Treating the Treatment-Resistant: A Randomized Controlled Trial of ACT for Treatment-Resistant Panic Disorder and Agoraphobia – Preliminary Results

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…Where Angels Fear to Tread

THE HIDDEN THIRD

Schlaepfer et al., 2012

What Constitutes Treatment Resistant?

Anxiety Disorder Association of America

- "…when there are residual symptoms or when symptoms do not improve at all after some form of therapeutic intervention."

  - Pollack et al., 2008

Research

- When a priori response/ remission criteria are not met.

Clinical/ Anecdotal

- When the patient doesn't do what is necessary
- When I've run out of therapeutic options

Level of Evidence: Overall

Failed Tx	Controlled Trials	Tested Alternative
Pharmacological		Pharmacological/ Biological
Pharmacological		Psychological (CBT)
Psychological (CBT)		Pharmacological/ Biological
Psychological (CBT)		Psychological

The Importance of Willingness During Exposure

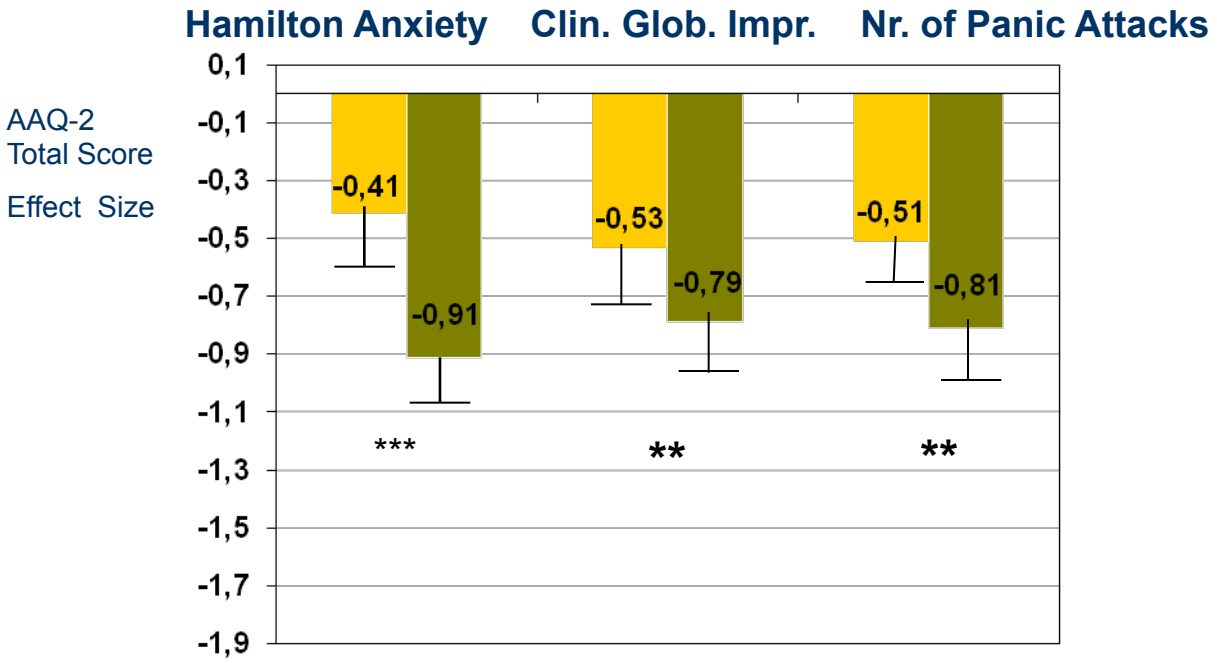
"How Willing Are You to Engage in Exposure"

Those Who Drop Out of Treatment differ Significantly from Those that Complete the Exposure:
$F(1,226) = 3.89$, $p < .05$

Reaction to Anxiety Suggests Possible Process Relevant for Non-Responding Patients

Lower levels of psychological flexibility associated with a poorer response

Psychological Flexibility/ Experiential Avoidance



As Measured at Post

non-responder responder

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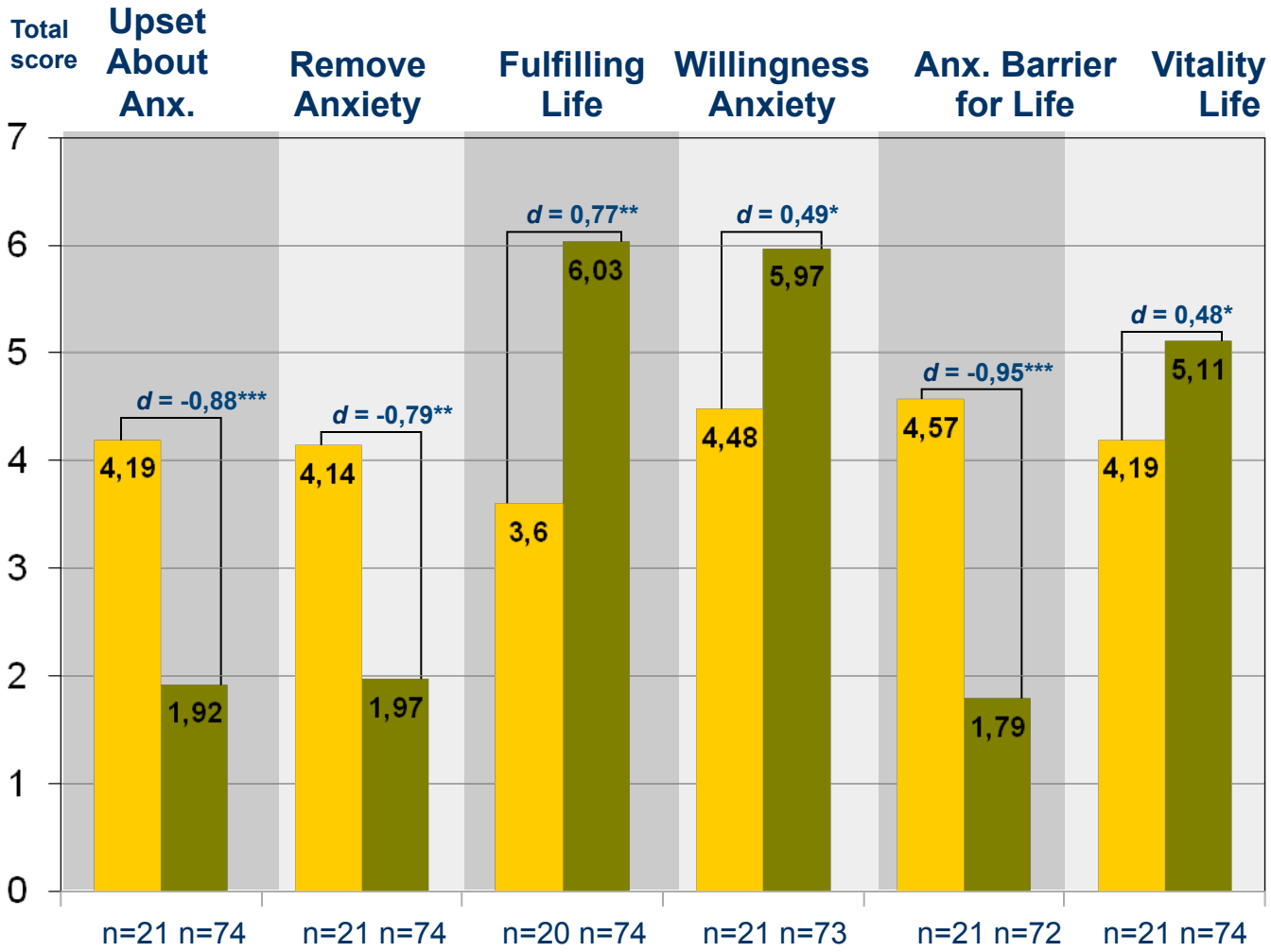
Responders and Non-Responders: The Effect of Psychological Flexibility

Effect Size Comparisons Across Facets of Psych Flex (F-ACT)

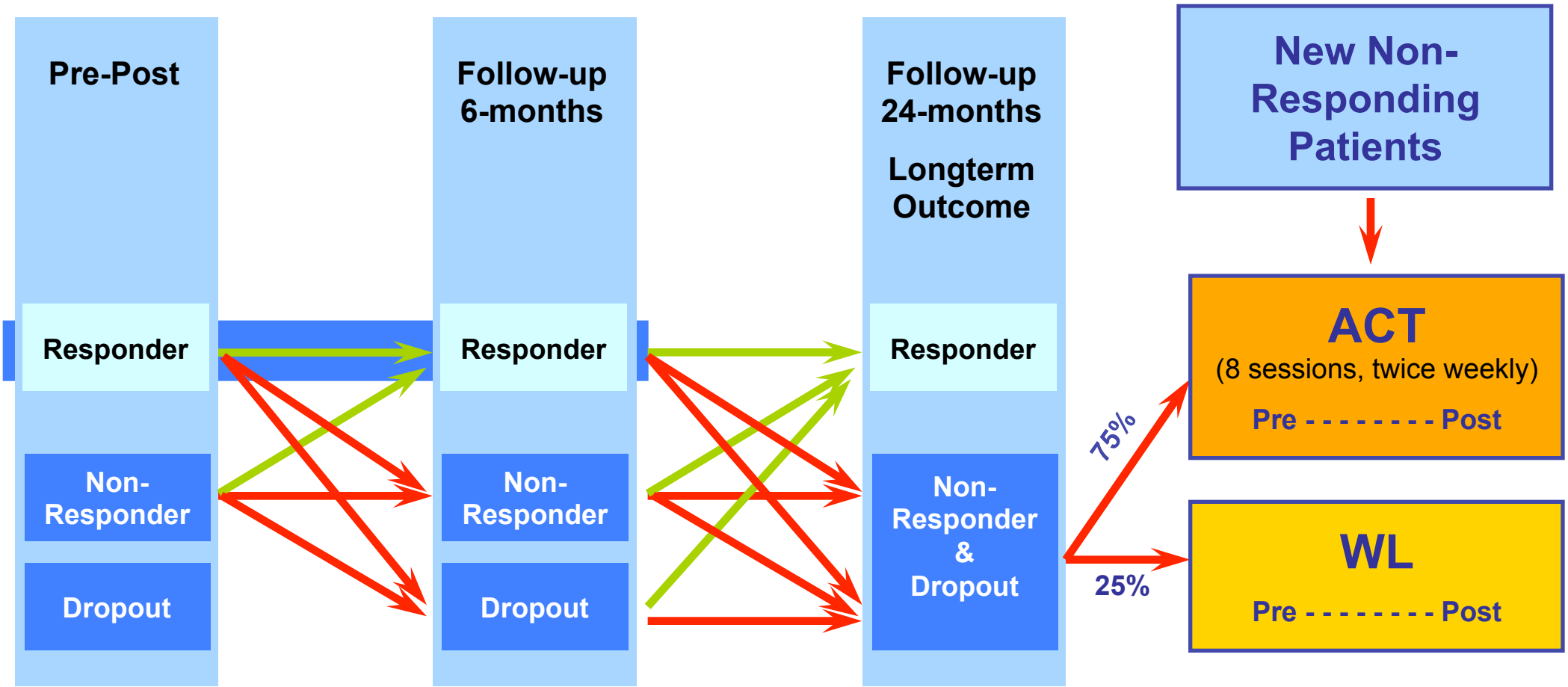


Items tappling into facets of **Psychological Flexibility** consistently differentiate „responders“ and „non-responders“

As measured at 2 Yr Follow Up

non-responder (MI ≥ 1.5 OR CGI func ≥ 4) responder (MI< 1.5 AND CGI func = 1,2,3)

Non-responders and Relapse: Can an Acceptance-based Strategy Help?



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Design and Methods
The study center & Therapists

Outpatient treatment center of the Technische Universität Dresden:

-Existing Trial Infrastructure

7 Graduate Student Therapists

- **No Previous Experience** with ACT

-Trained and licensed as part of study's certification procedures

- Average 6 Pt/ Therapist

-Weekly supervision

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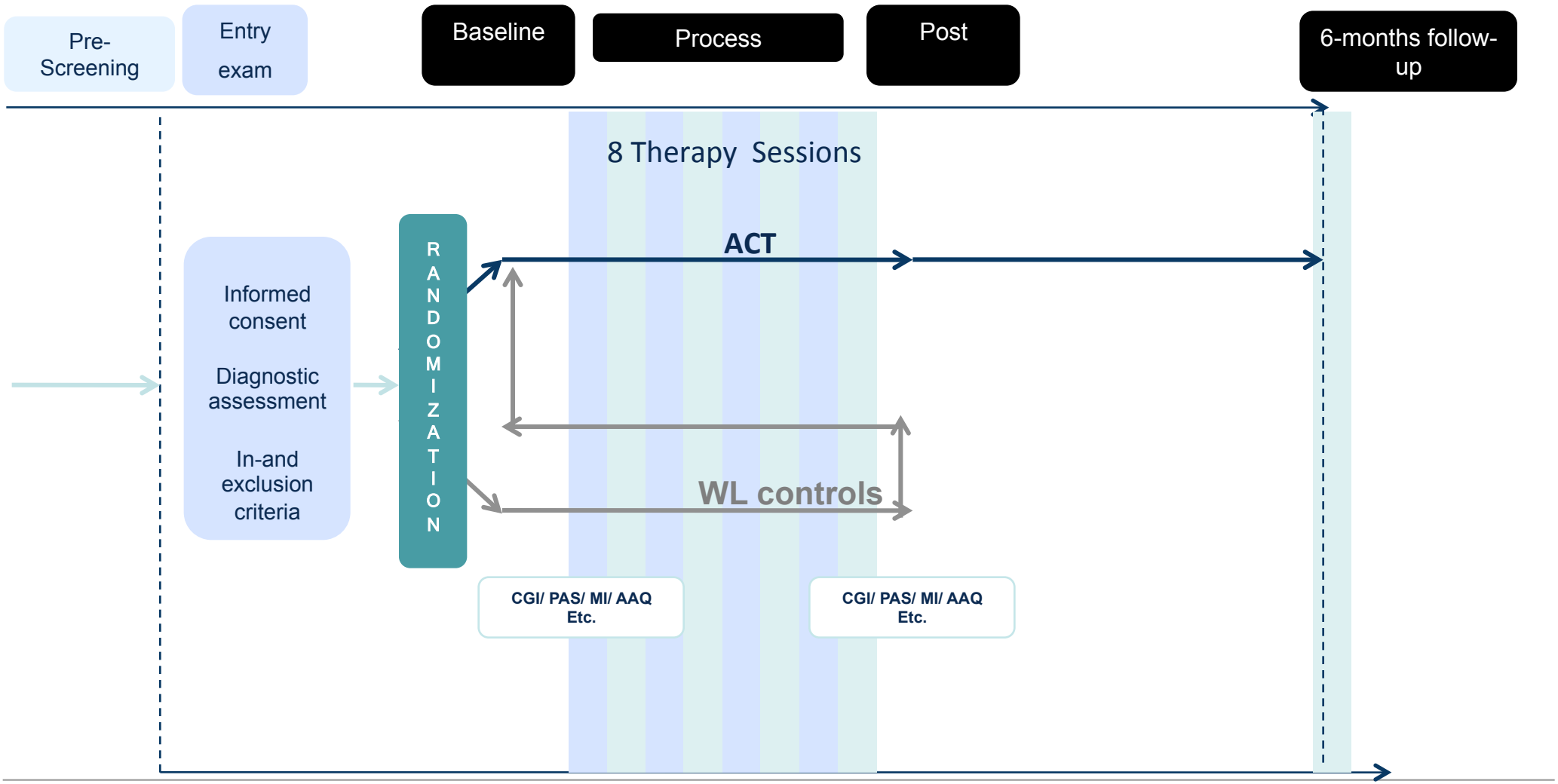

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Design and Methods

In- and exclusion criteria: Patients meeting DSM-IV-TR criteria for panic disorder with agoraphobia

Inclusion criteria

- Age 18-65
- DSM-IV Panic Disorder &/or Agoraphobia
- **Mobility Inventory ≥ 1.5**
- CGI-Score ≥ 4
- Ability to Attend Regularly
- Informed Consent
- **Adequate Previous Treatment**

Exclusion criteria

- Significant medical (somatic/mental) conditions
- acute suicidality
- DSM-IV Bipolar Disorder
- DSM-IV Psychotic Disorder
- DSM-IV Borderline Personality Disorder
- current psychological treatment for an axis I-Disorder
- current alcohol-, BZD-, drug dependence

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Design and Methods

Adequate Previous Treatment

- ≥ 20 Sessions of Psychotherapy
- Consisting of Elements of Empirically Supported Treatments

And/ or

- ≥ 4 Months of Prescription of Substances Approved by the Official Pharmacology Guidelines of the German Physician Society
- At sufficient Dosage

Sample

- N = 43 Individuals; 51 Cases (10 WL delayed patients)
- Sex: 69.8% Female
- Mean Age: 37.2 y.o. (SD = 9.3)

- Adequate Previous Treatment:
  - Psychotherapy: 88.4% (38/43)
  - Pharmacotherapy: 32.0% (14/43)
  - Both: 20.9% (9/43)

Mean 42.2 Sessions!

- At Least Sub-Adequate Previous Treatment:
  - Psychotherapy: 95.3% (41/43)
  - Pharmacotherapy: 48.8% (21/43)
  - Both: 51.1% (22/43)

Design and Methods
The Treatment

Session 1 Control is the Problem, Values	***Week 1***
Session 2 Acceptance, Control is the Problem, Mindfulness	
Session 3 **Mindfulness, Acceptance/ Willingness, Values**	***Week 2***
Session 4: Defusion, Mindfulness, Values, Self-as-Context	
Session 5 Defusion, Self-as-Context, Willingness, Values, Commitment	***Week 3***
Sessions 6-7: Defusion, Willingness, Values, Commitment	
Sessions 8: Defusion, Willingness, Values, Commitment, Relapse Prevention	***Week 4***

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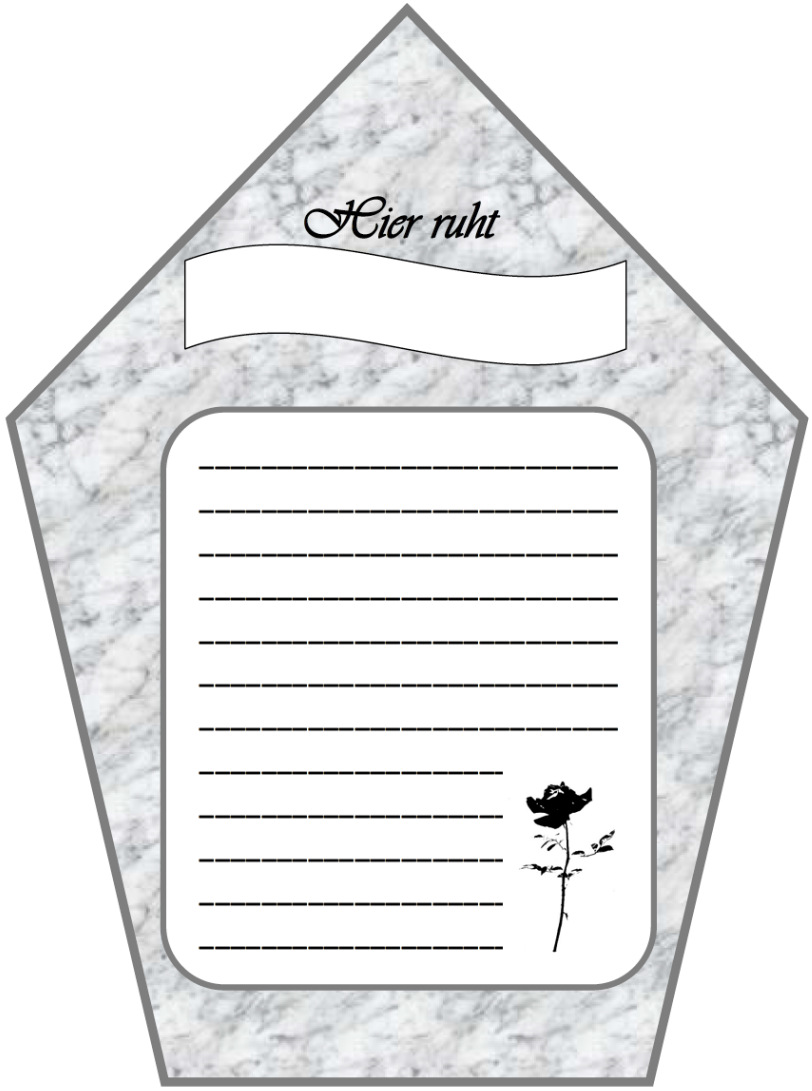
…With a Different Type of Conversation

Beschriften Sie Ihren eigenen Grabstein
„Wofür soll mein Leben stehen?“

Eine Lebensverbesserungsübung



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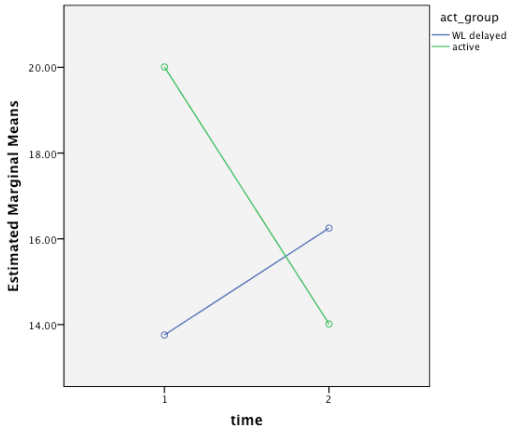
Preliminary Results

Outcome (Pre – Post vs. WL)

Primary Outcome Measures

Primary Outcomes

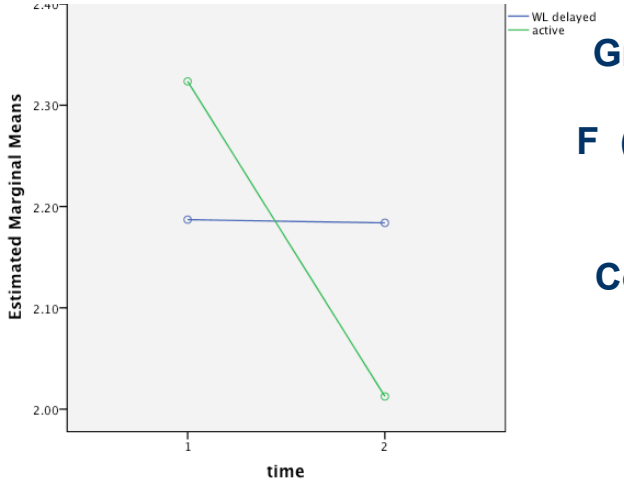
Panic and Agoraphobia Scale (PAS)



Group x Time Interaction: F (1, 40) = 6.7, p < .001

Cohen's *d* = 0.7

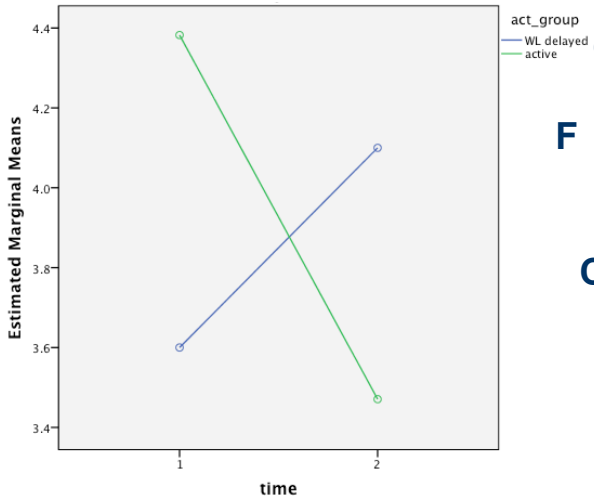
Agoraphobic Avoidance (MI)



Group x Time Interaction: F (1, 36) = 2.0, p < .07

Cohen's *d* = 0.5

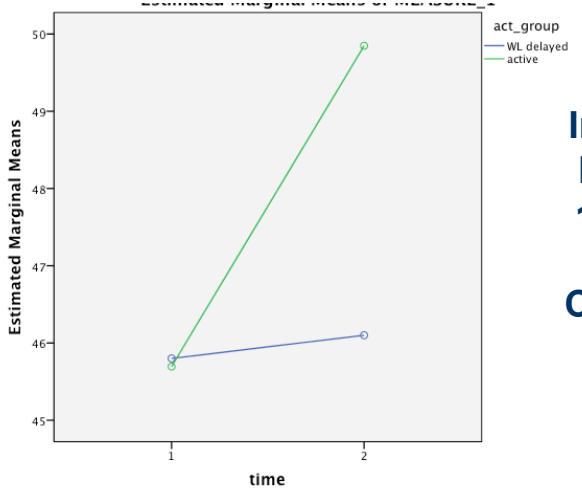
Clinical Global Impression (CGI)



Group x Time Interaction: F (1, 42) = 13.7, p < .001

Cohen's *d* = 0.9

Psychological Flexibility (AAQ-II)



Group x Time Interaction: F (1, 44) = 1.3, p < .13

Cohen's *d* = 0.4

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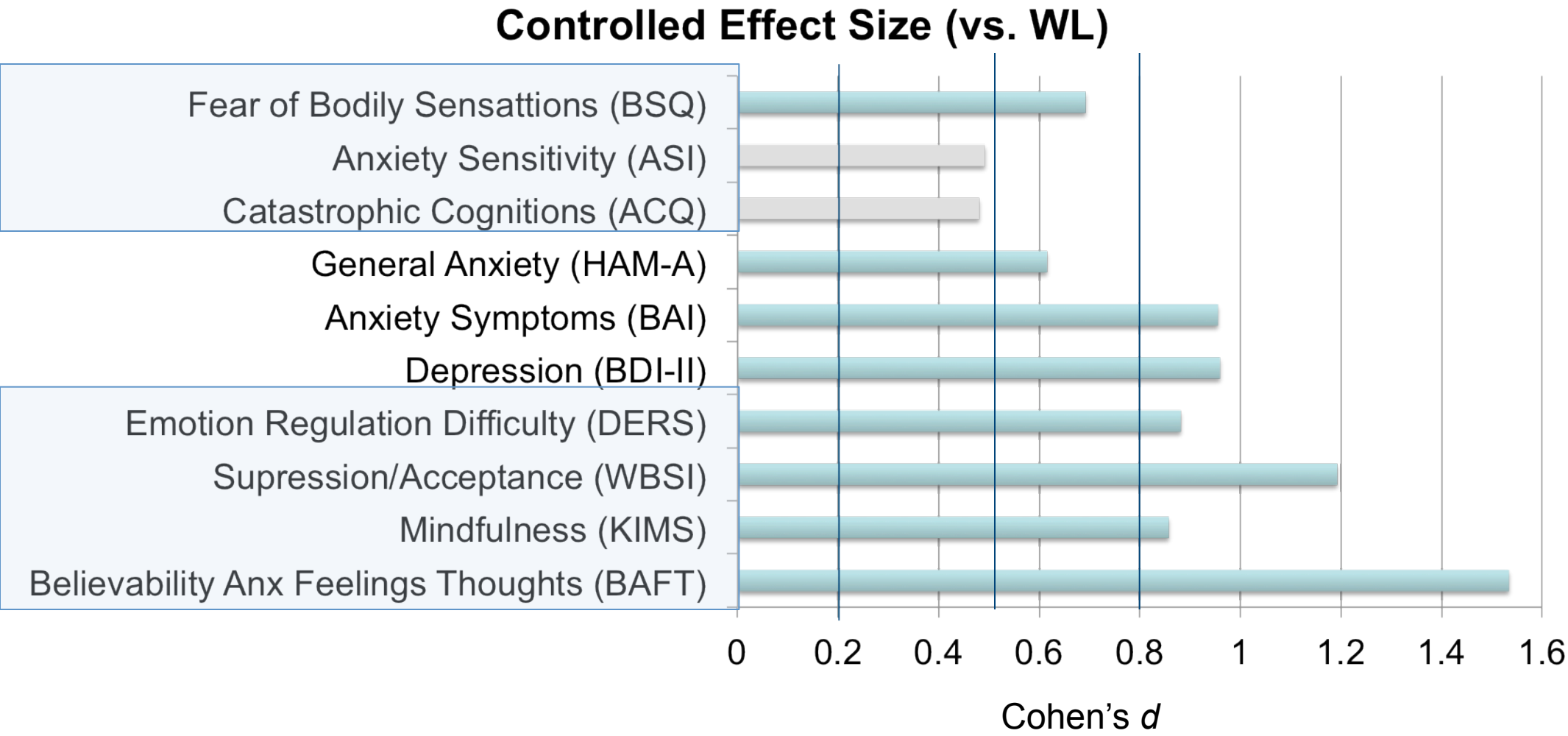
Preliminary Results

Outcome (Pre – Post vs. WL)

Secondary Outcome Measures

-Symptomatology
-Non Targeted Constructs
-Targeted Processes

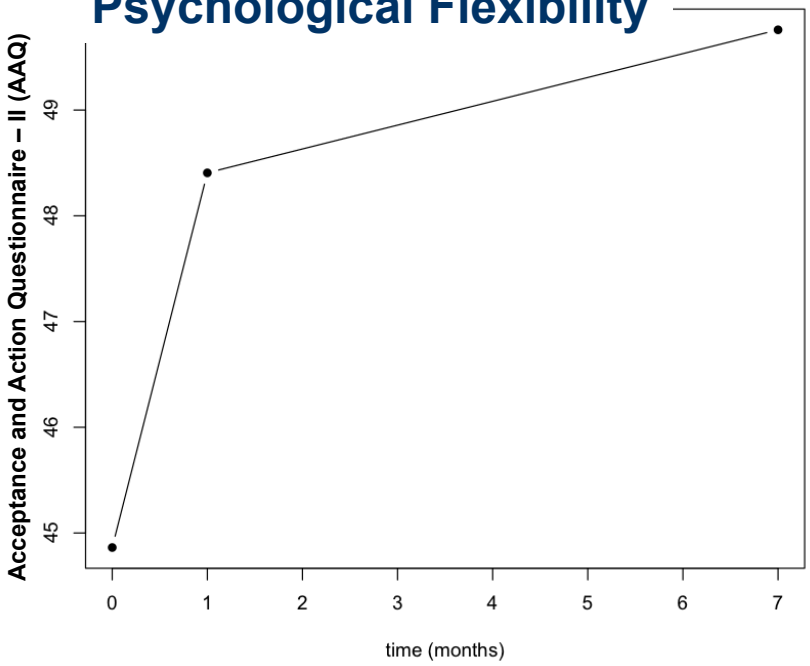

Controlled Effect Size (vs. WL)
Fear of Bodily Sensattions (BSQ)
Anxiety Sensitivity (ASI)
Catastrophic Cognitions (ACQ)
General Anxiety (HAM-A)
Anxiety Symptoms (BAI)
Depression (BDI-II)
Emotion Regulation Difficulty (DERS)
Supression/Acceptance (WBSI)
Mindfulness (KIMS)
Believability Anx Feelings Thoughts (BAFT)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
Cohen's d

Preliminary Results

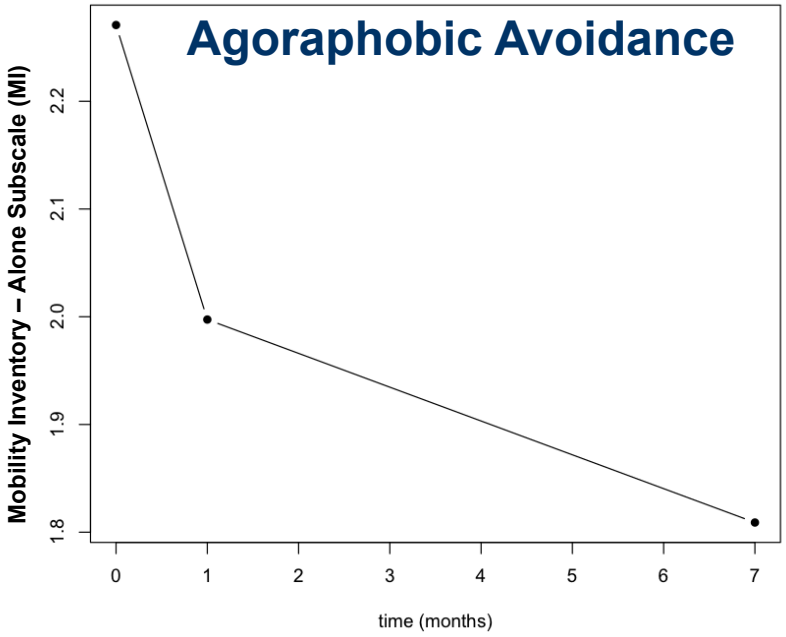
Follow-Up (6 Months)

Primary Outcome Measures

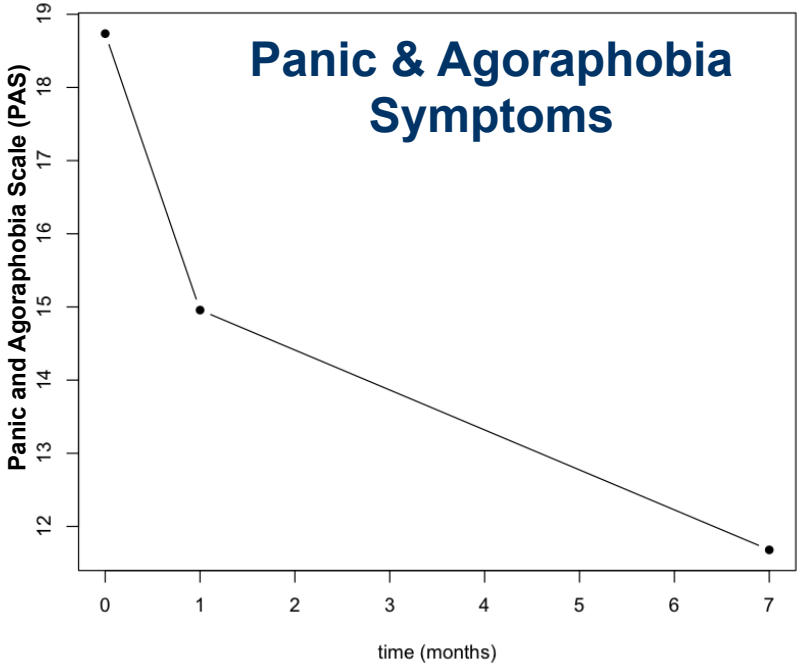
Psychological Flexibility



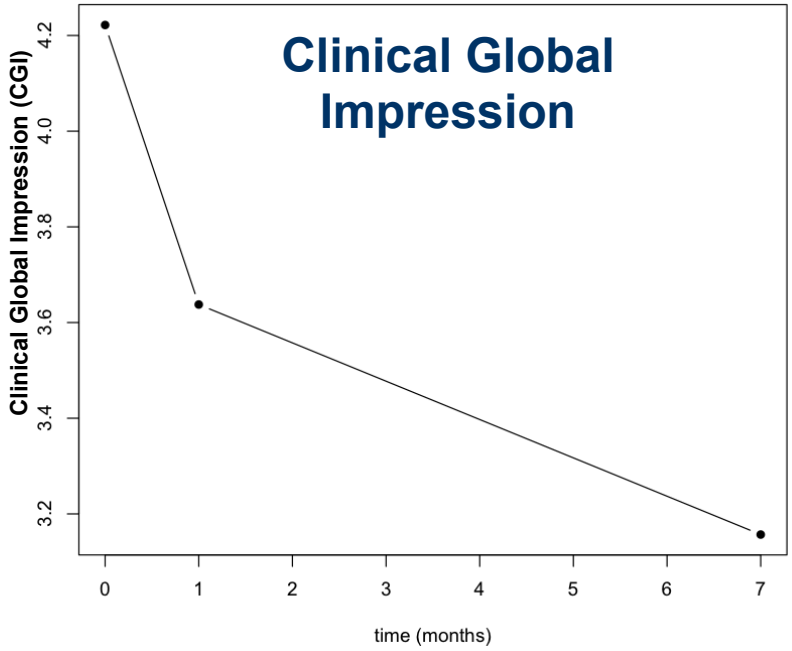
Agoraphobic Avoidance



Panic & Agoraphobia Symptoms



Clinical Global Impression



…and One More Thing

Drop Out Rate:

- **Overall: 5 Patients (9.4%)!**
- **“Real Rate”: 3 Patients (5.6%)**

Timing of Drop Out	Frequency
Prior to Session 1	1
After Session 1	1
After Session 3	1
After Session 5	1
After Session 8 (No Post)	1

…and the Response Now?

Response Rate:

Panic & Agoraphobia Symptoms		Clinical Global Functioning	
Post	6-Month Follow Up	Post	6-Month Follow Up
70%	80%	57%	52%

Conclusions

Where We Stand

- ACT (Psychological Approach) Appears Feasible for Treating Refractory Patients
  - …with longitudinal stability
  - …in a tough crowd
  - …using therapists with no prior ACT experience
  - …in 4 weeks
  - …with a manual

- Mindfulness-based approaches may be especially useful for patients with moderate to severe depression (Arch & Ayers, 2013)

- There is Hope for the "Hidden Third"

More Work Lies Ahead

- Session-by-Session Process
- Detailed Response Analysis
- Other Disorders
- Longer Follow-up
- Different Control Groups

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