

Collaborating parties:



Preliminary results of a randomized clinical trial of EMDR in alcohol dependent outpatients

Wiebren Markus MSc, general mental health-psychologist & PhD- candidate IrisZorg
Hellen Hornsveld PhD, general mental health-psychologist & EMDR Europe trainer

Grants:



Study objective

To develop an effective set of EMDR interventions, aimed at addiction, integrating:

- Previous modified EMDR protocols (Popky, Hase, Knipe)
- Research on:
 - Working memory theory
 - Flashforwards
 - Positive valenced memories

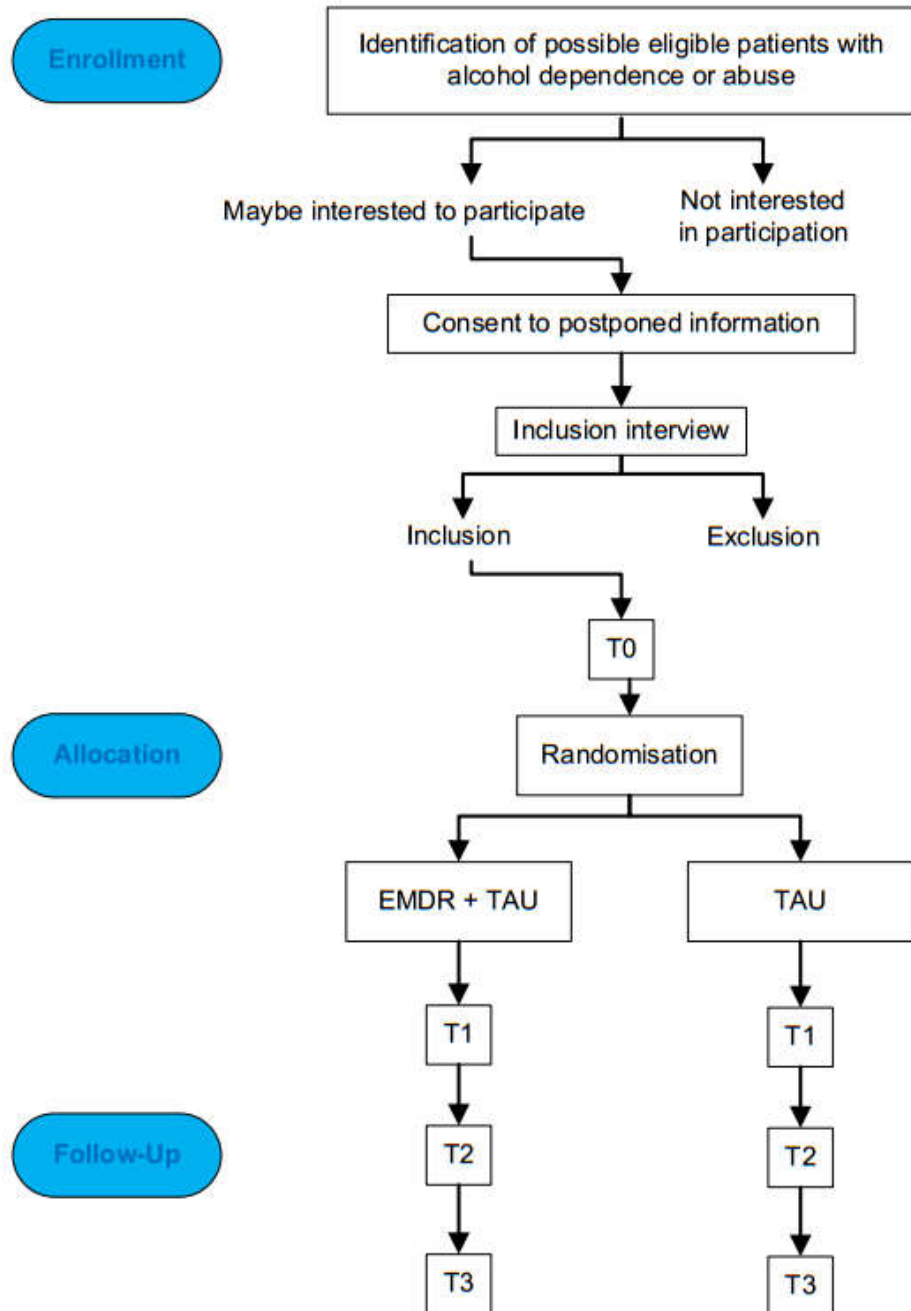
Main hypotheses

- Primary: the addition of EMDR to TAU will result in:
 - Less alcohol use
 - Longer time-to-(re)lapse (T1-T2: first 4 wks 'post-treatment')
 - Less craving
- Secondary: the addition of EMDR to TAU is:
 - Safe (adverse events)
 - Feasible (acceptance and drop-out)

Hypotheses in line with Hase, Schallmayer and Sack (2008)

EMDR study protocol (7 x 90 min.)

- **Session 1:**
 - Rationale, goal, rules
 - Installation ***positive treatment goal*** (≈ DeTUR; Popky, 2009)
 - Desensitization of ***negative flashforwards of prolonged abstinence*** (≈ Logie & De Jongh, 2014)
 - Desensitization of ***positive memories*** (≈ Knipe, 2009)
- **Session 2-3:**
 - Desensitization of ***memories of loss of control*** (≈ CravEx; Hase, 2009/≈Two-method approach; De Jongh, Ten Broeke, & Meijer, 2010)
- **Session 4-5:**
 - Desensitization of early ***memories that ‘proof’ a self-defeating conviction*** (≈Two-method approach; De Jongh, Ten Broeke, & Meijer, 2010)
- **Session 6:**
 - Desensitization of ***trigger situations*** (≈ DeTUR; Popky, 2009; ≈ CravEx; Hase, 2009)
- **Session 7:**
 - Remaining targets
 - Desensitization of ***negative flashforwards of relapse*** (≈ Logie & De Jongh, 2014)
 - ***Future templates*** of trigger situations



RCT design

- **Eligible:**
 - Primary alcohol dependence
 - ≥ 18 years
 - Good proficiency Dutch language
- **Exclusion:**
 - Absolute: PTSD (to be treated first)
 - Case-by-case: severe, therapy interfering
 - Substance use
 - Psychiatric symptoms (severe suicidality, aggression, psychosis etc.)
- In total 109 patients have been randomized (55 allocated to TAU + EMDR)
- **TAU:** outpatient behavioral and medical addiction care
- **EMDR** (max. 7 x 90 min. sessions) provided by trained and supervised EMDR therapists
- **Assessments:**
 - Semi-structured interviews
 - Participant-report (questionnaires)
 - Implicit/reaction time tasks
 - Bloodsamples

Assessments

Outcome variable	Measurement	T0 Baseline	T1 (+ 8 wks) Post EMDR	T2 (+ 12 wks) Follow-up	T3 (+ 8 months) Follow-up
Heavy drinking days, past 28 days	Time-Line FollowBack (TLFB) method	X	X	X	X
Total drinking, past 28 days	Time-Line FollowBack (TLFB) method	X	X	X	X
Mean drinks per occasion, past 28 days	Time-Line FollowBack (TLFB) method	X	X	X	X
Proportion drinkers (T1-T2)	Time-Line FollowBack (TLFB) method			X	
Time-to-(re)lapse, (T1-T2)	Time-Line FollowBack (TLFB) method			X	
Biomarker severity alcohol use	GGT + CDT	X	X	X	X
Alcohol craving, past week	Penn Alcohol Craving Scale (PACS)	X	X	X	X
Safety	Changes in existing problems (T0-T3) Adverse events (T0-T1) Serious Adverse Events (T0-T3)	X	X	X	X
Feasibility (T0-T1)	Acceptance rating Study dropout Treatment dropout	X	X		

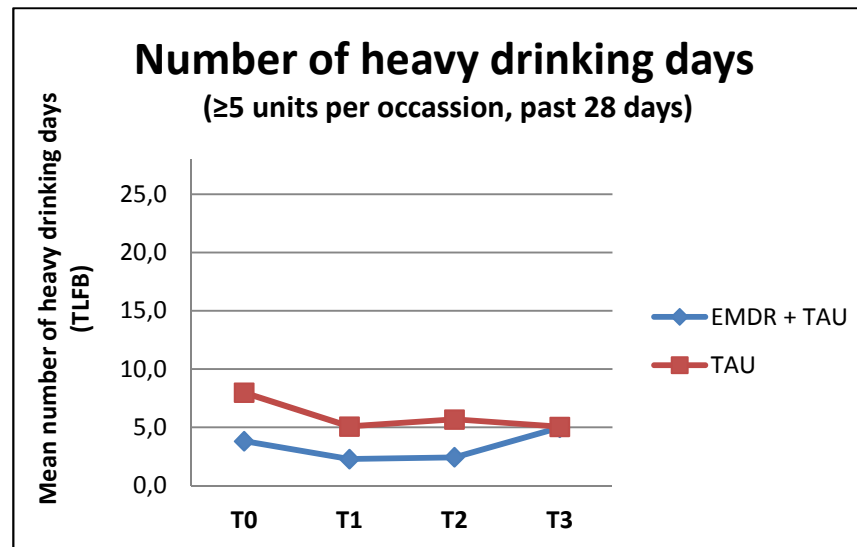
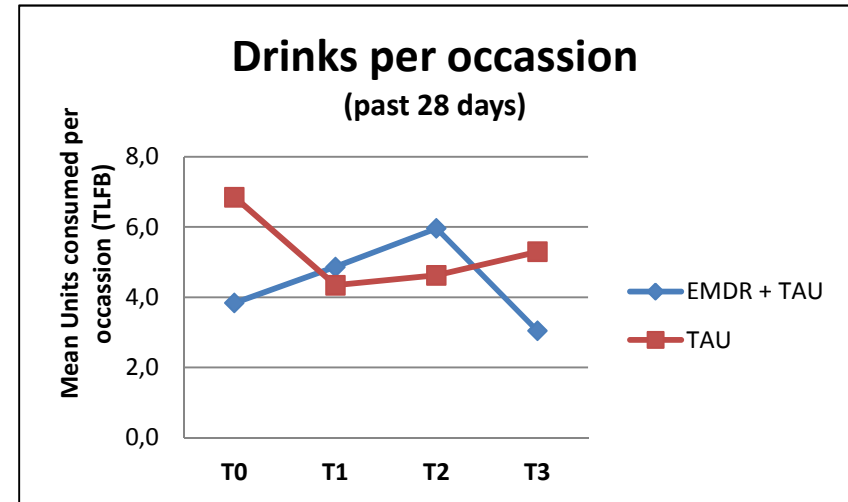
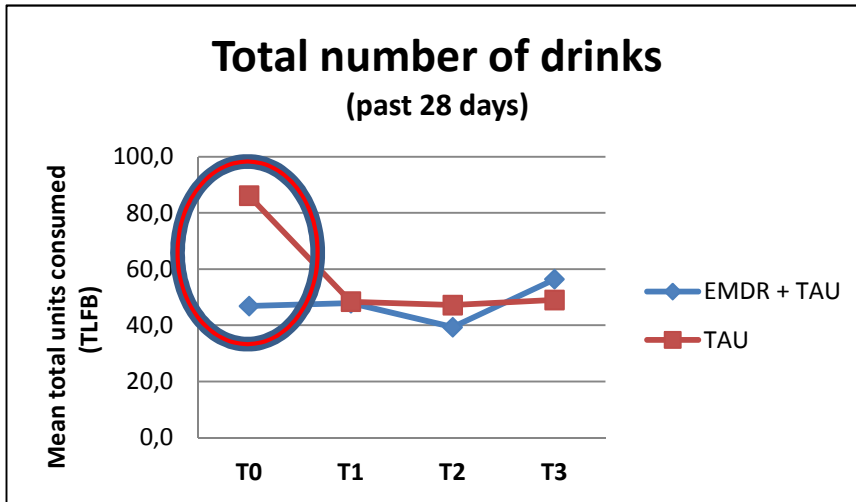
Sample characteristics ($n=109$)

- **Gender:** 75 male, 34 female
- **Nationality:** 96% Dutch
- **Marital status:** 75% not married/divorced
- **Educational level:** 66% ≤ 12 years of education
- **Mean age:** 47 (± 12) yrs
- **Mean time-in-treatment at baseline:** 36,9 ($\pm 61,1$) wks

No sign. differences between groups at baseline on demographics and outcome variables

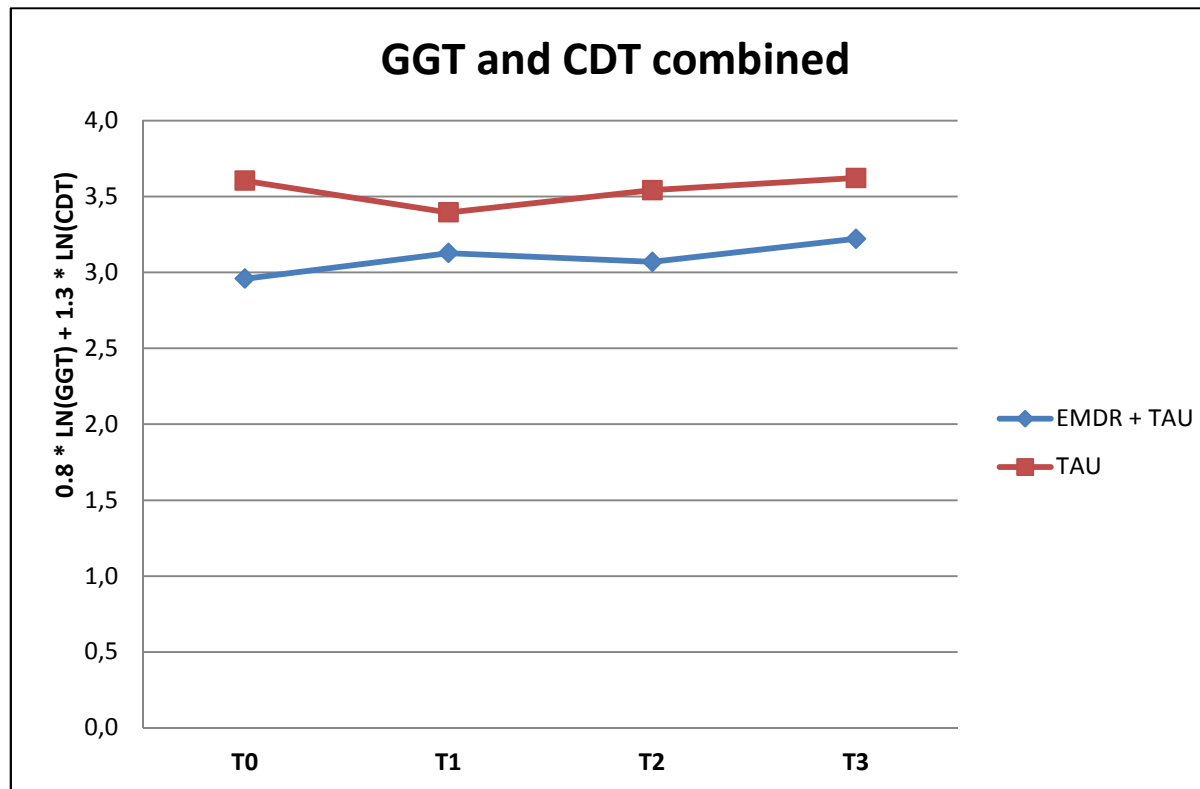
Main findings (1): participant-reported drinking behavior

(ITT: $n = 71$ (TLFB); $p = \text{n.s.}$)



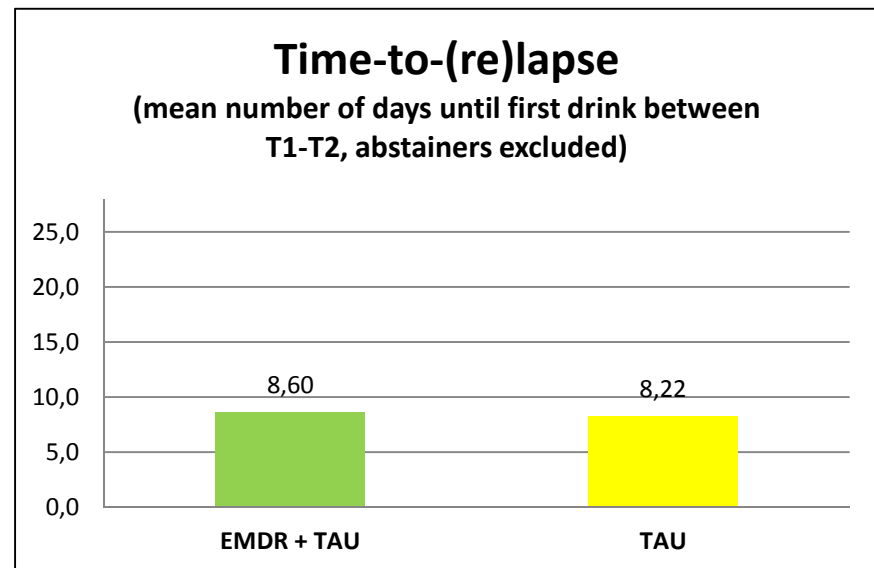
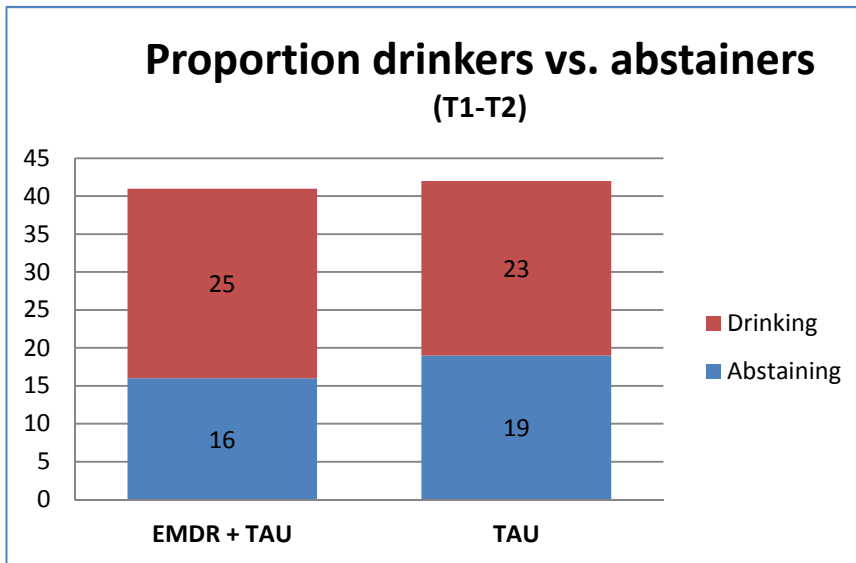
Main findings (2): blood samples reflecting drinking behavior

($n = 45$; $p = \text{n.s.}$)



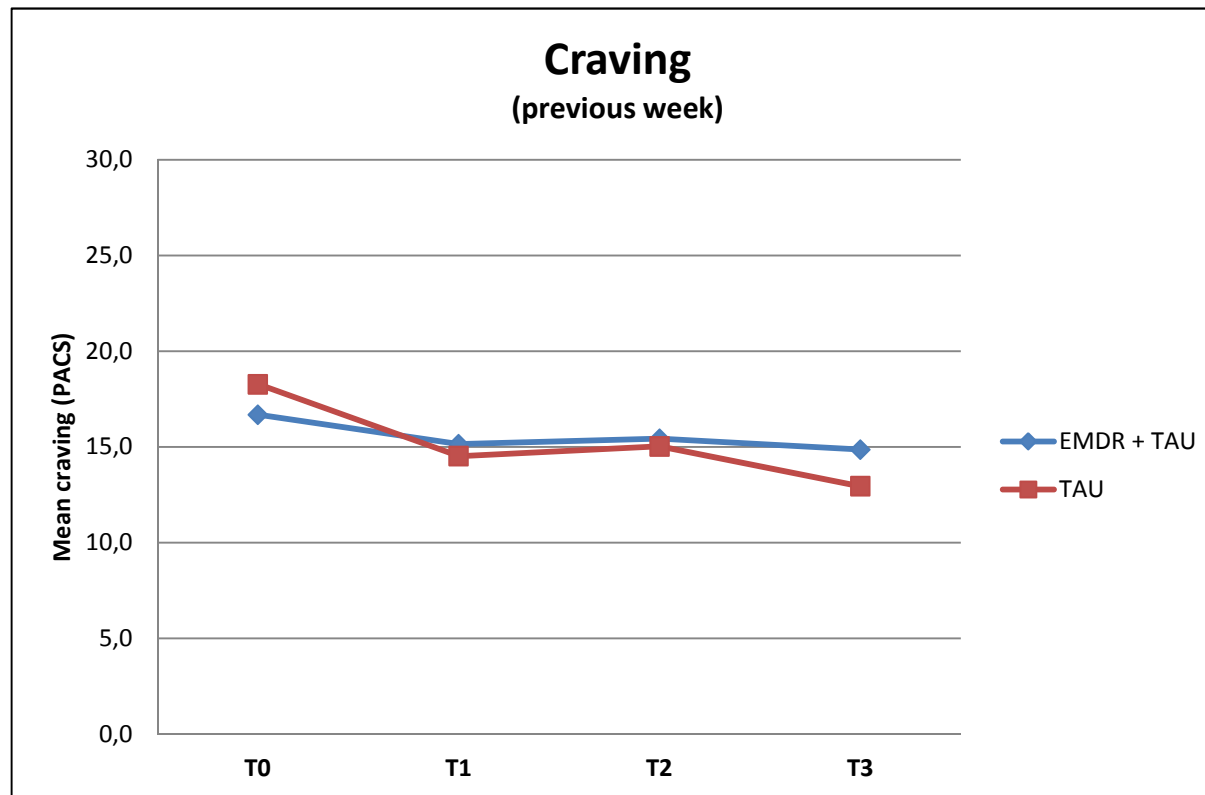
Main findings (3): time-to-(re)lapse

($n = 83/48$ (TLFB); $p = \text{n.s.}$)



Main findings (4): participant-reported craving

($n = 72$ (PACS); $p = \text{n.s.}$)



Primary hypotheses revisited

The addition of EMDR to TAU did not result in significant:

- Less alcohol use
- Longer time-to-(re)lapse (T1-T2: first 4 wks 'post-treatment')
- Less craving

Effect-sizes are small to medium

However:

- The TAU group scored higher (non-sign.) on drinking behavior indices at T0
- The combined GGT + CDT T0 score was sign. higher in the EMDR non-completers than completers
- 12/19 EMDR non-completers are also study dropouts

Conclusion:

- Chance of EMDR dropout is associated with severe alcohol use

Secondary findings (1): safety

(*n*=72/90)

Participant-reported **changes in existing problems (T0-T3)**:

- Similar decreases except: EMDR + TAU sign. more sleep- and aspecific problems at T3

Participant-reported **adverse events over T0-T1**:

- Admittance to a clinical facility: 3 (TAU)/0 (EMDR + TAU)
- Suicidal tendencies: 7 (TAU)/5 (EMDR + TAU)
- Self-harm: 3 (TAU)/3 (EMDR + TAU)
- Increase in psychiatric symptoms: 6 (TAU)/2 (EMDR + TAU)
- Self-reported increase in drinking: 4 (TAU)/4 (EMDR + TAU)

Therapist-reported **Serious Adverse Events (SAE; T0-T3)**:

- 1 homicide (EMDR + TAU)
- 2 relapse in combination with psychiatric crisis, attributed (in part) to EMDR (EMDR + TAU)
- SAE in TAU may have been underreported

Conclusion:

- Problems and adverse events are $\approx$ in both groups
- EMDR treatment may trigger **subthreshold PTSD** and subsequent relapse/crisis in vulnerable patients

Secondary findings (2): feasibility

(*n* =109/90)

Positive treatment *expectancies* at T0 were sign. higher in TAU group

Positive treatment *effects* at T1 were sign. higher in TAU group

Positive experiences regarding **EMDR** (T1):

- Gave piece of mind and positive view of the future, highly effective, ***better coping, no more drinking, negative memories processed, no more bad dreams***

Negative experiences regarding **EMDR** (T1):

- Felt vulnerable after discussing negative events, ***too much*** too handle, ***intrusive memories*** arose, ***relapse***, didn't like procedure, didn't help, became exhausted, confused, experienced headache

Study drop-out (T0-T3):

- TAU: 12/54
- EMDR + TAU: 12/55

Treatment 'drop-out' (EMDR: non-completers/TAU: too low treatment intensity: <5 sessions between T0-T1):

- TAU: 21
- EMDR + TAU: 19 EMDR = 19 TAU

Conclusion:

- Acceptability of EMDR may vary with expectancies
- Different participants may experience opposite effects: affecttolerance may be key
- Dropout is high (35%), but not increased in EMDR + TAU

Differences with Hase et al. (2008)

	Hase, Schallmayer & Sack, 2008	Markus et al. (in preparation)
Sample	Detoxified , inpatient alcoholics	Both abstaining and drinking outpatient alcoholics
Sample size	34	109
Measures	Participant-report	Participant-report Implicit tasks Biomarkers
Study dropout	88% TAU and 65% EMDR + TAU	22% TAU and 22% EMDR + TAU
Treatment dropout	12% TAU and 12% EMDR + TAU	39% TAU and 35% EMDR + TAU
EMDR duration	2 hours	10 hours
Targets	MR of relapse MR of triggers	MR of relapse/loss of control MR of triggers FF of prolonged abstinence Positive MR Installation positive treatment goal MR of self-efficacy reducing small-t trauma FF of relapse
Treatment integrity safeguards	Protocol One expert therapist	Protocol Extensive training and supervision All sessions recorded and randomly rated by independent raters + feedback
Serious Adverse Events possibly related to EMDR	None reported	2 patients relapsed due to psychiatric crisis

**How should we explain these
preliminary findings?**

Discussion (1): design issues?

Variance influenced by:

- **TAU** is quite **heterogenous** delivered by multiple **therapists**, at multiple **sites**
- Outpatient setting: **heterogenous sample** regarding severity of drinking
- **Time of inclusion** (cross-sectional): regardless of treatment phase (TAU), level of craving and drinking status
- **Broad inclusion**: all comorbidity (except PTSD), heavy drinking (as long as not therapy interfering), poly-substance use
- **Use of psychopharmaceuticals**: anti-craving, abstinence enforcing, etc.

Discussion (2): problematic EMDR delivery?

Diversity in EMDR qualifications/experience:

- Eight EMDR therapists had EMDR Level I training, two advanced level training
- On average **3,5** (range 1-9) **yrs EMDR experience**
- On average 22,4 (range 4-50) EMDR treatments completed before RCT

Diversity in pre-post outcomes:

- % of non-completers per therapist varied from 0-60%
- However, pre-post changes in primary outcome measures not correlated with therapist
- Low number of participants per therapist (2-9) limit conclusions

Complexity of EMDR protocol, but:

- All EMDR therapists recieved **intensive protocol training by EMDR trainer**
- **Monthly group supervision (with video feedback)** provided by EMDR trainer, available for **email consultation**
- All sessions were videotaped, a random sample was **rated independently**. Ratings were satisfactory (**on average 89,5% fit (70-100) with protocol as intended**)

Discussion (3): wrong application of the EMDR protocol?

- First impressions: $\pm 50\%$ has begin SUD/LoU/LoPA rating lower than 5,5!
- Is high SUD/LoU/LoPA a prerequisite for clinical meaningful change?
 - Further analyses of videotaped sessions:
 - Pre-post differences in SUD/LoU/LoPA
 - Number of targets per category
 - Desensitization time per target
- EMDR drop-out possibly reflects affect tolerance issues which may need to be adressed first
- Or ... targeting addiction itself with EMDR:
 1. Only works with specific groups:
 - E.g. behavioral addictions, highly motivated patients, addicts with high craving, etc.
 2. Needs to be tailored:
 - Addiction is multifactorial determined and maintained
 - Case-conceptualization: analysis of function and meaning of behaviors

Discussion (4): EMDR protocol flawed?

- Adjusted approaches of others
- Not incorporated Miller's Feeling-State approach
- Or ... targeting addiction itself with EMDR simply doesn't work:
 - Effect in EM studies $\neq$ clinical effect in EMDR
 - Very high frequency of repeated exposure $\neq$ PTSD
 - Self-initiated use/behavior (instrumental learning) $\neq$ PTSD
(classic conditioning)
 - Addiction memory $\neq$ trauma memory?

Recommendations

- Adding EMDR to TAU to target the addiction is not recommended in *outpatient* alcoholics
- Back to the drawing board?
 - Experimental studies:
 - Study separate interventions (component studies)
 - High vs. low SuD/LoU/LoPA
 - Use functional analyses: relief vs reward motives
 - Compare emotive vs addiction MR
 - Clinical studies:
 - Use a more homogenous sample (e.g. smokers/gamblers without additional problems)
 - Compare to waiting list or narrowly defined TAU
 - Screen for subthreshold PTSD and low affect tolerance
 - If positive, then prioritize/exclude
 - Address **expectancies**: psychoeducation and commitment