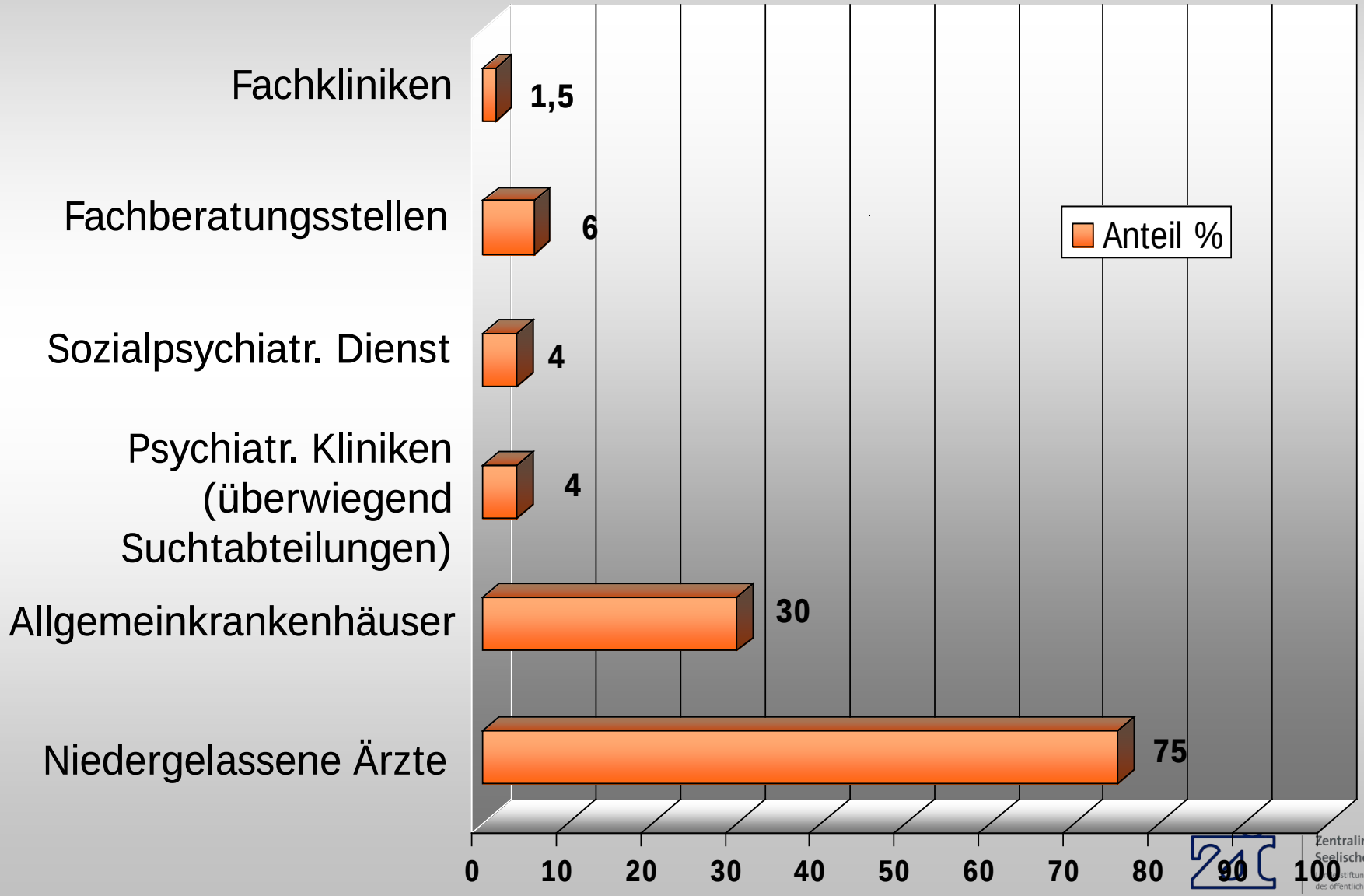
- Komplexes gewachsenes Suchthilfesystem
- Die Akutbehandlung alkoholbezogener Störungen erfolgt in der Regel in internistischen Abteilungen von Allgemein-krankenhäusern oder suchtmedizinischen Abteilungen von psychiatrischen Kliniken.
- Die Postakutbehandlung erfolgt in der Regel in spezialisierten Suchtfachkliniken oder auch im ambulanten Rahmen durch Suchtberatungsstellen, Ambulanzen und niedergelassene Kollegen
- Zuweisung und Vermittlung in spezifische Behandlungsangebote durch Allgemein- und Fachärzte, Suchtberatungsstellen, ärztliche und psychologische Psychotherapeuten und innerbetriebliche Sozial- und Suchtberatungen

Das Behandlungsangebot

- Vielfältige Ansätze
- Traditionelle Entwicklung von großer Bedeutung
- Häufig eklektische Ansätze
- Bewährung in der Praxis und in Nachbeobachtung der einzelnen Einrichtungen
- Kaum kontrollierte Studien
- Verfahren, deren Evidenz nachgewiesen ist, finden keine stringente Anwendung

Anteil der Alkoholabhängigen in verschiedenen Einrichtungen

Wienberg 2002



The treatment gap in Europe

- Schizophrenia: 18%
- Bipolar disorder: 40%
- Major depression: 45%
- Panic disorder: 47%
- Phobias: 62%
- Alcohol abuse/dependence: 92%

Kohn et al. Bull World Health Organ 2004;82 (11): 858–866

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Ansatzpunkte zur Optimierung

- Qualifizierte Alkoholentzugsbehandlung
- Entwicklung von Suchthilfenetzwerken
- Etablierung evidenzbasierter Behandlungsansätze in der Praxis
- Entwicklung neuer therapeutischer Ansätze
- Erweiterung des Grundlagenwissens

Ergebnisse nach stationärer Entwöhnungsbehandlung I

	Langzeittherapie Küfner & Feuerlein 1989	Langzeittherapie Zemlin et al. 1999
Behandlung	Stationäre Entwöhnungs-behandlung 4 bis 6 Monate (21 Kliniken)	Stationäre Entwöhnungs-behandlung 6 Monate
der Zeitpunkt Nachuntersuchung	6 Monate	1 Jahr
Anzahl der Patienten	1.410	3.060
Abstinenzrate	67%	60%

K. Mann Deutsches Ärzteblatt (2002)

Ergebnisse nach stationärer Entwöhnungsbehandlung II

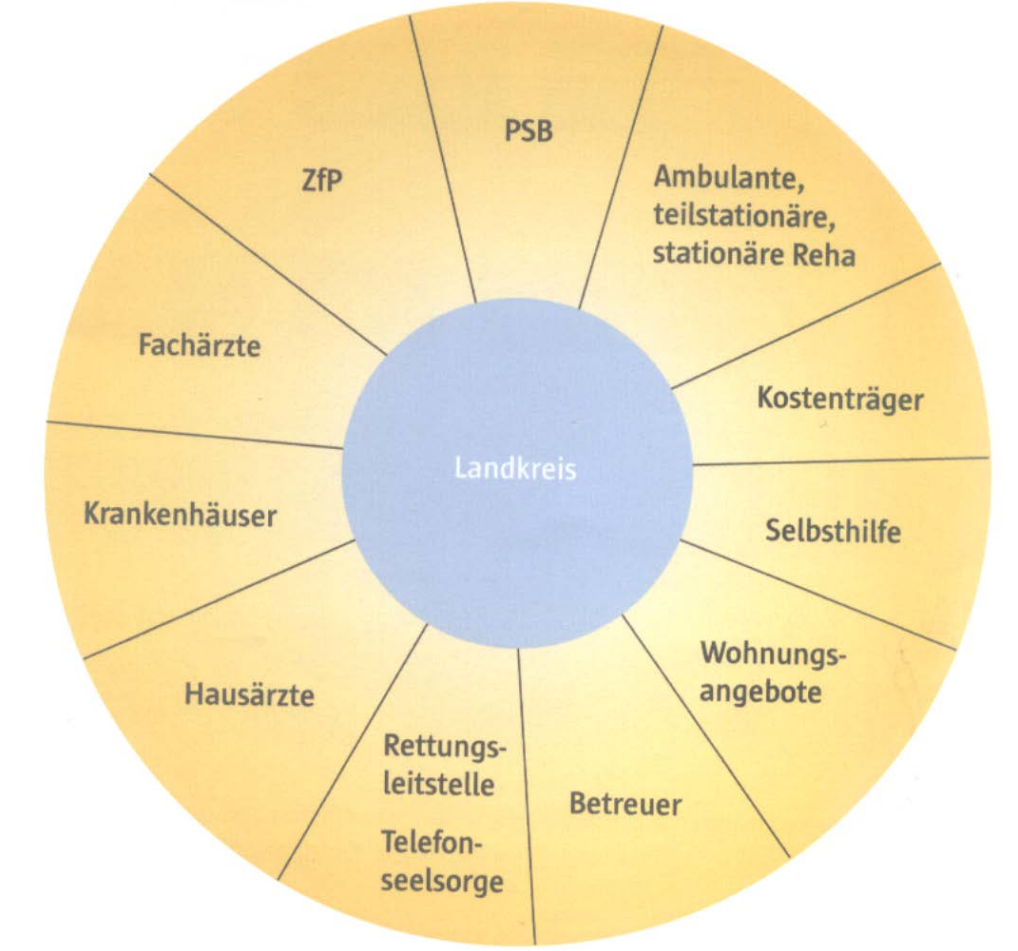
	Stationär/ Ambulante Therapie *Mann & Batra 1993*	Stationär/ Ambulante Therapie *Mann et al. 1995*
Behandlung	6 Wochen stationär 1 Jahr ambulant	6 Wochen stationär 1 Jahr ambulant
der Zeitpunkt der Nachuntersuchung	1 Jahr	1 Jahr
Anzahl der Patienten	790	212
Abstinenzrate	68%	67%

K. Mann Deutsches Ärzteblatt (2002)

Kriterien des Landes BW für Kommunale Suchthilfenetzwerke

- kooperative Mitwirkung aller an der Versorgung Beteiligter
- Niederschwellige wohnortnahe Zugangsmöglichkeit
- Interdisziplinäre Fallkonferenzen
- Angebot von Konsiliar- und Liaisondiensten
- Sicherstellung der zeitnahen Auf- bzw. Übernahme von Hilfesuchenden
- Verbindliche Mitwirkung mindestens einer Psychosozialen Beratungsstelle und einer suchtmedizinisch qualifizierten stationären (psychiatrischen) Akutbehandlungseinheit
- Verfügbarkeit von ambulanten, teilstationären und vollstationären Behandlungsmöglichkeiten
- Entwicklung einer einheitlichen Dokumentation
- Verbindlich praktizierte Kooperationsvereinbarungen
- Vereinbarung einer verbindlichen Finanzierungsregelung bei der Übernahme neuer Aufgaben

Entwicklung von Suchthilfenetzwerken (Bsp. Landkreis Konstanz, Dr. Höcker)



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Ärztliche Kurzintervention

Wirksamkeit

- Info, Aufklärung und Ratschlag bis 30 Min Dauer:
  50% reduzieren Alkoholkonsum
- Kurzintervention / brief intervention:
  Effekte nach 48 Monaten noch nachweisbar

Übersicht:

Küfner H: Ergebnisse von Kurzinterventionen und Kurztherapie bei Alkoholismus – ein Überblick. Suchtmedizin 2000; 181-192

Wirksamkeit von Kurzintervention

Metaanalyse von Kaner et al. (2007)

Cochrane Database Syst Rev

- 21 Studien
- Konsumreduktion 41 g/Woche

Metaanalyse Moyer et al. (2002) *Addiction*

- Größere Effekte bei Ausschluss von Abhängigen

Motivierende Gesprächsführung

„Motivational Interviewing“ *(Miller & Rollnick 1999)*
Standardisierte Intervention für wenig Motivierte

Ziele:

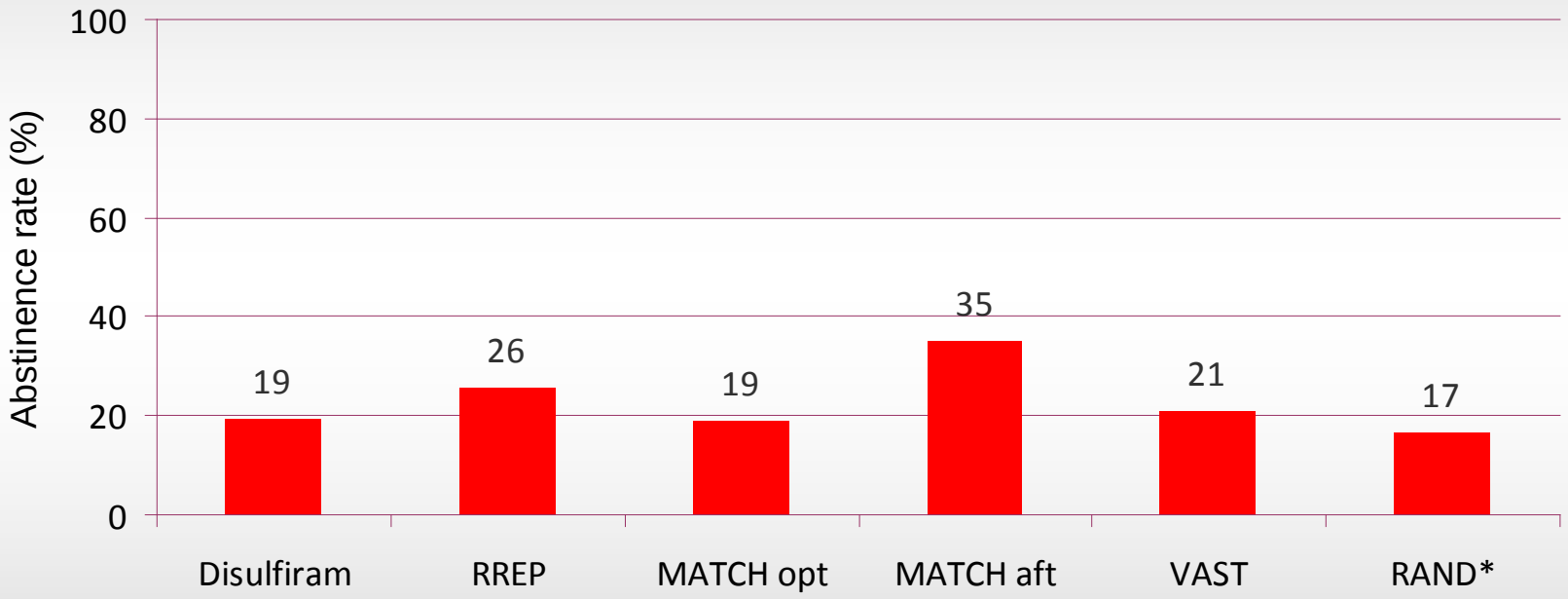
- Förderung von Veränderungsbereitschaft
- Aufbau von Vertrauen in die Selbstwirksamkeit
- Vereinbarung von gemeinsam festgelegten Zielen
- Anbindung

Beispiele für Selbstmotivierende Aussagen

- Ich denke, das Problem ist größer als ich dachte
- Ich bin deswegen wirklich in Sorge
- Ich glaube es wird Zeit, über das Aufhören nachzudenken
- Ich glaube, ich kann es schaffen

Kontinuierliche Abstinenz über 12 Monate

12-month drinking outcomes in multi-site treatment trials

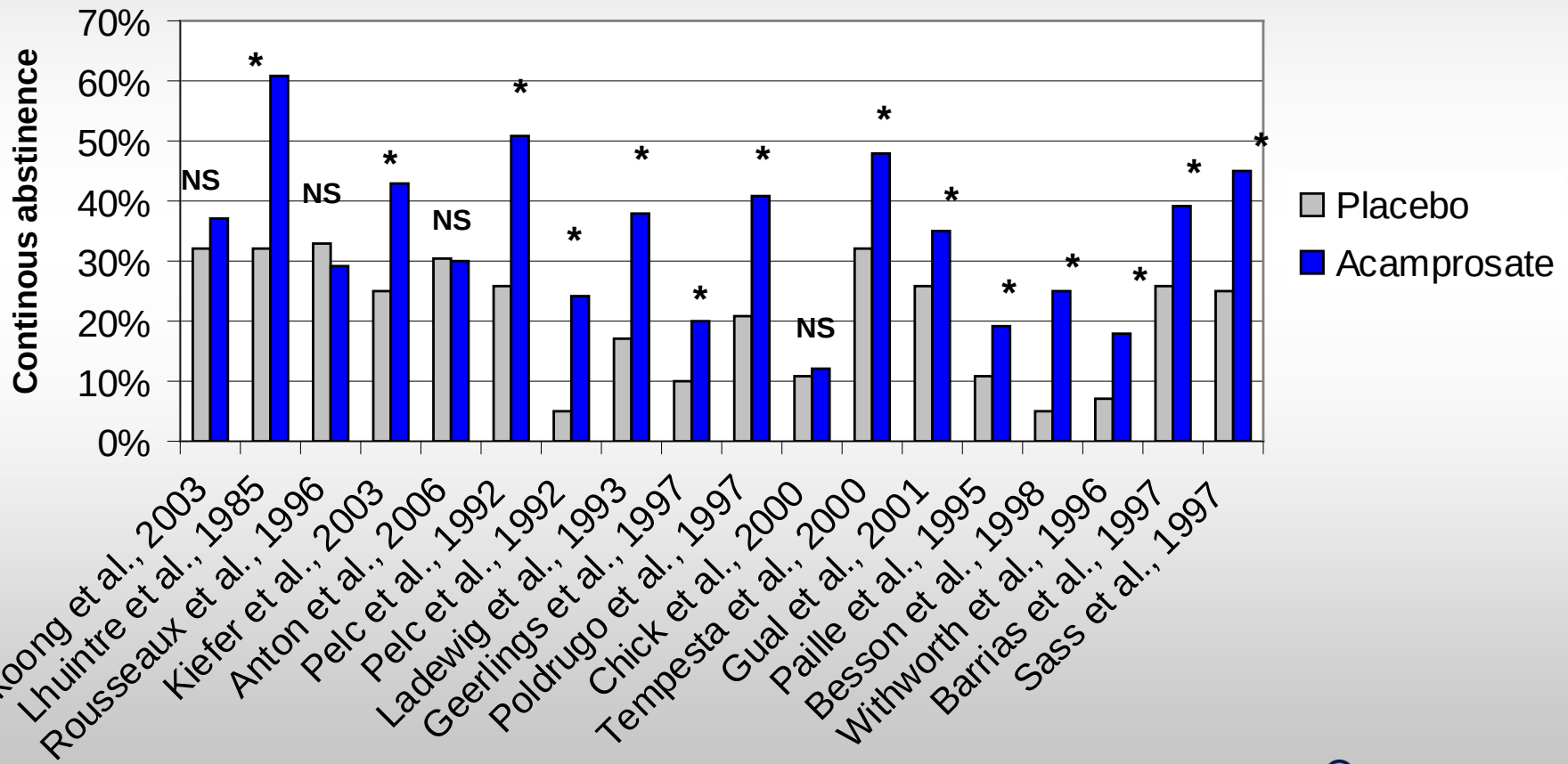


On average, >70% of patients relapse within the first 12 months after initiating an abstinence treatment plan

RREP (relapse, replication and extension project), VAST (veterans affairs study of treatment for substance abuse) and RAND were uncontrolled studies of treatment as usual; the two MATCH studies were randomised controlled; opt=outpatient; aft=aftercare
*At least 12 months of continuous abstinence during 18-month follow-up period

Miller et al. J Stud Alcohol 2001; 62: 211–220

RCTs with Acamprosate vs Placebo



Mann & Hermann, Europ Arch Psychiatry 2010

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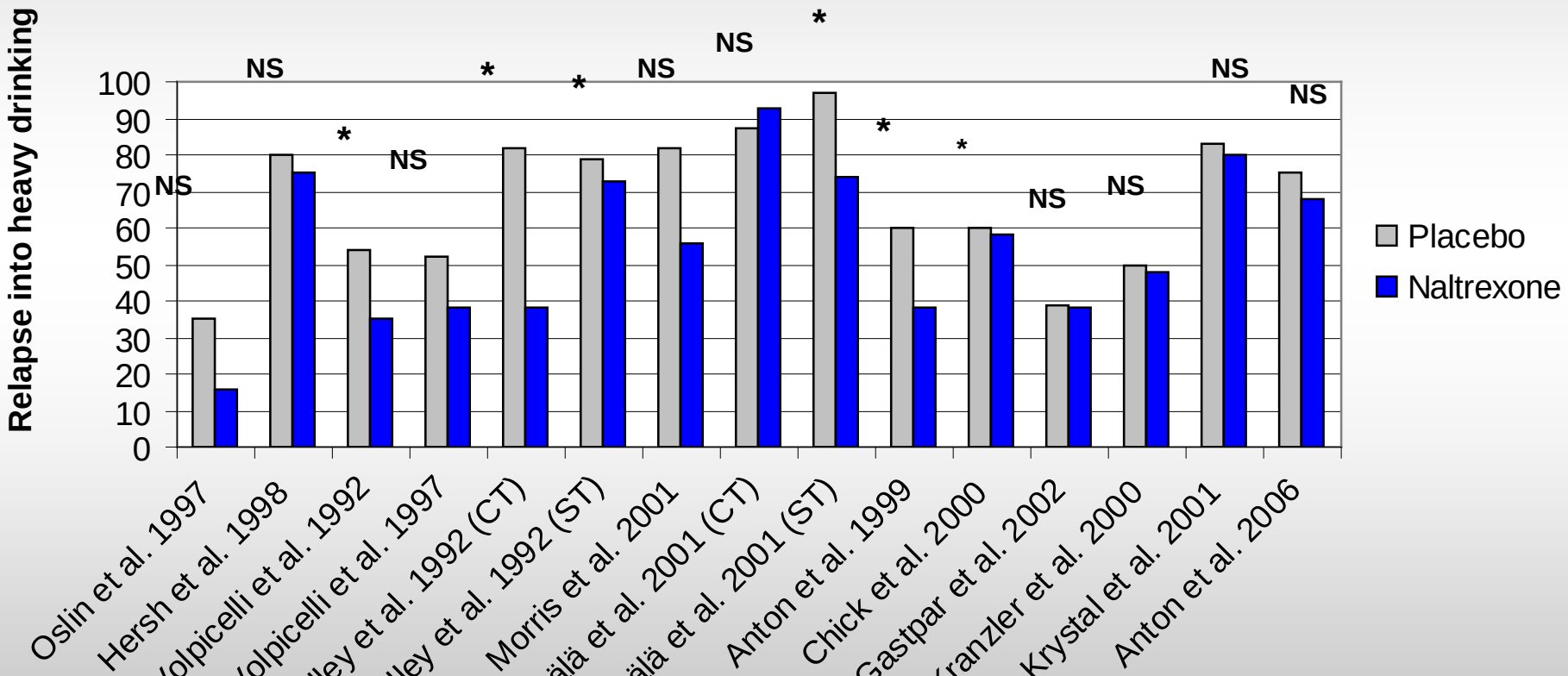
RCTs with Naltrexone vs Placebo



Mann, CNS-Drugs 2004

Cochrane analysis: Acamprosate

- Metaanalysis
  - 24 RCTs, 6.915 Pat. Acamprosate
- Acamprosat reduces risk to 86% compared with Placebo (RR=0.86, CI = 0.81-0.91)
- „Effects of industry-sponsored trials RR 0.88 (95% 0.80 to 0.97) did not significantly differ from those of non-profit funded trials RR 0.88 (95% CI 0.81 to 0.96).
- No indication for publication bias (p = 0.861)“

Rösner et al. 2010

Cochrane Analysis: Naltrexone

- Metaanalysis
  - 50 RCTs, 7.793 Pat. Naltrexone
- Naltrexone reduces the risk to 83% compared with Placebo (CI 0.76-0.90))
- „Effects of industry-sponsored studies, RR 0.90 (95% CI 0.78 to 1.05) did not significantly differ from those of non-profit funded trials, RR 0.84 (95% CI 0.77 to 0.91)
- No indication for publication bias (P = 0.765)“

Rösner et al. 2010

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UK ALCOHOLISM TREATMENT TRIAL (UKATT)

- MET: 3 sessions
- Social Behaviour Network therapy (SBNT) 8 sessions
- Pragmatic trial under conditions in which they would be applied in practice
- Economic evaluation measuring direct and indirect costs (i.e. reduction of future health care costs and other costs of society)

UKATT: hypotheses and sample

Hypotheses	Sample
- Clients with low levels of readiness to change do better with MET - Clients with more symptom severity do better with SBNT - Clients high in anger do better with MET	Alcohol dependence or abuse N = 742 3 months follow-up: 93.0% 12 months follow-up: 83.2%

Effectiveness of treatment (UKATT)

Hypotheses	Sample	Methods, measures	Results
(1) (see above)	• N = 742 • Mean age 41.6 (10.1) • 74.1% male Three months follow-up: • 689 patients (93.0%) •12 months follow-up: • 617 patients (83.2%)	• see above	• Both treatments led to similar improvements in reported alcohol consumption, dependence and problems, also in mental health • No significant differences occurred between the two types of treatment (although sample size allowed for detecting even small effects) → SBNT equally effective

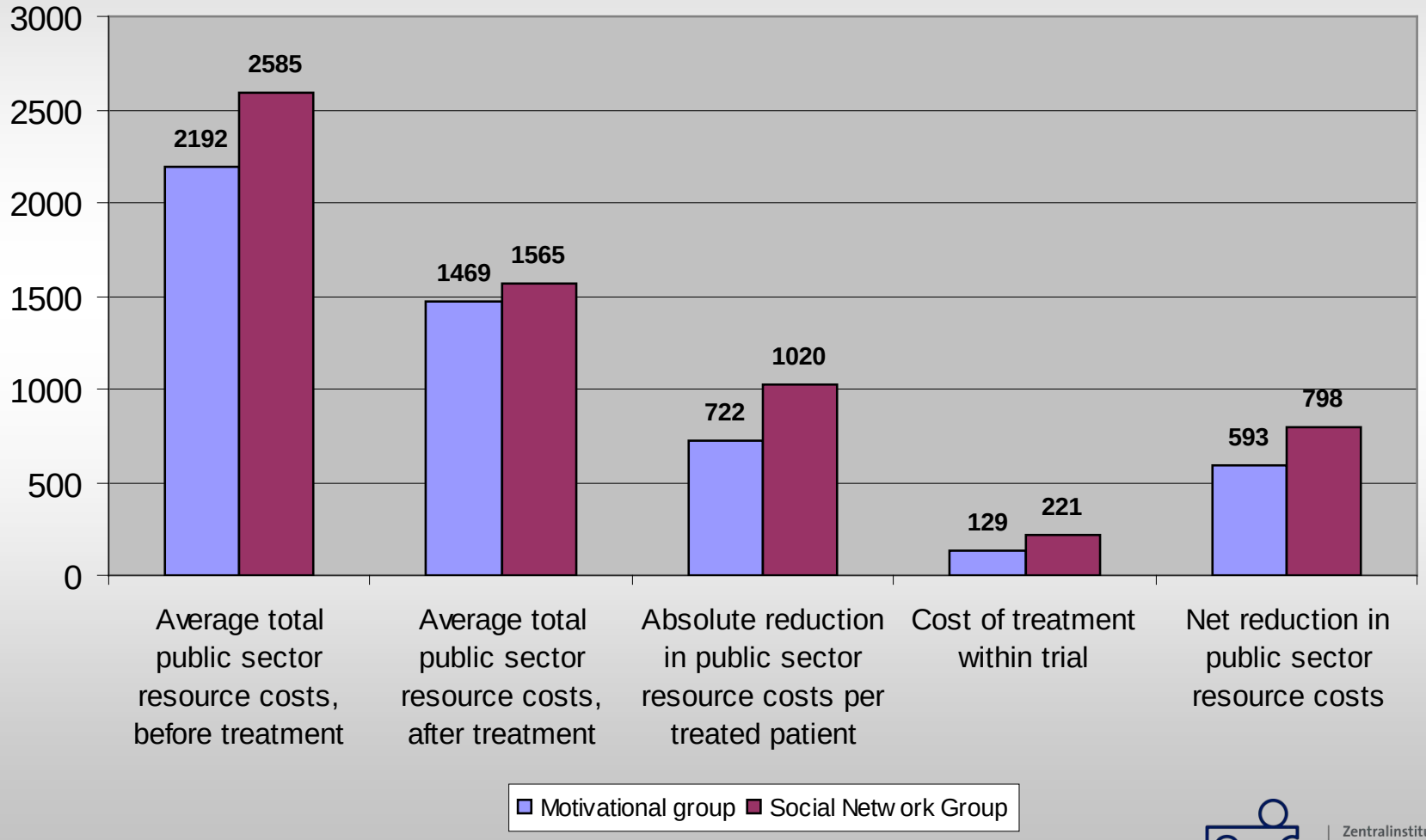
Effectiveness of treatment UKATT

Results

- Both treatments led to improvements in alcohol consumption, dependence and problems, also in mental health status
- No significant differences occurred between the two types of treatment
- NO MATCHING EFFECT

Treatments costs and savings (£)

Godfrey et al 2006



Project MATCH - RESULTS

- Patients in all treatment modalities improved
- Drinking days per month fell from 25 to 6
- Drinks per day decreased from 15 to 3
- Decreased depression, alcohol related problems and use of other drugs
- Maintained for 12 months
- At 39 months outpatient sample maintained improvement

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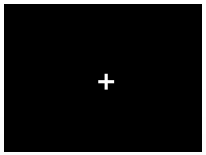
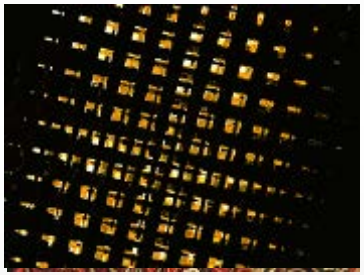
Alcoholic drinks

fMRI paradigm I

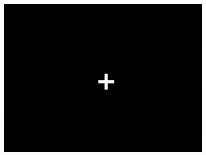
3 Alcohol stimuli
(6.6 s)
5 blocks of 19.8 s



Fixation cross
19.8 s



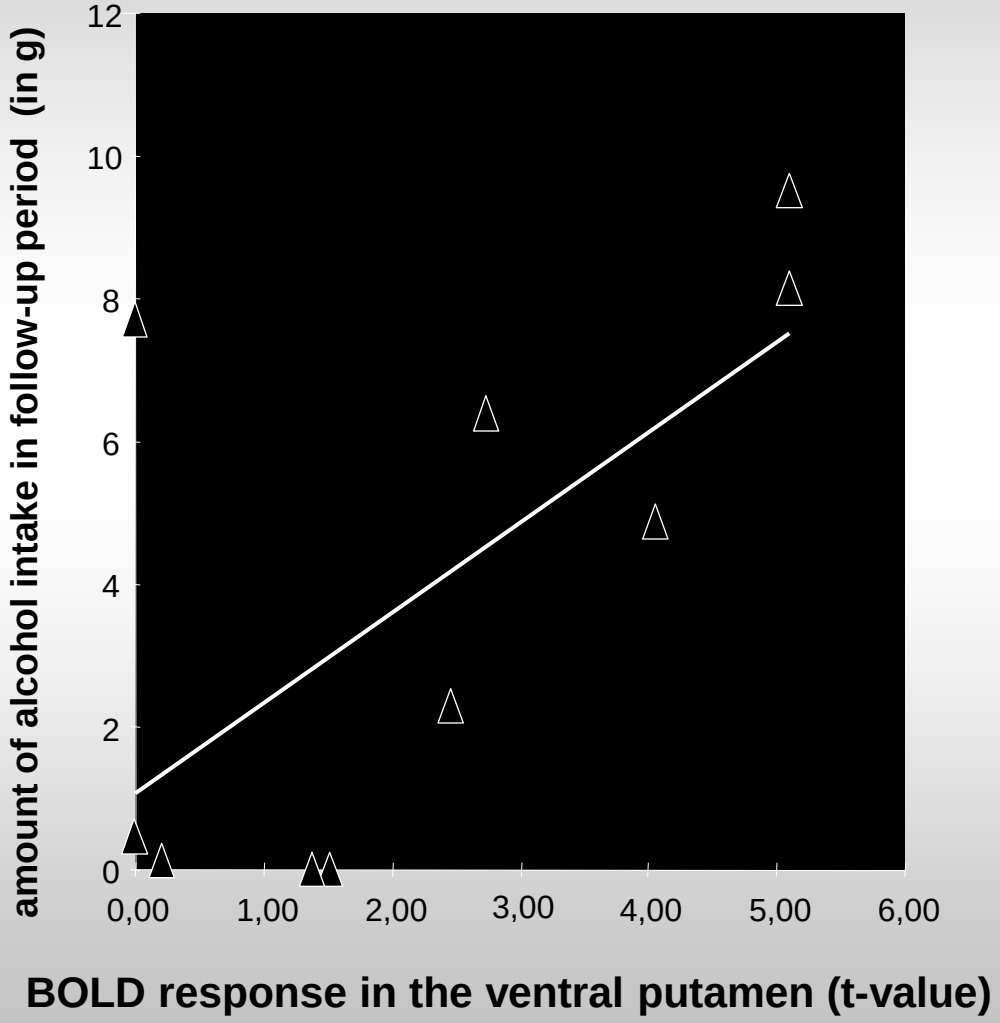
3 abstract stimuli
(je 6.6 s)
5 blocks of 19.8 s

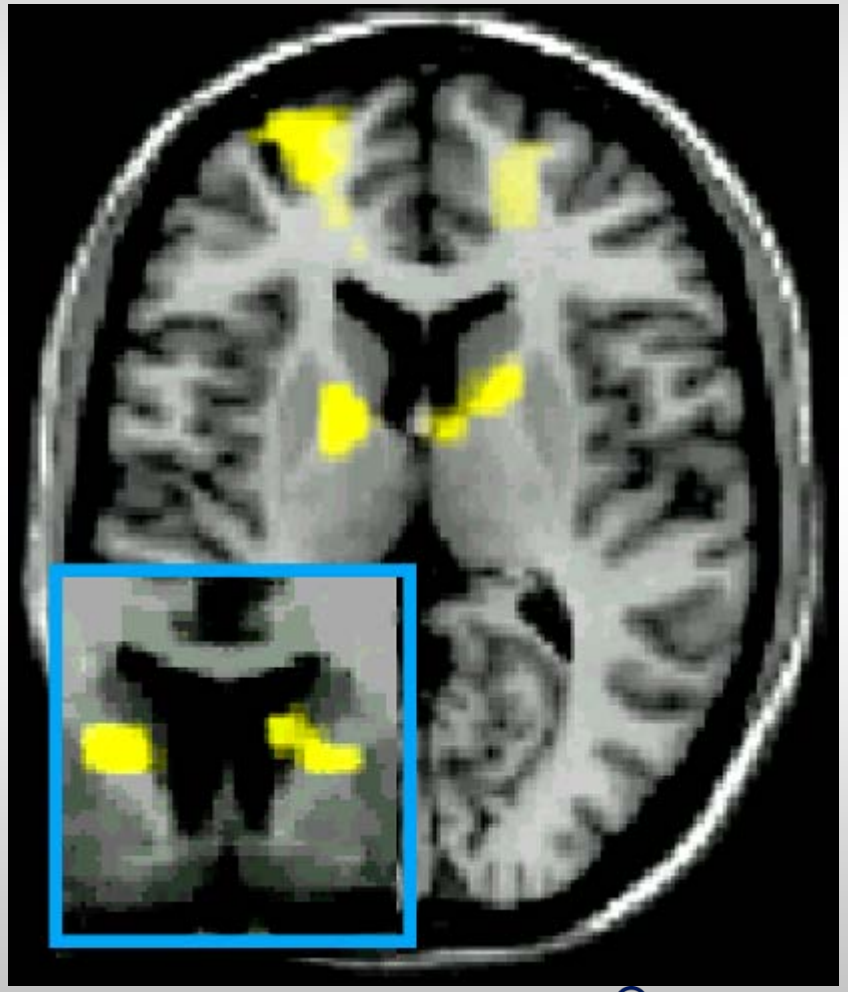


Fixation cross
19.8 s

3 neutral stimuli
(6.6 s)
5 blocks à 19.8 s

Bold response and clinical outcome





Grüsser S. et al. Psychopharmacology 2004

Hypotheses

fMRI cue reactivity & treatment response:

Activation (BOLD-response) of striatal-prefrontal circuits („reward system“) by appetitive alcohol cues

- is predictive of outcome
- can be reduced by naltrexone (not acamprosate),
- and by cue exposure treatment (CET)

PREDICT Study / fMRI sub project

- 73 alcohol dependent patients
- 58 men, 15 women
- Age 43 8 years
- 28 Acamprosate, 36 Naltrexone, 9 Placebo

Patients with 2 fMRI sessions:

N=49

supported by BMBF Grant #01 EB 0410 KM

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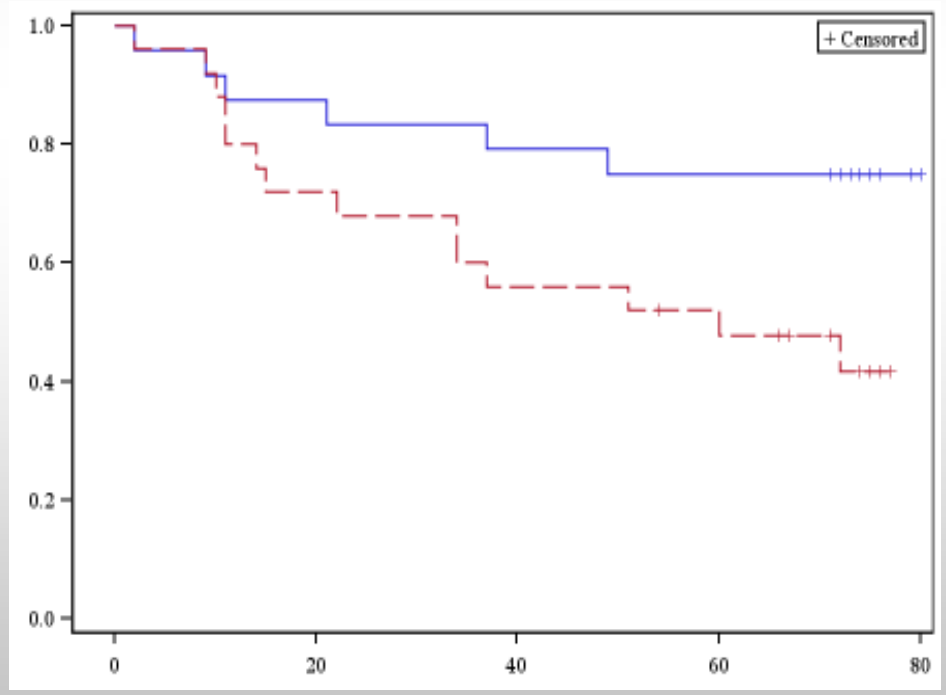
Cue reactivity and relapse risk

- Ventral striatum: association in between BOLD signal („alcohol-neutral“) and days to first severe relapse (Cox regression, p=.0011)



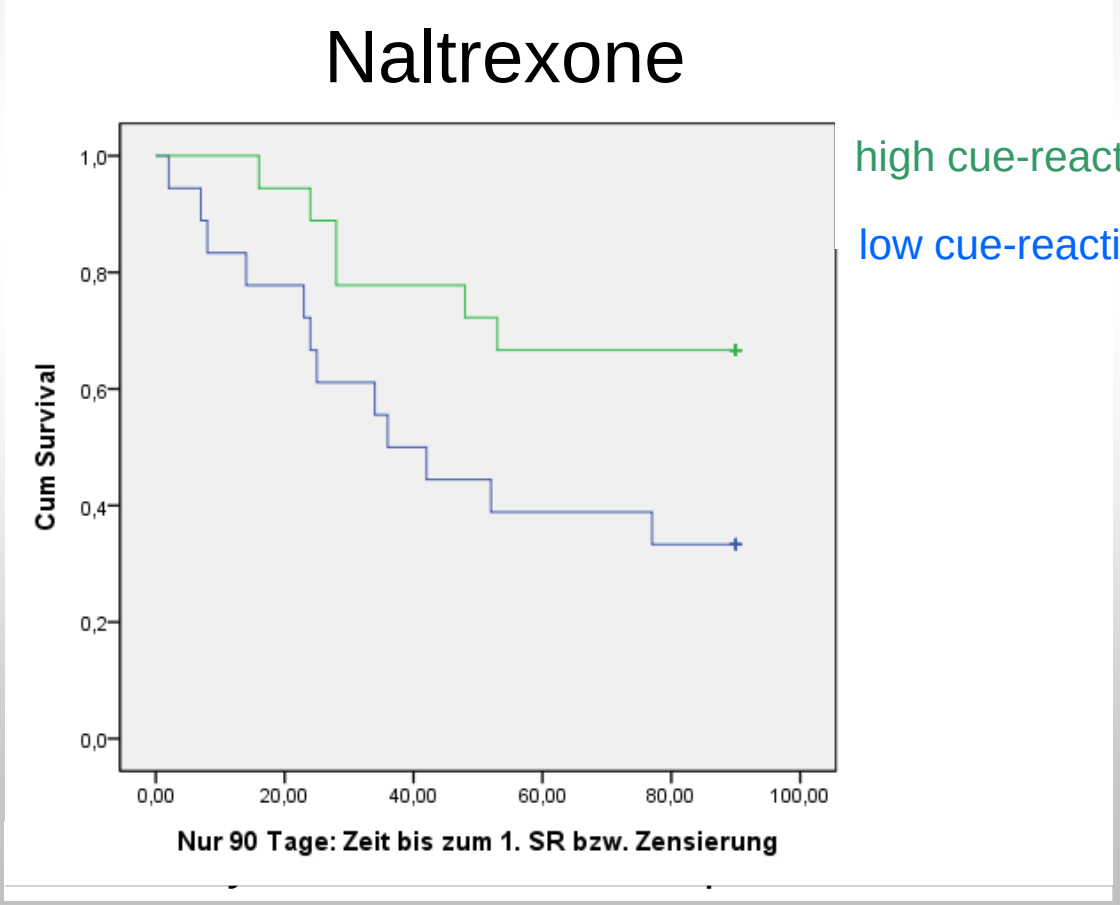
low cue-reactivity

high cue-reactivity

p=.02

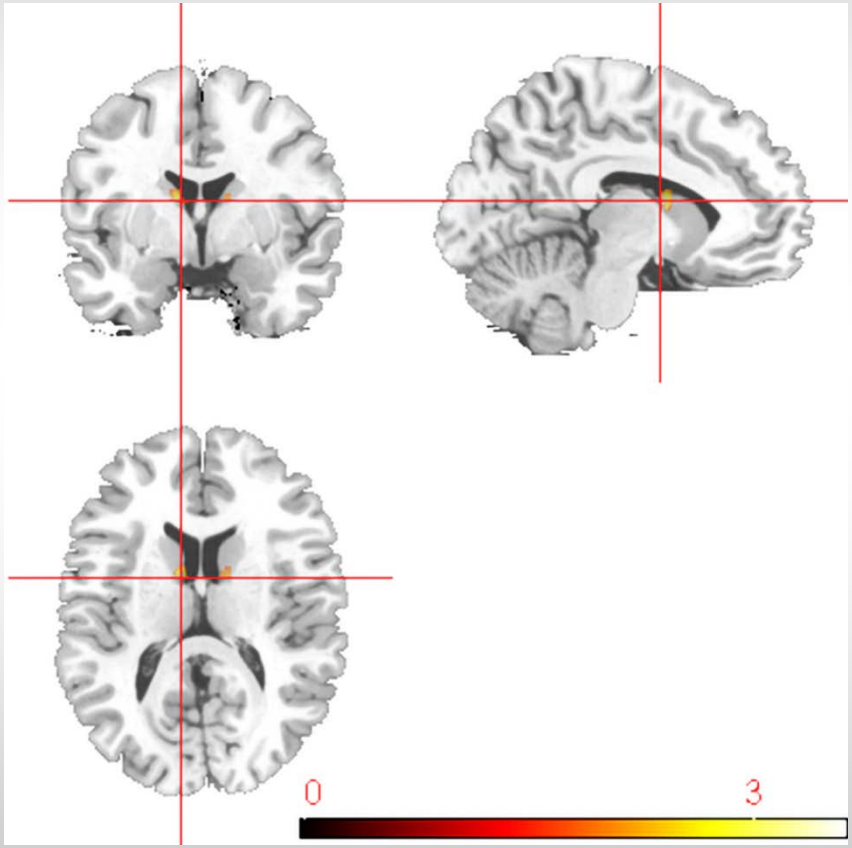
Association medication – fMRI - relapse

- outcome: time until 1st severe relapse
- interaction medication x cue reactivity („alcohol-neutral“, ventral striatum), p =.025



p=.035

Cue Exposure Treatment (Extinction training)



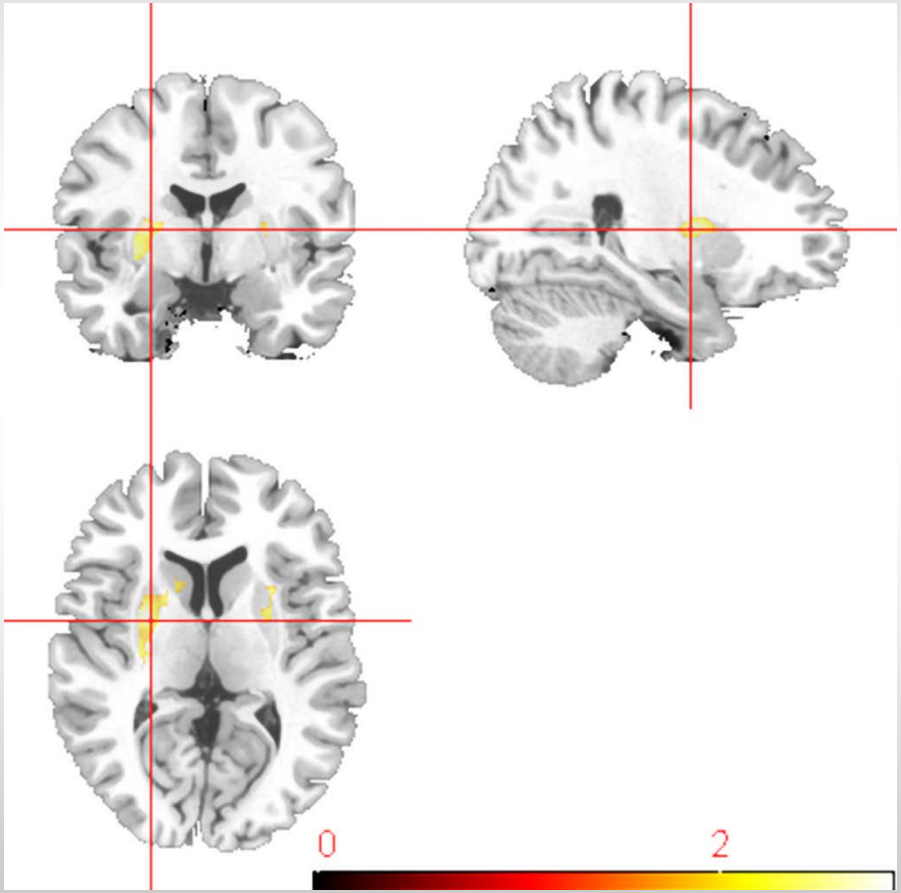
decrease of cue-induced activation (contrast “alcohol-neutral stimuli”) in alcohol-dependent patients (N=30) after three weeks of treatment

p<0.05 FWE-SV-corrected

cluster size >= 10 voxels

Vollstädt-Klein, Löber, v.d. Goltz, Mann, Kiefer (2010)

Cue Exposure Treatment (Extinction training)



larger decrease of cue-induced activation (contrast “alcohol-neutral stimuli”) after three weeks of cue-exposure treatment (N=15) compared to standard treatment (N=15)

p<0.05 FWE-SV-corrected

cluster size >= 10 voxels

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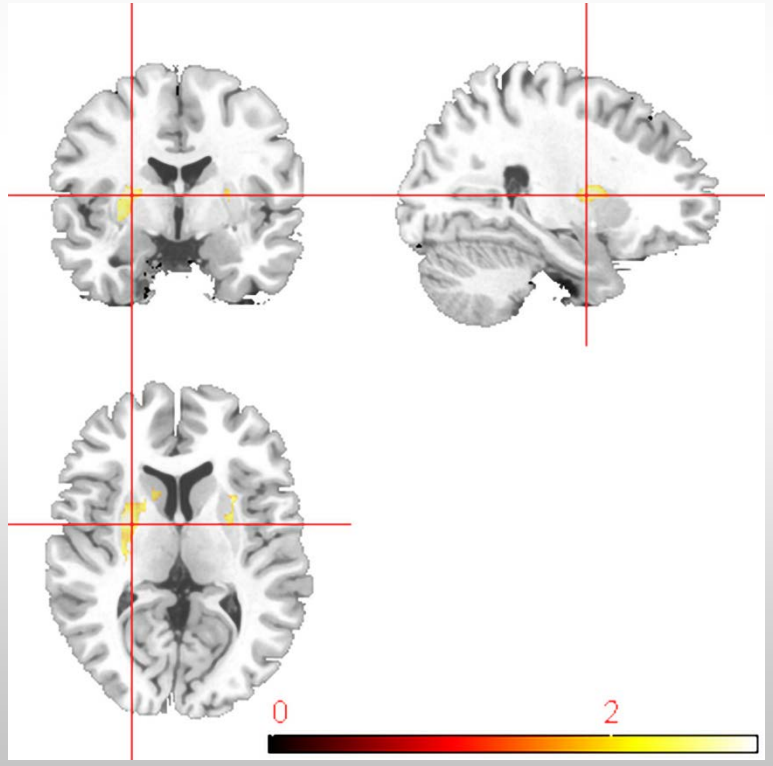
Vollstädt-Klein, Löber, v.d. Goltz, Mann, Kiefer (2010)

Extinction training (CET)

T1 vs. T2: larger decrease of fMRI cue-reactivity after three weeks of CET (N=15) compared to standard treatment (N=15)

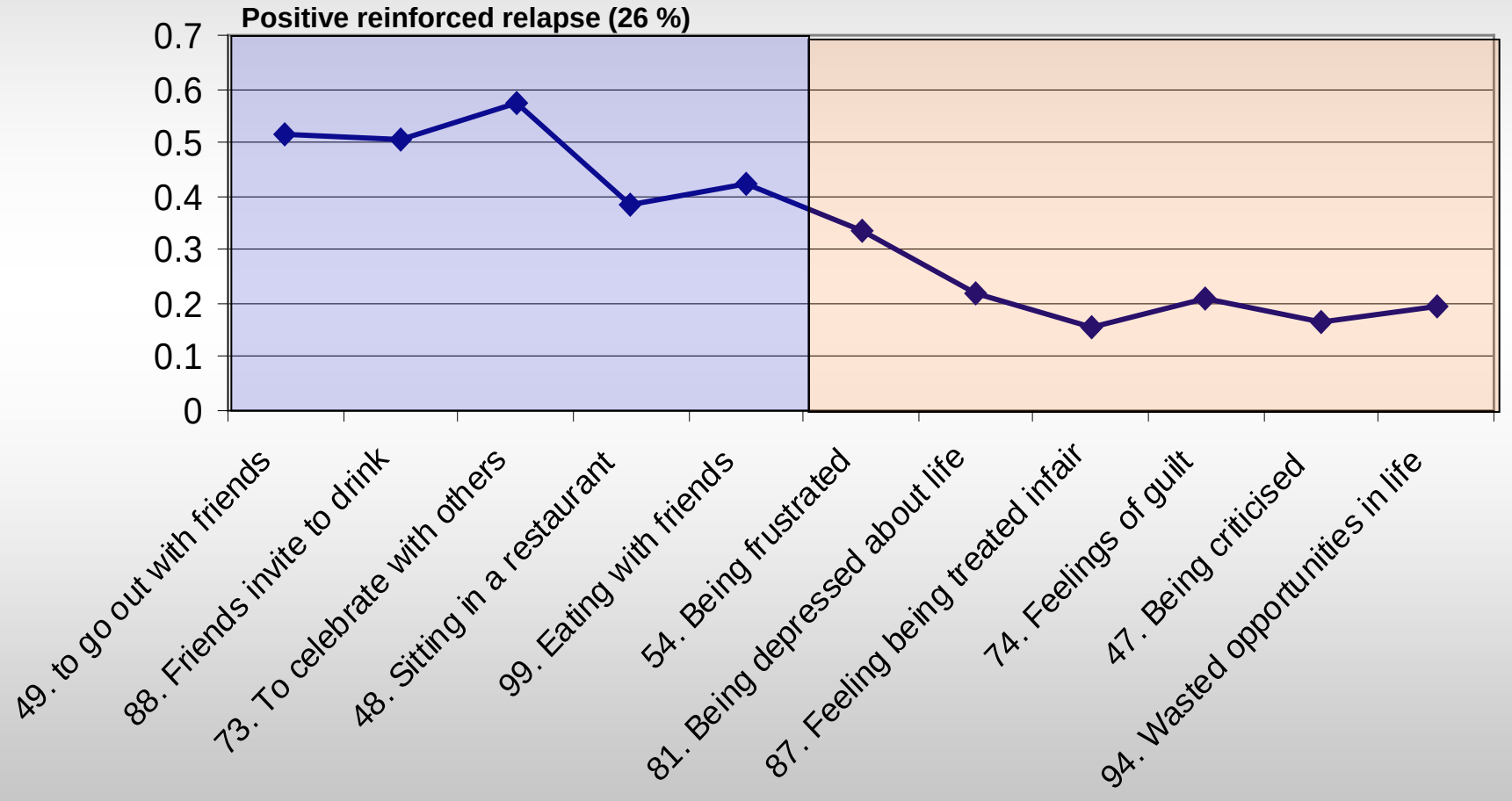


ventral / dorsal striatum: p<.05 ROI-FWE-corrected; cluster size >= 10 voxels

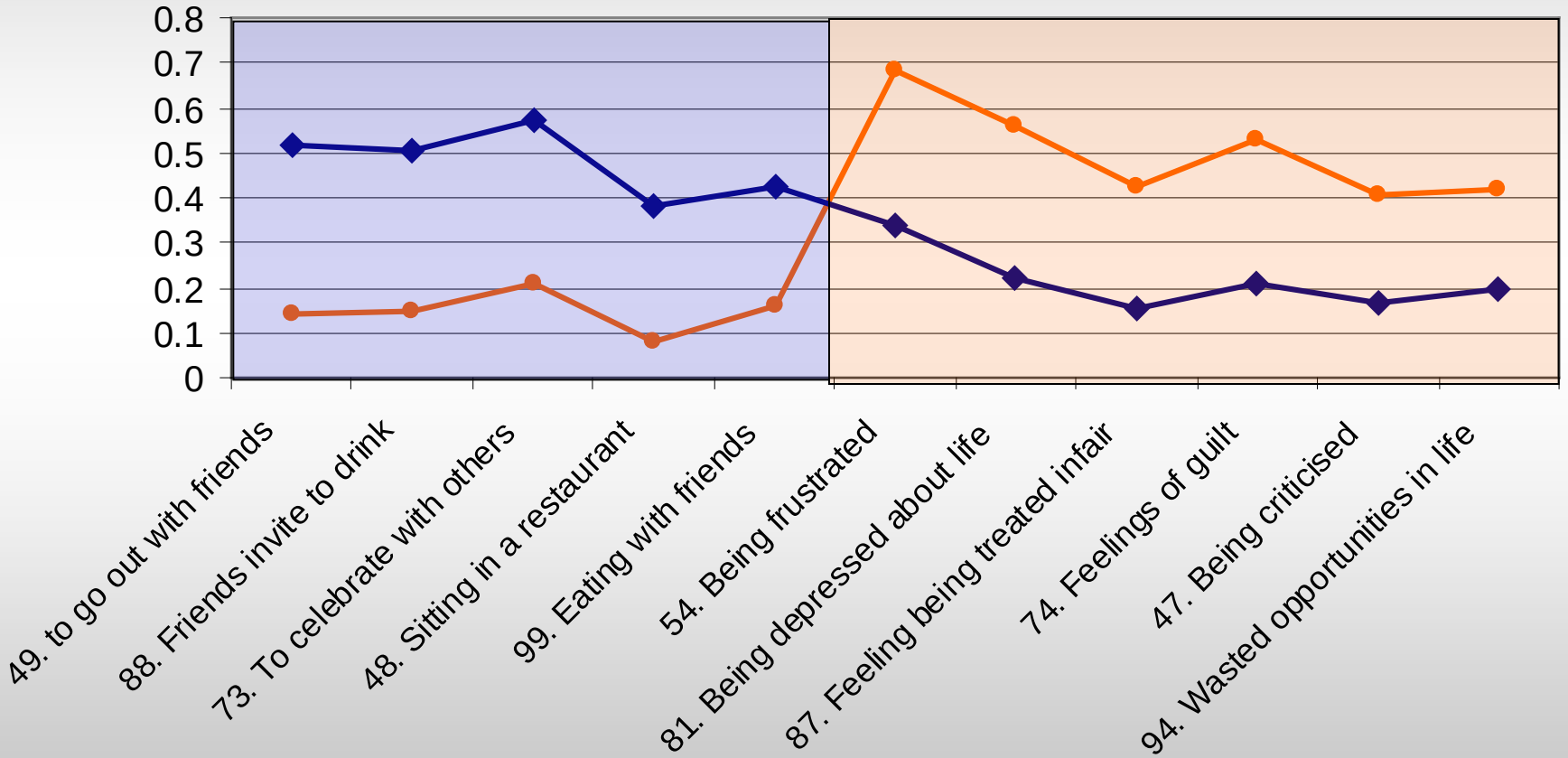
Vollstädt-Klein, Löber, v.d. Goltz, Mann, Kiefer

Latent class analysis IDS (4 classes)

Glöckner-Rist, Lemenager & Mann: Addictive Behavior , epub



Latent class analysis IDS (4 classes)



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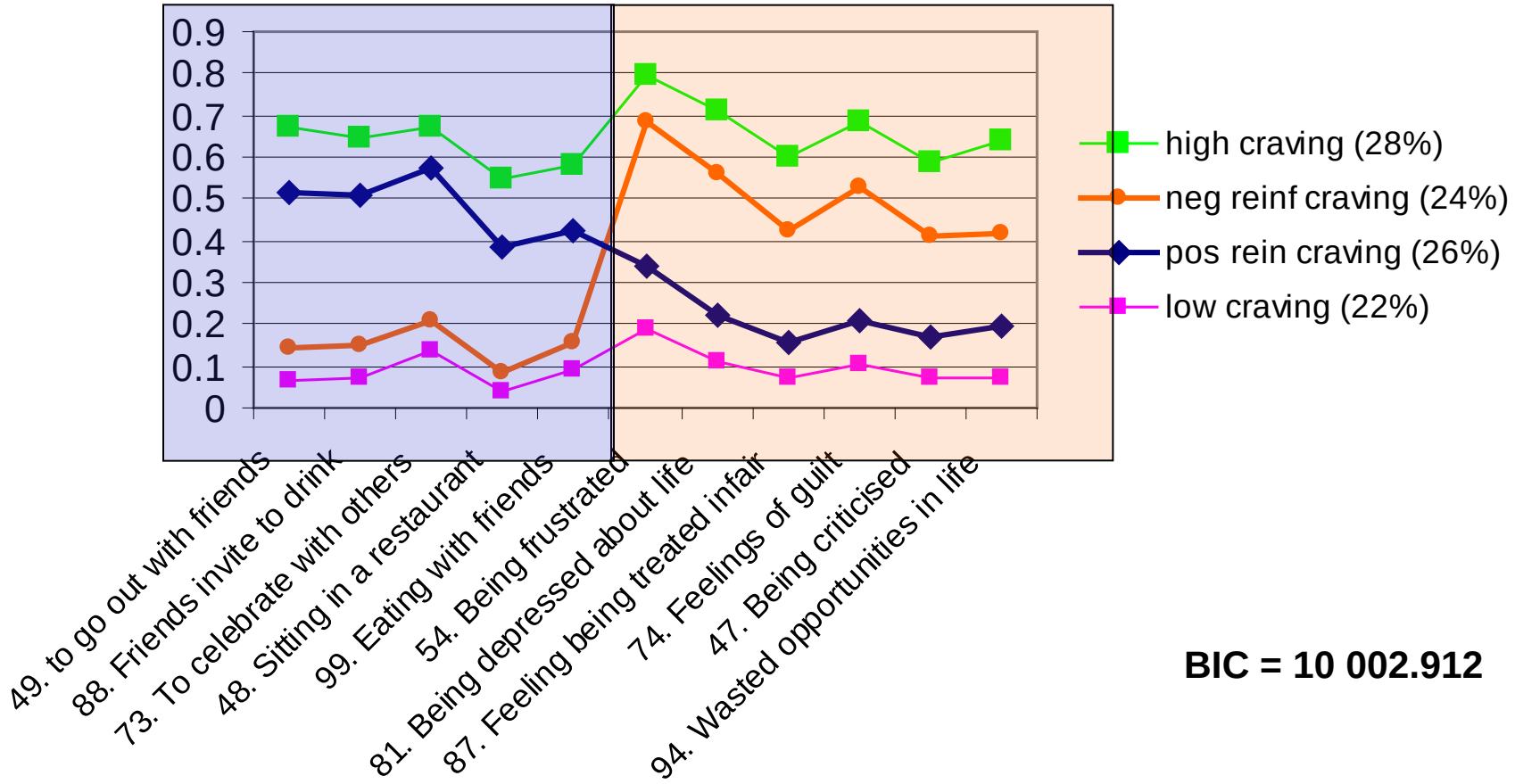
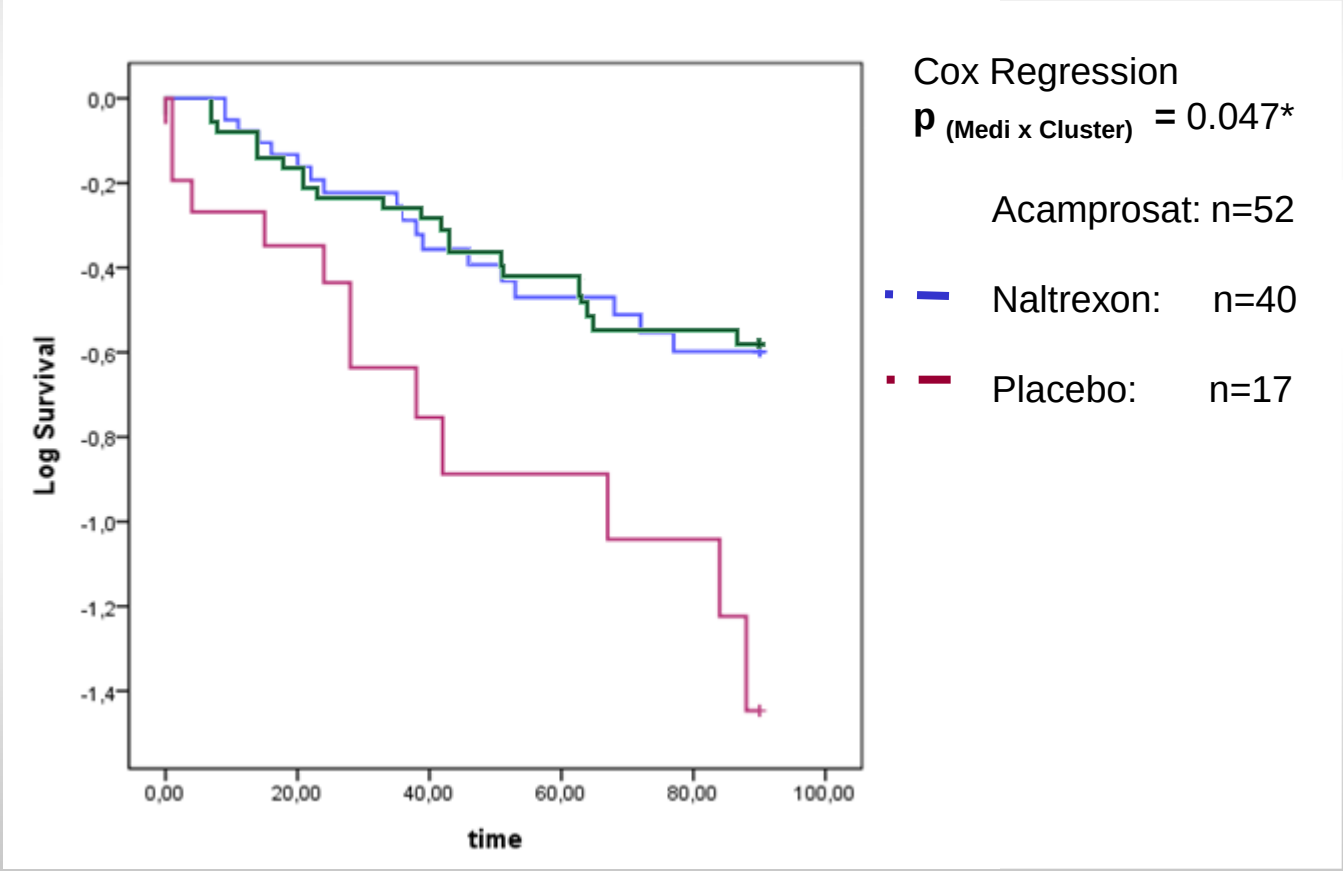
Latent class analysis IDS (4 classes)



BIC = 10 002.912

Effect of pos. reinf. craving on relapse risk

Estimated Survival Function (COX: 2 factors + int.) for pos reinf Craver n=109 (90 days after randomization)



p (NALT vs. PLAC) = 0.017 (Log Rank) **p (ACAM vs. PLAC) = 0.012(Log Rank)**

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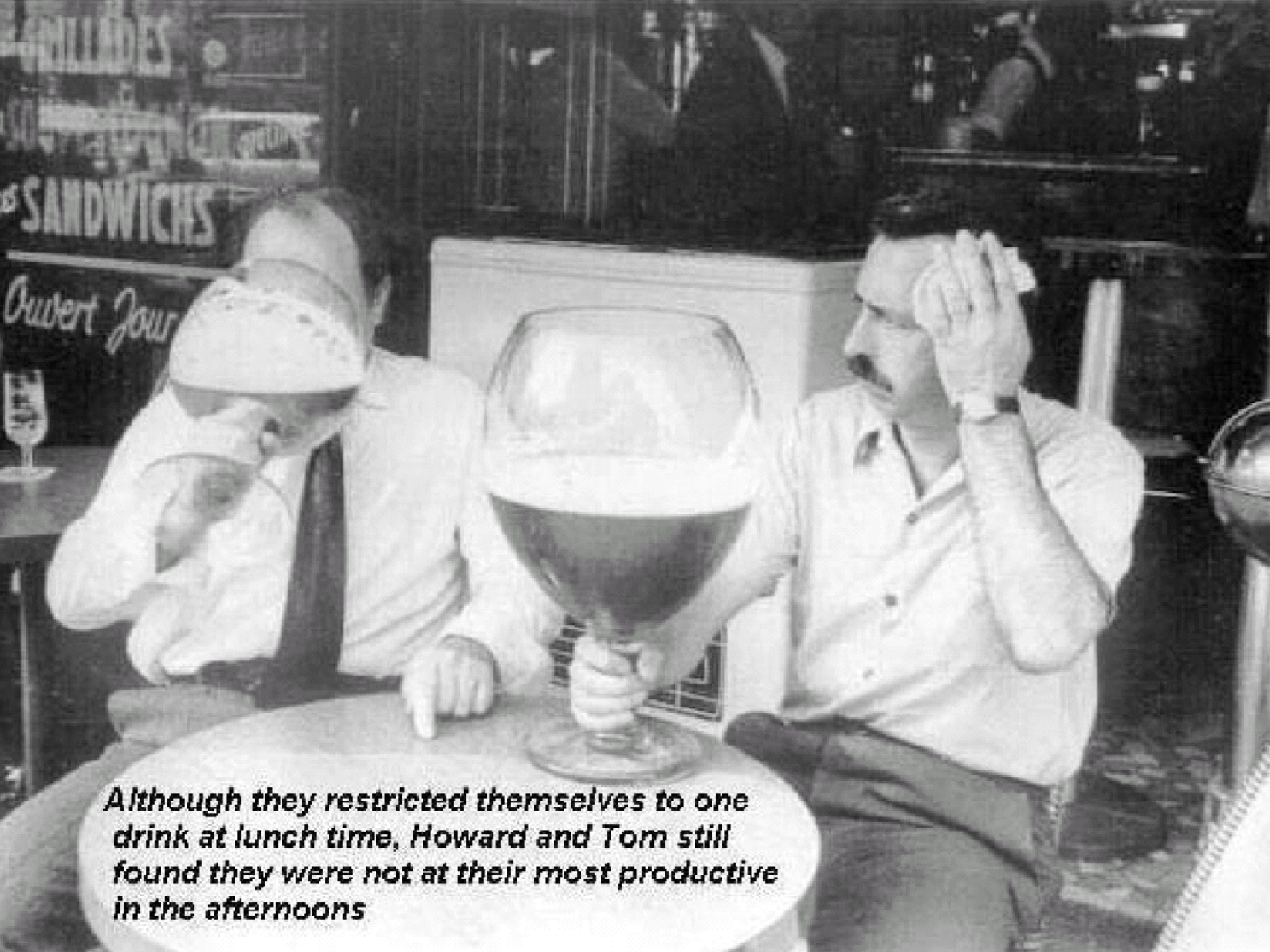


Although they restricted themselves to one drink at lunch time, Howard and Tom still found they were not at their most productive in the afternoons

Gliederung:

1. “Krankheitslast” und Kosten

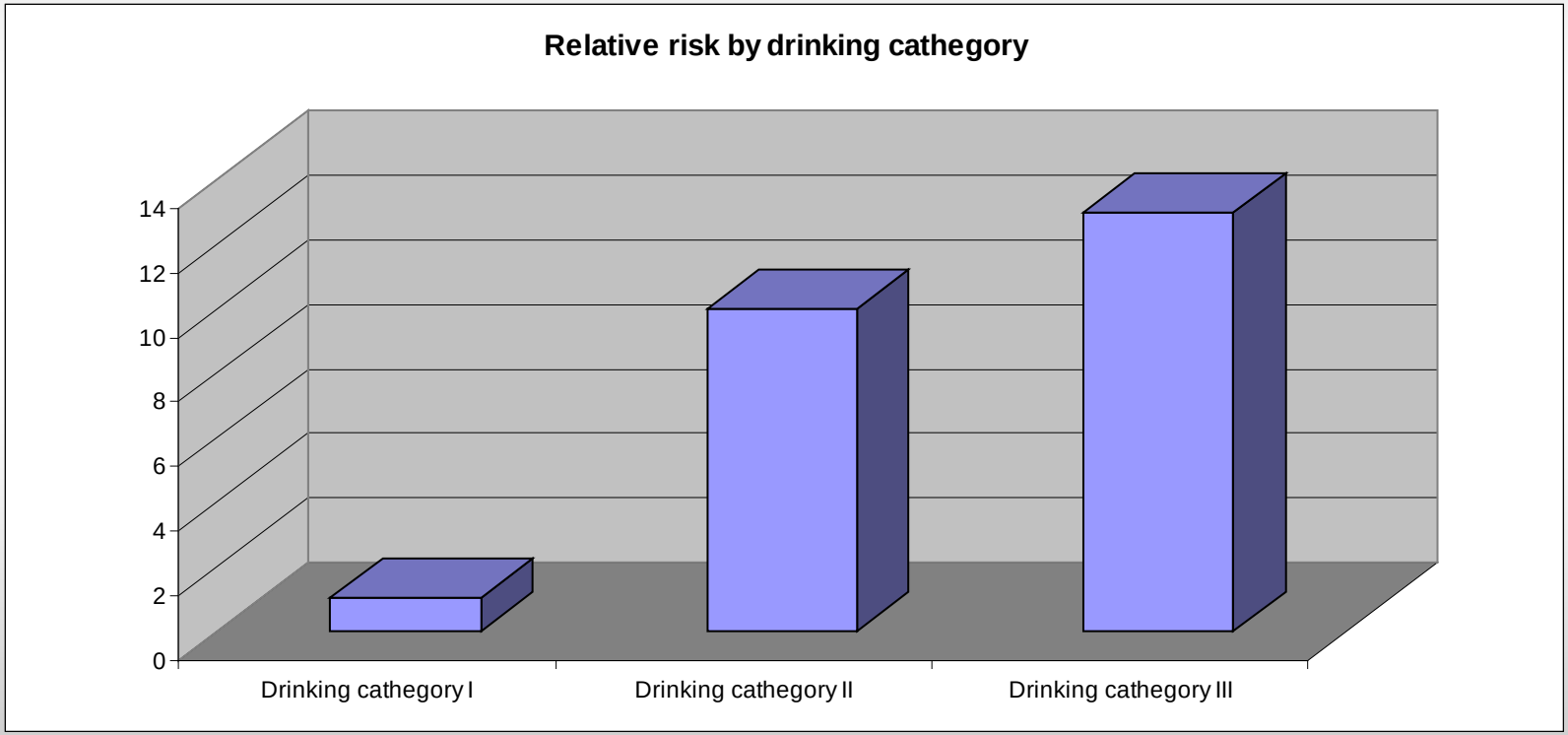
2. Hilfesystem, Psycho- und Pharmakotherapie

3. Aktuelle Entwicklungen
   - Individualisierte Therapie
   - Therapieziele

   (Abstinenz; Kontrolliertes Trinken; Risikoarmes Trinken)

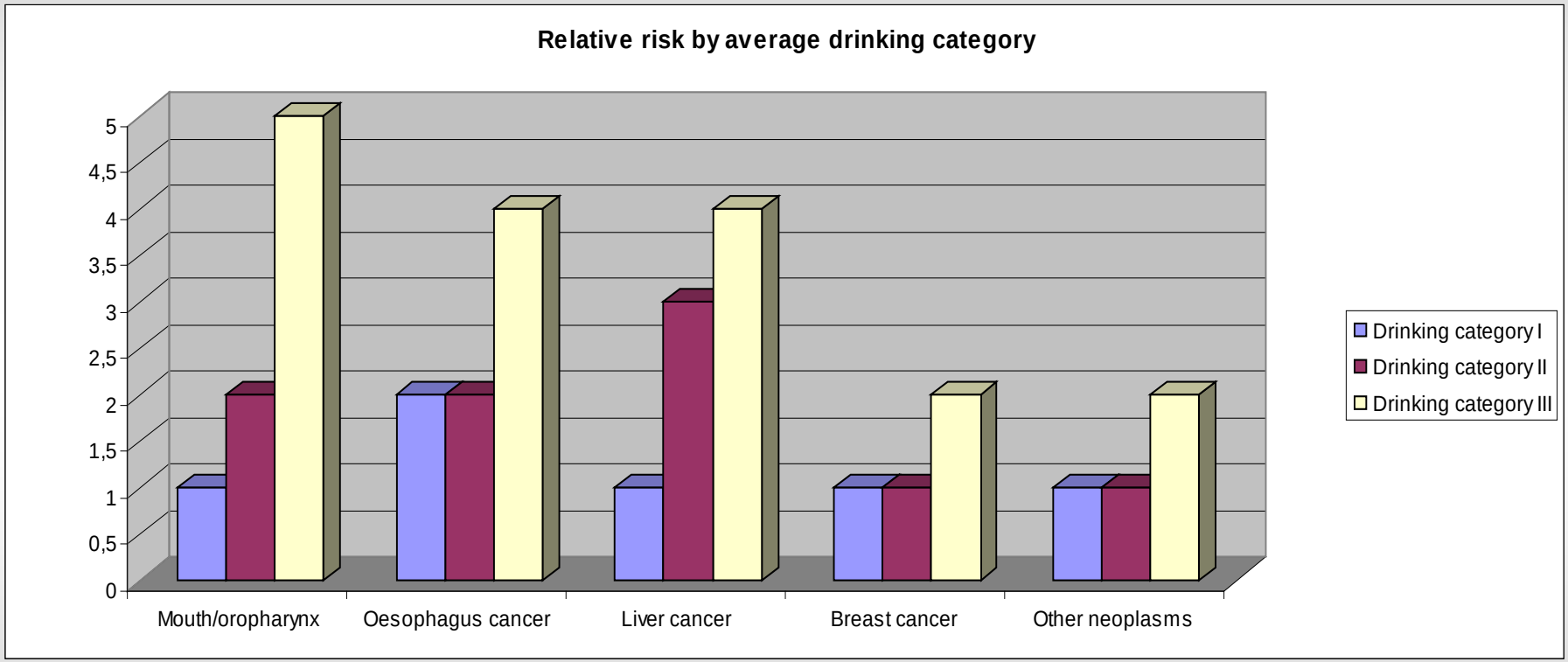
Trinkmengenreduktion als Therapieziel

Liver cirrhosis



***WHO Global Status Report 2004**

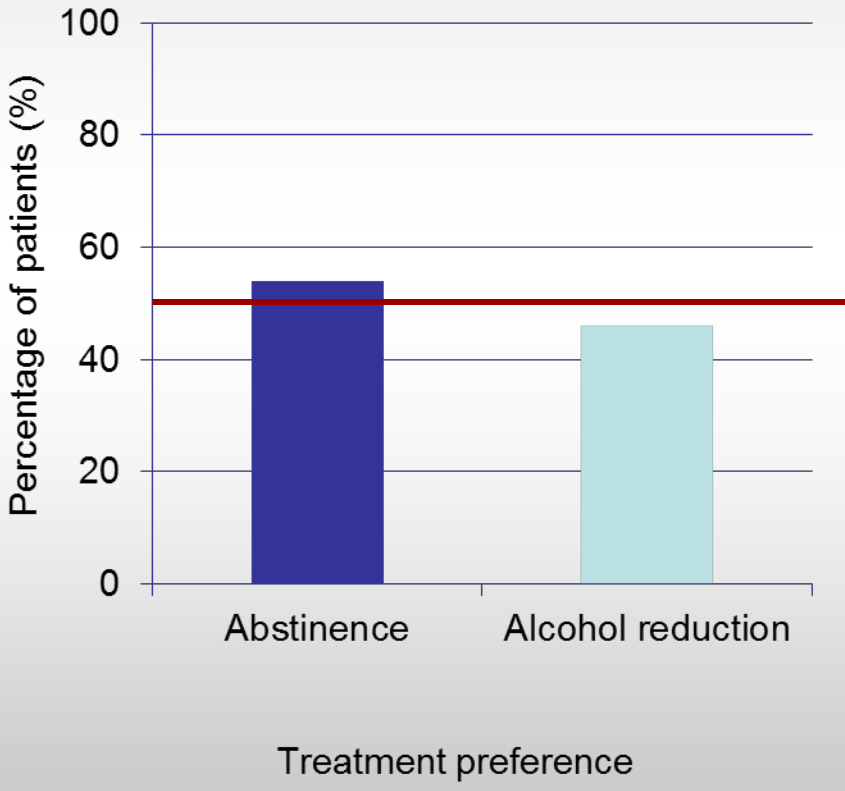
Trinkmengenreduktion als Therapieziel



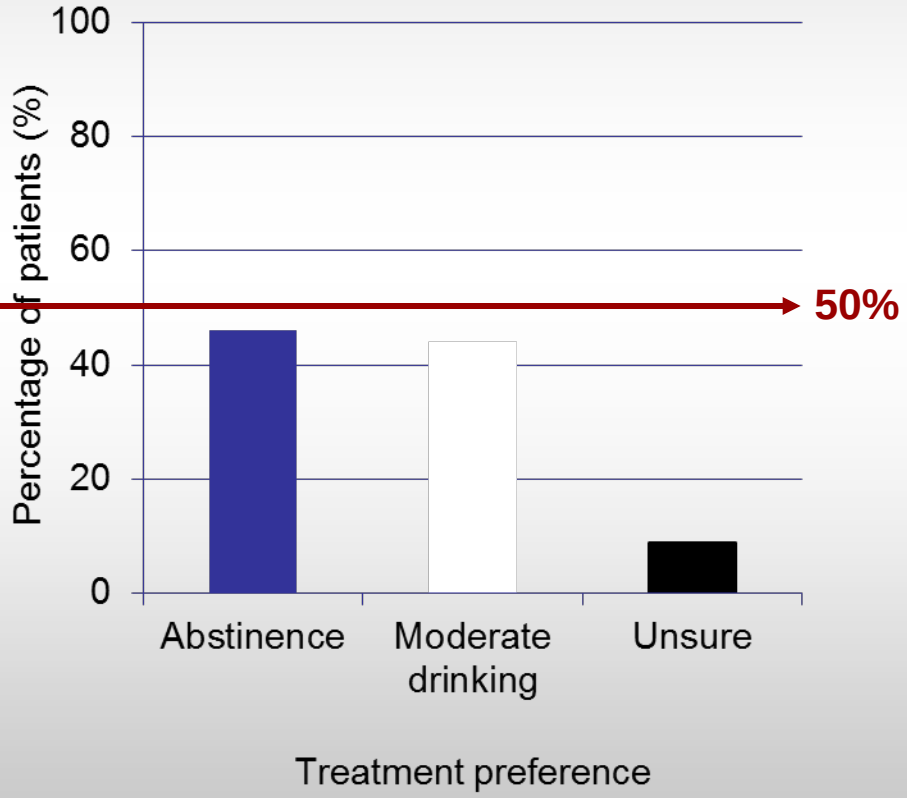
Drinking I: up to 20/40g (female/male) pure alcohol per day;
category II: 20/40 to 40/60 g pure alcohol per day
category III: more than 40/60 g pure alcohol per day.
For comparison: a 75 cl. bottle of wine contains about 70 g of pure alcohol.

Patient treatment goal preference

UK survey of patients with alcohol problems (n=742)



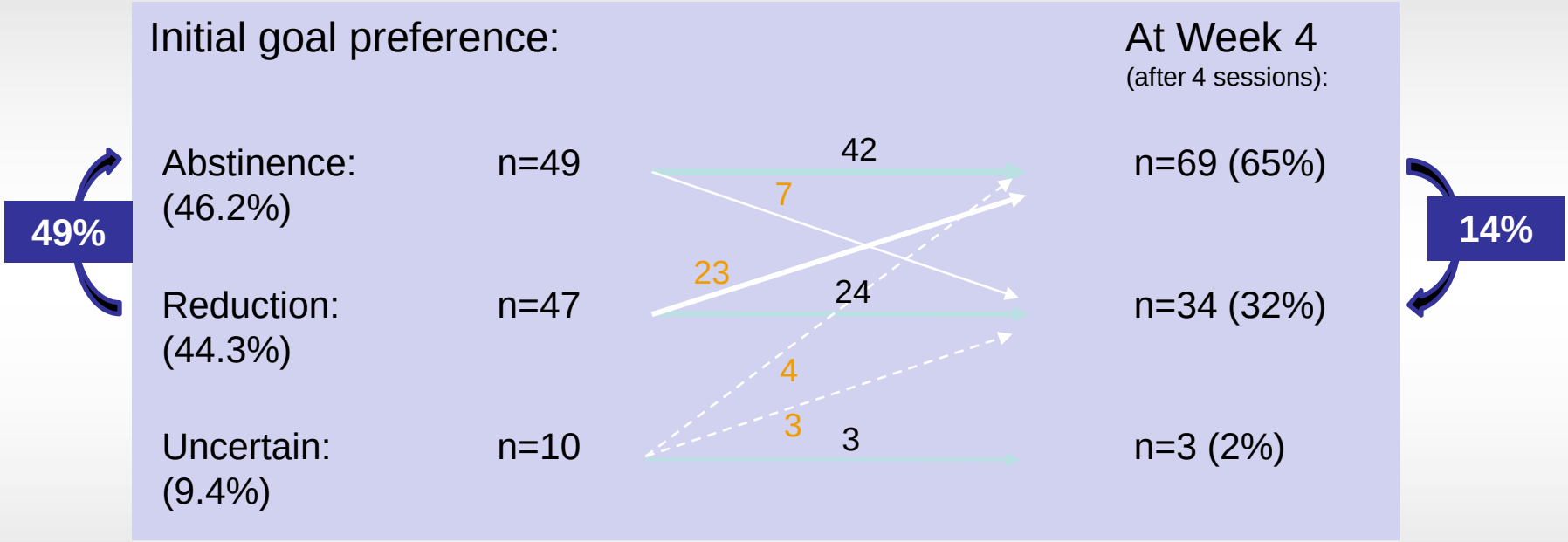
Canadian study of patients with chronic alcoholism (n=106)



Heather et al. Alcohol Alcohol. 2010;45(6):562–578
Hodgins et al. Addict Behav. 1997;22(2):247–255

Movement between goals

Initial goal preferences and changes at 4 weeks



49% of patients with an initial preference for a reduction goal changed to an abstinence goal within 4 weeks

Many patients who initially have reduction as a treatment goal may decide to become abstinent after initial experience with reducing alcohol consumption

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Hodgins et al. Addict Behav. 1997;22(2):247–255

NIAAA, 2005

This is the view of recently revised clinical guidelines issued by the National Institute on Alcohol Abuse and Alcoholism (2005):

"… The safest course is abstinence, and that would be the usual clinical recommendation. Still, it is best to determine individualised goals with each patient. Some patients may not be willing to endorse abstinence as a goal, especially at first. If an alcohol-dependent patient agrees to reduce drinking substantially, it is best to engage them in that goal while continuing to note that abstinence remains the optimal outcome."

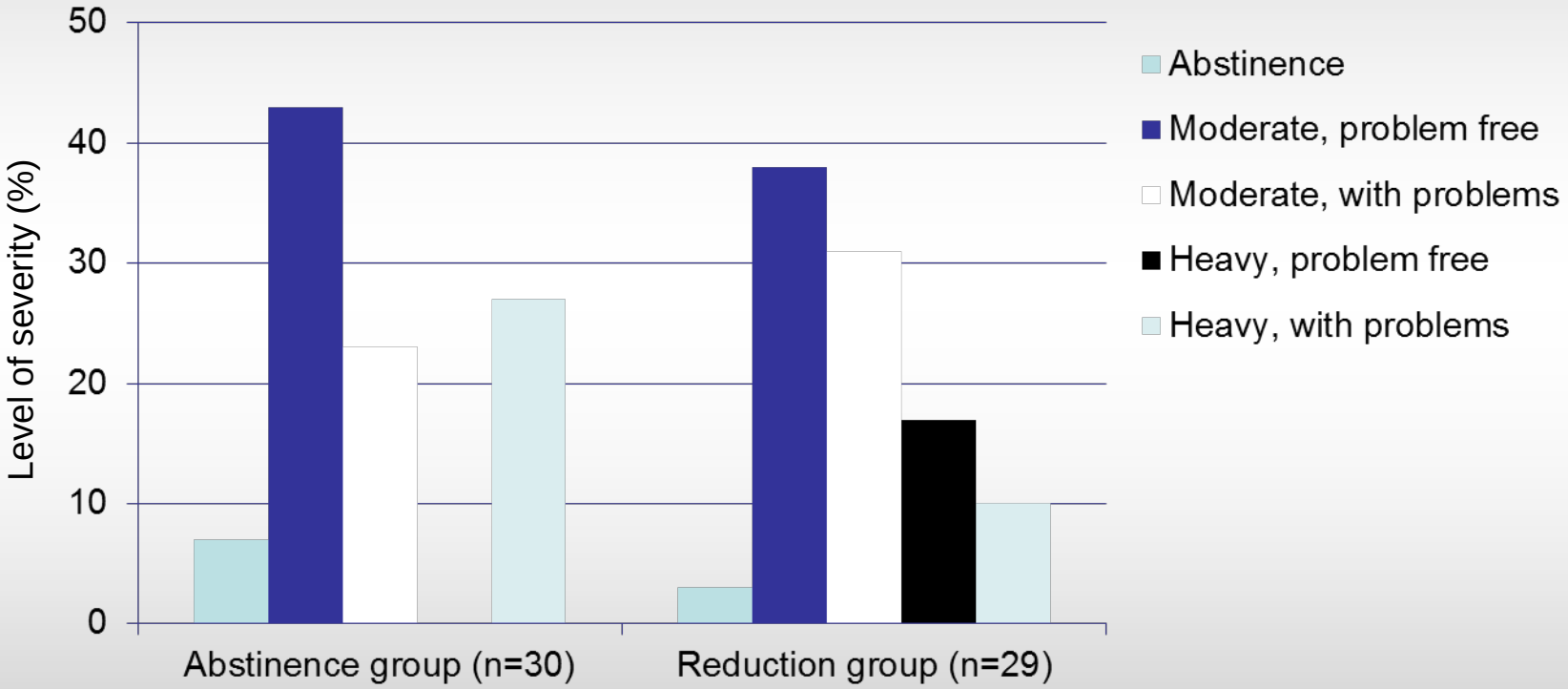
Reducing alcohol consumption benefits health

"There are health benefits to the heavier drinker from reducing or stopping alcohol consumption. Even for chronic diseases, such as liver cirrhosis and depression, **reducing or stopping alcohol consumption is associated with rapid improvements in health**"

Alcohol in Europe: a public health perspective
A report for the European Commission

Reduction is an effective treatment outcome

Drinking outcome at discharge (6 months after treatment)



While <10% of patients remained abstinent after 6 months of treatment, 40% reduced their drinking to moderate, problem free levels

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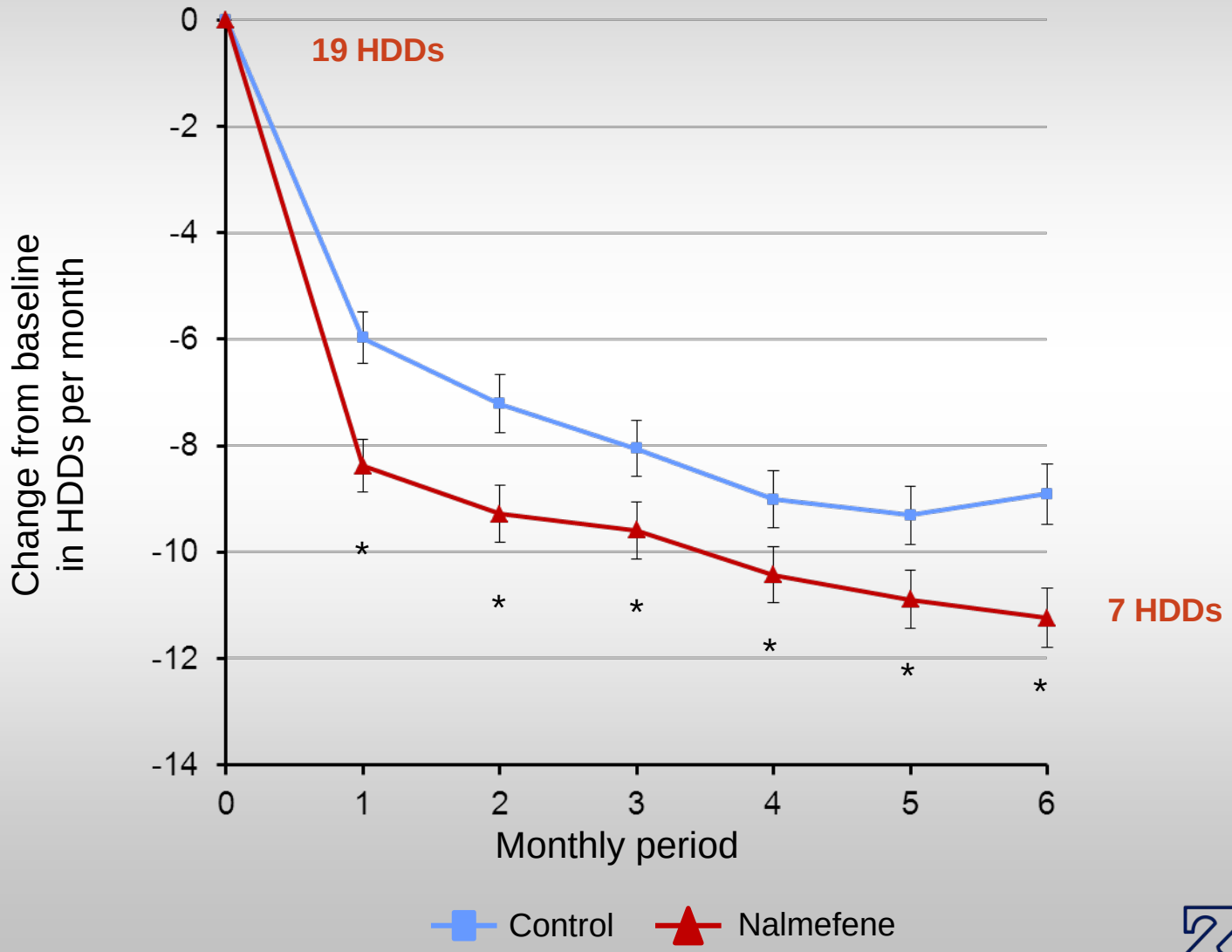
Sanchez-Craig et al. J Consult Clin Psychol 1984;52(3):390–403

RCT: Nalmefene vs placebo (N=605)

Mann et al. Biol. Psychiatry (epub ahead of print)



*p<0.05 vs placebo; data show adjusted mean ± SE

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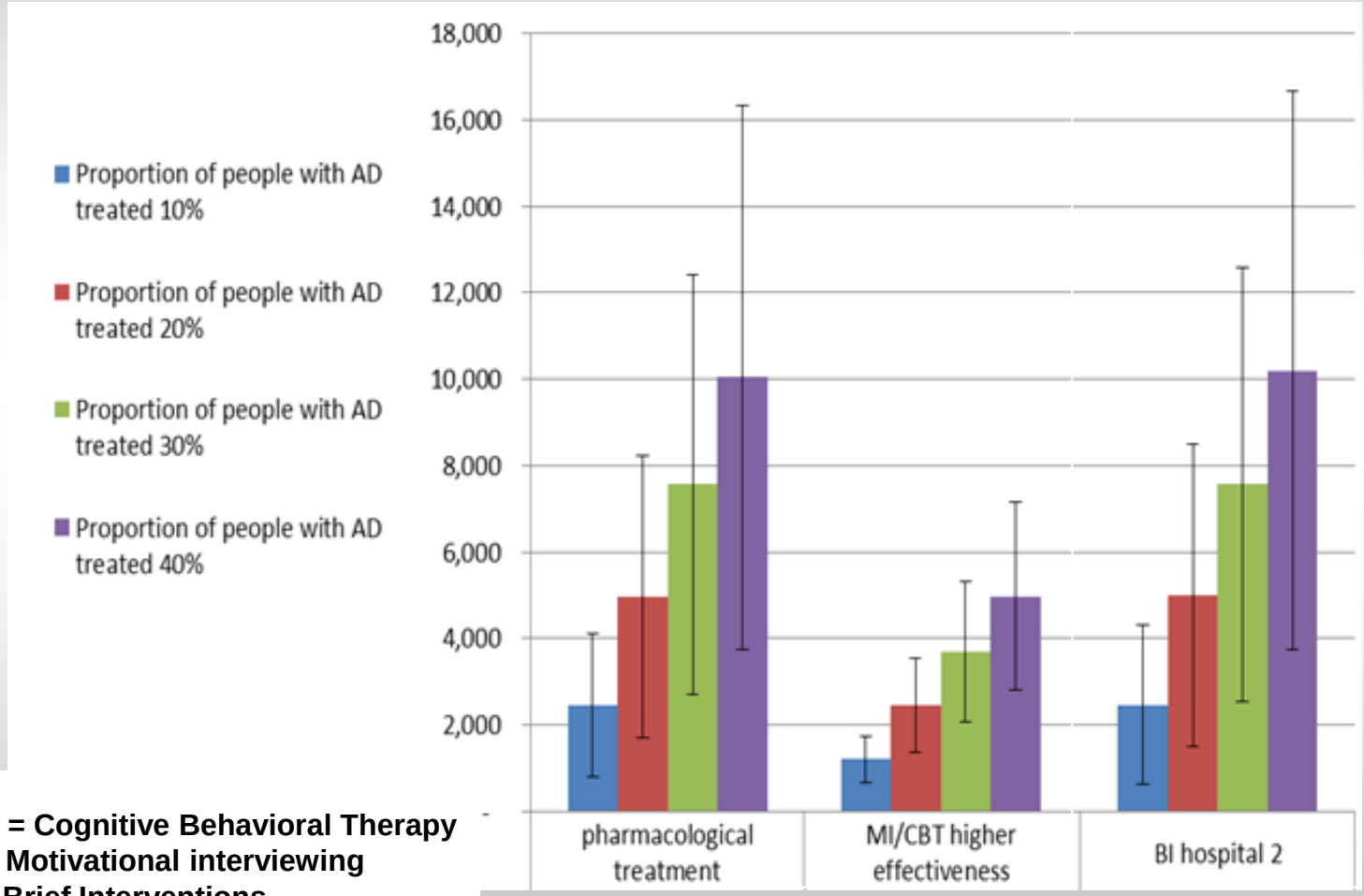
Estimated number of deaths avoided over one year by increasing treatment rates for AD in the EU in 2004 – men



CBT = Cognitive Behavioral Therapy
MI = Motivational interviewing
BI = Brief Interventions

Rehm et al. Alcohol consumption, alcohol dependence and attributable burden of disease in Europe: Potential gains from effective interventions for alcohol dependence. Centre for Addiction and Mental Health. Canada, 2012

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ALCOHOLISM: CLINICAL AND EXPERIMENTAL RESEARCH

Vol. 34, No. 11
November 2010

Efficacy and Safety of Baclofen for Alcohol Dependence: A Randomized, Double-Blind, Placebo-Controlled Trial

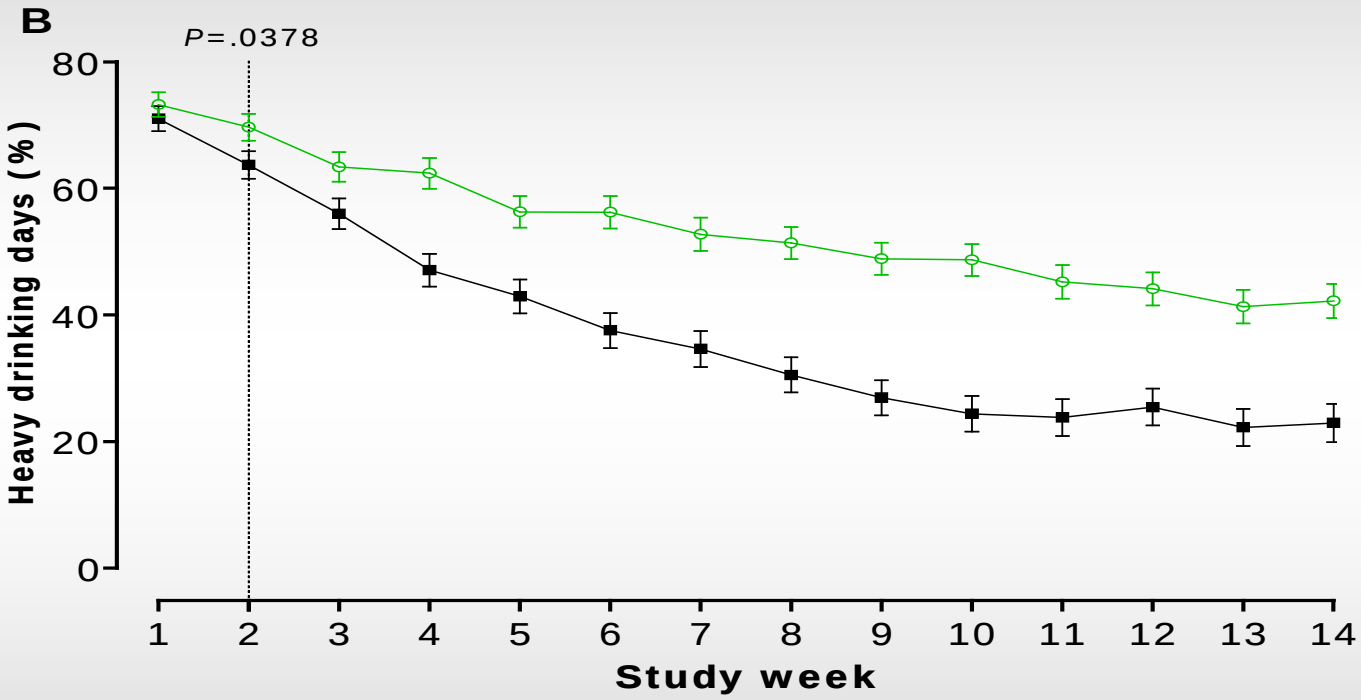
James C. Garbutt, Alexei B. Kampov-Polevoy, Robert Gallop, Linda Kalka-Juhl, and Barbara A. Flannery

Background: Recent clinical trials and case-reports indicate that baclofen, a $GABA_B$ agonist, may have efficacy for alcohol dependence. Baclofen has been shown to enhance abstinence, to reduce drinking quantity, to reduce craving, and to reduce anxiety in alcohol-dependent individuals in 2 placebo-controlled trials in Italy. However, the clinical trial data with baclofen is limited. The purpose of the present study was to test the efficacy and tolerability of baclofen in alcohol dependence in the United States.

Baclofen (GABAB Agonist)

bessert Entzug	N = 5	***Addolorato et al. 2002***
stützt Abstinenz	N = 39 4 Wochen	gebessert: 14/20 Baclofen 4/19 Plazebo ***Addolorato et al. 2002***
stützt Abstinenz	N = 12 12 Wochen 30 mg	***Flannery et al. 2004***
stützt Abstinenz (Pat. mit Leberzirrhose)	N = 84 12 Wochen	gebessert: 30/42 Baclofen 13/42 Plazebo ***Addolorato et al. 2007***

Percentage of Heavy Drinking Days from Study Week 1



Number of participants left

Topiramate	179	173	161	156	145	140	134	130	124	121	119	117	114	113
Placebo	185	183	182	181	179	176	167	164	159	153	150	149	146	144

The pre-specified approach of not imputing missing data is illustrated; data were analyzed using a repeated-measures mixed model.

Alkohol und Tabak

Grundlagen und Folgeerkrankungen

Herausgegeben von
Manfred V. Singer
Anil Batra
Karl Mann

Thieme

Diagnose der Alkoholabhängigkeit nach ICD 10 (mind. 3 der folgenden 6 Kriterien sind nachweisbar):

- Starker Wunsch (oder Zwang), Alkohol zu konsumieren
- Minderung der Kontrolle über Beginn, Umfang und Beendigung des Konsums von Alkohol
- eine Toleranzentwicklung
- das Auftreten von Entzugserscheinungen
- die Vernachlässigung anderer Neigungen und Interessen zugunsten des Alkoholkonsums
- die Fortführung des Alkoholkonsums trotz eindeutig eingetretener körperlicher, psychischer oder sozialer Folgeschäden

Ein „schädlicher Gebrauch“ liegt vor bei Gesundheitsschädigungen infolge Alkoholkonsums

- psychische Gesundheitsschädigung
- (z.B. kognitive Störung oder depressive Episode) physische Gesundheitsschädigung
- (z.B. Gastritis oder Pankreatitis)
- Kriterien einer Abhängigkeit werden nicht erfüllt.

DSM-IV criteria for substance abuse

A. Substance use leading to impairment or distress (by one (or more) within a 12-month period:

- Substance use resulting in a failure to fulfill major role obligations at work, school or home
- Substance use in situations in which it is physically hazardous
- Substance-related legal problems
- Substance use despite social or interpersonal problems

B. The symptoms have never met criteria for substance dependence