Measuring Researcher Allegiance in Psychotherapy Research

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Researcher Allegiance in Psychology

What is Researcher Allegiance?

'the belief in superiority of an intervention and of the theory of change that is associated with the intervention'
(Leykin & DeRubeis, 2009)

Intellectual conflict of interest that is consistent with one's **professional or personal commitment** for one type of therapy

RA is beneficial in psychology as it simply reflects a **higher level of skills** in those who are well-trained in delivering an intervention[3,7].

What is Researcher Allegiance?

'the belief in superiority of an intervention and of the theory of change that is associated with the intervention'
(Leykin & DeRubeis, 2009)


may unintentionally **reduce objectivity,**


lead to **questionable research practices,**


and may consequently **distort the outcomes** (or the interpretation of outcomes) of RCTs

Consequences of RA: A debate in the field

AUTHOR'S RA IS **CORRELATED** WITH STUDY RESULTS

Luborskey et al., 1999; 1975; Berman et al., 1985, Botella& Beriain, 2010

AN INCREASE OF 1 POINT IN THE RA SCALE WAS ASSOICATED WITH AN EFFECT SIZE INCREASE (d = 0,109) **IN FAVOR OF THE PREFERRED TREATMENT**

Munder et al., 2013

RA WAS FOUND TO BE A **SIGNIFICANT PREDICTOR** OF THE TREATMENT EFFECT

Munder et al., 2013

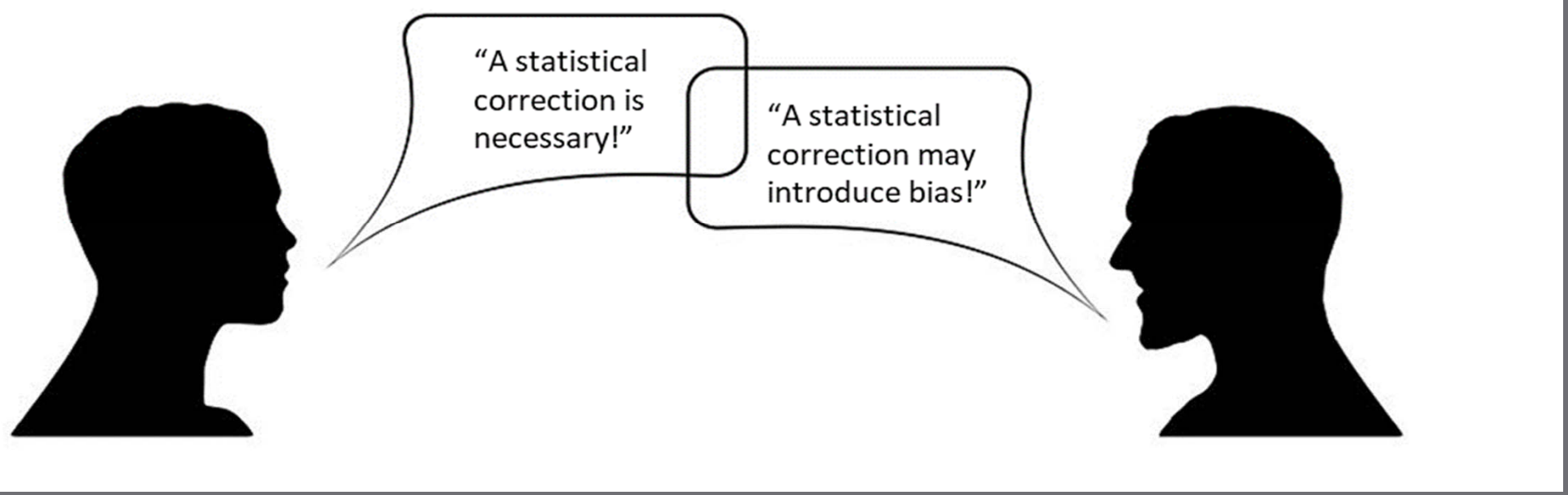
CORRELATION **DOES NOT MEAN** CAUSATION!

Leykin & DeRubeis, 2009

RA IS NOT AN IMPORTANT BIAS AS IT WAS **NOT FOUND TO INFLUENCE** THE ACTIVE TREATMENT EFFECT

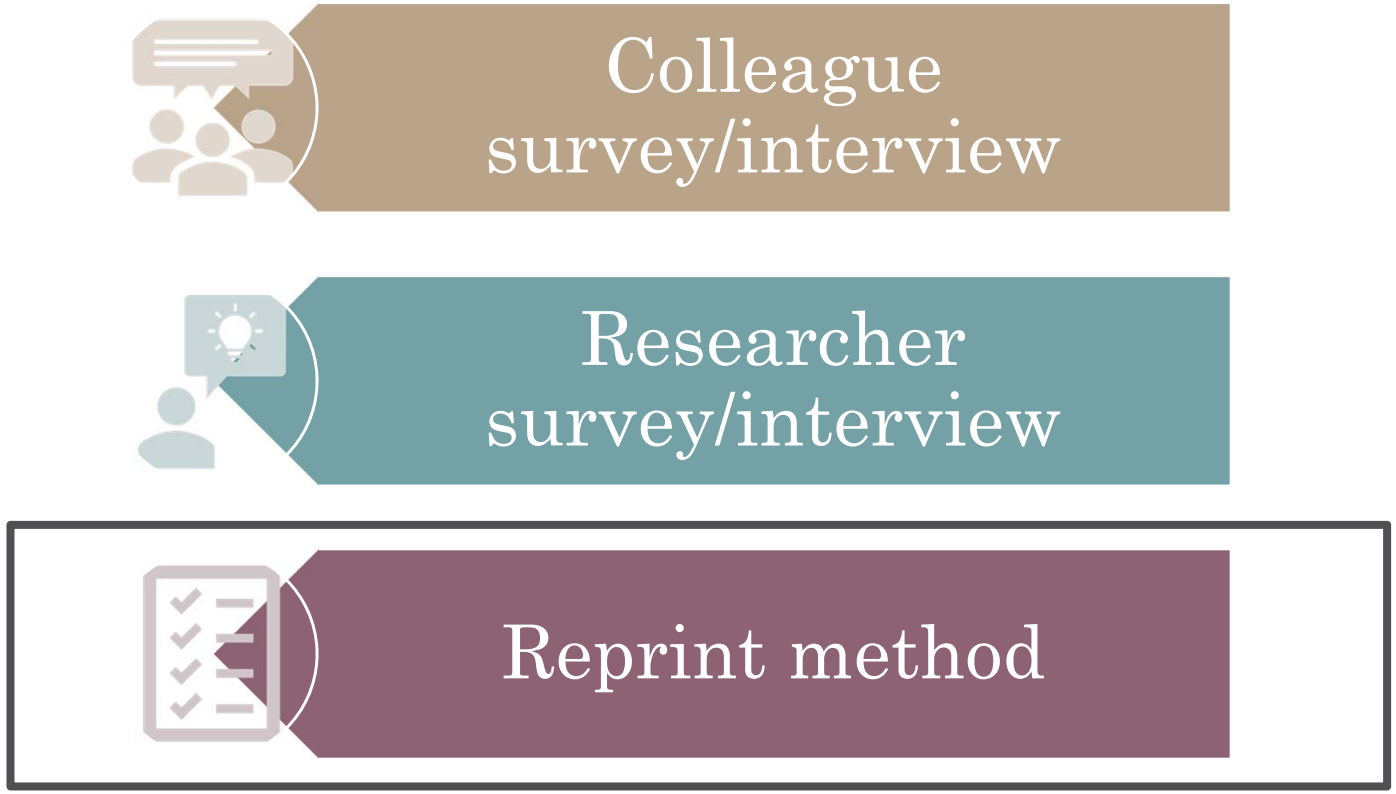
Gaffan et al., 1995; Tolin, 2010; Spielmans et a., 2011

Consequences of RA: A debate in the field



Measuring Researcher Allegiance

The operationalization of RA differs strongly across studies and there is no generally accepted way of operationalizing or measuring it.



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Research report

Psychotherapy for depression: A randomized clinical trial comparing schema therapy and cognitive behavior therapy

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ABSTRACT

Background: The efficacy of Cognitive Behavior Therapy (CBT) for depression has been robustly supported, however, up to fifty percent of individuals do not respond fully. A growing body of research indicates Schema Therapy (ST) is an effective treatment for difficult and entrenched problems, and as such, may be an effective therapy for depression.
Methods: In this randomized clinical trial the comparative efficacy of CBT and ST for depression was examined. 100 participants with major depression received weekly cognitive behavioral therapy or schema therapy sessions for 6 months, followed by monthly therapy sessions for 6 months. Key outcomes were comparisons over the weekly and monthly sessions of therapy along with remission and recovery rates. Additional analyses examined outcome for those with chronic depression and comorbid personality disorders.
Results: ST was not significantly better (nor worse) than CBT for the treatment of depression. The therapies were of comparable efficacy on all key outcomes. There were no differential treatment effects for those with chronic depression or comorbid personality disorders. Limitations: This study needs replication.
Conclusions: This preliminary research indicates that ST may provide an effective alternative therapy for depression.

1. Introduction

Cognitive Behavior therapy (CBT) is recommended as one of the first-line treatments for individuals with major depression (Ellis et al., 2003; National Institute for Clinical Excellence (NICE), 2004). Despite the proven effectiveness of CBT only 40–50% with depression will make a full recovery with their first course of treatment, and some are likely to have a poor outcome despite completing treatment. Moreover, 3–5% may develop a chronic clinical course of depression which is resistant to treatment (Fournier et al., 2009; Hollon et al., 2005; Kessler et al., 1994). Other than chronicity, a number of other factors have been proposed to limit the effectiveness of CBT. Perhaps with the most contradictory evidence, is the treatment outcome when personality disorders are comorbid. A number of studies indicate that treatments are less effective when a comorbid personality disorder is present (e.g. Bagby et al., 2008; Gorwood et al., 2010), with a recent meta analysis reporting the risk of poor outcome doubles (Newton-Howes et al., 2006). Other studies and reviews report no difference in outcome between depressed individuals with and without personality disorders (Kelly et al., 2009; Kool et al., 2005; Niemeyer and Musch, 2013; van den Hout et al., 2006).

Limitations in the effectiveness of traditional CBT for depression, and growing recognition that depression is a chronic and/or recurrent disorder for many people often associated with other comorbid axis I and II problems, has led to increased use by clinicians of Schema Therapy (ST) in the treatment of depression. Schema Therapy was initially developed by Young (1990) for the treatment of personality dysfunction. In contrast to traditional CBT, ST concentrates immediately and specifically on the schema and related developmental processes that prevent individuals having their core needs met in an adaptive manner. It has been proposed that these schema must be modified in order to bring about lasting change, particularly for individuals with more difficult or entrenched problems such as chronic or recurrent depression (Overholser, 1997; Riso et al., 2003; Safran and Segal, 1990; Young, 1990). Further, it has been proposed that any treatment that fails to reorganize or disrupt these fundamental assumptions leaves people cognitively at risk for the reactivation of maladaptive schemas during times of personal stress (Segal et al., 1988), and therefore at increased risk of depression reoccurring. These propositions are supported by research indicating that therapy that focuses more on interpersonal and developmental issues promotes long lasting recovery from depression and, importantly, reduces the risk of relapse (Hayes et al., 1996). Schema change has been associated with the resolution of symptomatic distress (Nordahl and Nysaeter, 2005).

Despite the widespread application of ST, there is still limited research investigating the efficacy of this therapy. Existing research indicates that ST is an effective treatment for borderline personality disorder (Farrell et al., 2009; Giesen-Bloo et al., 2006; Nadort et al., 2009; Nordahl et al., 2005; Nordahl and Nysaeter, 2005), substance dependence (Ball, 1998), chronic agoraphobia (Bamber, 2004) and borderline personality disorder and post-traumatic stress disorder in war veterans (Young, 2005). In the recent randomized clinical trial comparing ST and transference focused psychotherapy, ST also had a significantly lower rate of drop out from treatment than transference focused therapy (Giesen-Bloo et al., 2006). To date the efficacy of ST in treating depression has not been examined, however, specific schemas identified by Young have been shown to be a risk factor for depression (Halvorsen et al., 2010) and preliminary evidence suggests that ST may be effective for depression (Hawke and Provencher, 2011).

The primary aim of the current study was to compare the efficacy of ST with that of traditional CBT for individuals with a current major depressive episode. It was hypothesized that ST would be superior to CBT in achieving sustained change (percentage improvement on the Mongomery Asberg Depression Rating Scale (MADRS)) in depression. Secondary aims were to compare sustained change on self-report (percentage improvement on Beck Depression Inventory-II (BDI-II)) between ST and CBT and to compare the rates of remission and recovery.

Given the proposition that ST may be more effective for chronic problems and/or entrenched problems, we also examined whether or not ST would be more effective in those with chronic depression. Similarly, given that ST was initially developed for those with personality disorders, and given the equivocal treatment outcome findings when depression is comorbid with personality disorders, we examined whether or not ST would produce better outcomes for those depressed patients with a personality disorder.

2. Method

2.1. Participants

Participants (males n=31; females n=69) recruited for this study had a principal current diagnosis of major depressive disorder (DSM-IV American Psychiatric Association, 1994) and were over the age of 18 years. Participants were assessed and treated in an outpatient clinical research unit in the Department of Psychological Medicine, University of Otago, Christchurch, New Zealand. Participants were required to be free of any centrally active drug, other than an occasional hypnotic and the oral contraceptive pill for a minimum of two weeks. Exclusion criteria were a history of mania (bipolar I disorder), schizophrenia, major physical illness which would interfere with treatment, moderate or severe alcohol or drug dependence, and failure to respond to a recent (past year) adequate trial of CBT or ST. Participants were referred from general practitioners and mental health services or could self-refer. Recruitment occurred between 2004 and 2008.

2.2. Procedure

After an initial telephone screen for inclusion and exclusion criteria by a research nurse all potentially suitable participants were seen by a clinical psychologist for an initial assessment, and if suitability was confirmed, written informed consent was obtained and a baseline research assessment was scheduled.

The baseline assessment consisted of a structured clinical interview for DSM-IV Axis I disorders (SCID, Spitzer et al., 1992) conducted by a clinician and completion of self-report measures, and a neuropsychological assessment conducted by a research assistant. Following completion of the baseline assessment, participants were randomized to weekly therapy sessions of ST or CBT for six months, followed by monthly sessions for six months. The shift from weekly to monthly sessions was to continue the focus on factors maintaining the depression and/or to assist patients to maintain gains made after the weekly sessions.

This study had a parallel group design with participants being randomized in a 1:1 ratio based on computerized randomization sequence of permutated blocks of 20. The randomization procedure and allocation to treatment type was performed by a person independent from the study and was made available to the therapist and patient once the baseline assessment had been completed. While some flexibility in the number of therapy sessions was permitted to mimic usual clinical practice, the length of time treatment was available for participants in CBT and ST was matched (one year) for the comparison of outcome. An adequate dose of therapy was defined a priori as at least 15 weekly sessions and at least 3 monthly sessions.

Therapists (six clinical psychologists) provided both ST and CBT. Therapists were competent in CBT, which is a key component of professional training as a clinical psychologist in NZ. In addition, as required by their professional body, all therapists had attended CBT training to maintain competency. CBT was delivered according to Beck and Beck and colleagues' manuals (Beck et al., 1979; Beck, 1995). ST was delivered according to Young's published manuals (Young, 1990; Young and Klosko 1993; Young et al., 2003) and the week-long training workshops (involving lectures, videotape and experiential exercises) conducted by Young in NZ. Therapists were all female, had at least two years prior experience treating depressed patients, and were required to treat two patients in each modality to a satisfactory level of competence before commencing treatment of patients in the clinical trial. To ensure continued treatment fidelity, both therapist competence in delivering the two therapies and adherence to the treatment manuals, close individual and group supervision was provided. In addition, all therapy sessions were recorded, and randomly selected sessions were reviewed by the clinical supervisor using the Cognitive Therapy Rating Scale for CBT (Dobson et al. 1985) and a modified form of the CTS for ST. An adequate level of competency on the CTS is defined as a score of 40 or more. Therapists had fortnightly clinical supervision, which included close attention to treatment fidelity. During supervision particular attention was focused on any therapy session rating approaching the cutoff of 40, so overall considerable effort was made to maintain high CTS ratings for both therapies. The average CTS rating over the course of the study for CT was 47.12 (SD=7.65) and for ST was 54.4 (9.1) from the randomly selected sessions.

Personality was assessed by independent non-treating clinicians using the Structured Clinical Interview for DSM-IV personality disorders symptoms (SCID-II, First et al., 1997). Assessment using the SCID-II was guided by items previously affirmed by the patient on the Structured Clinical Interview for DSM-IV Personality Questionnaire (SCID-PQ, First et al., 1997), which was completed at baseline. Items not affirmed on the SCID-PQ were assumed to be true negatives, however if a clinician had reason to believe these were false negatives further items were assessed. This method is in accordance with instructions for using the SCID-II and enabled the assessment of personality disorder symptoms to be based upon self-report combined with a structured clinical interview. Inter-rater reliability was examined in a previous study, not this study, with the same raters assessing the presence of any personality disorder was 0.78.

2.3. Outcome

Sustained change was defined *a priori* as percentage improvement on the clinician-rated MADRS and the self-report Beck

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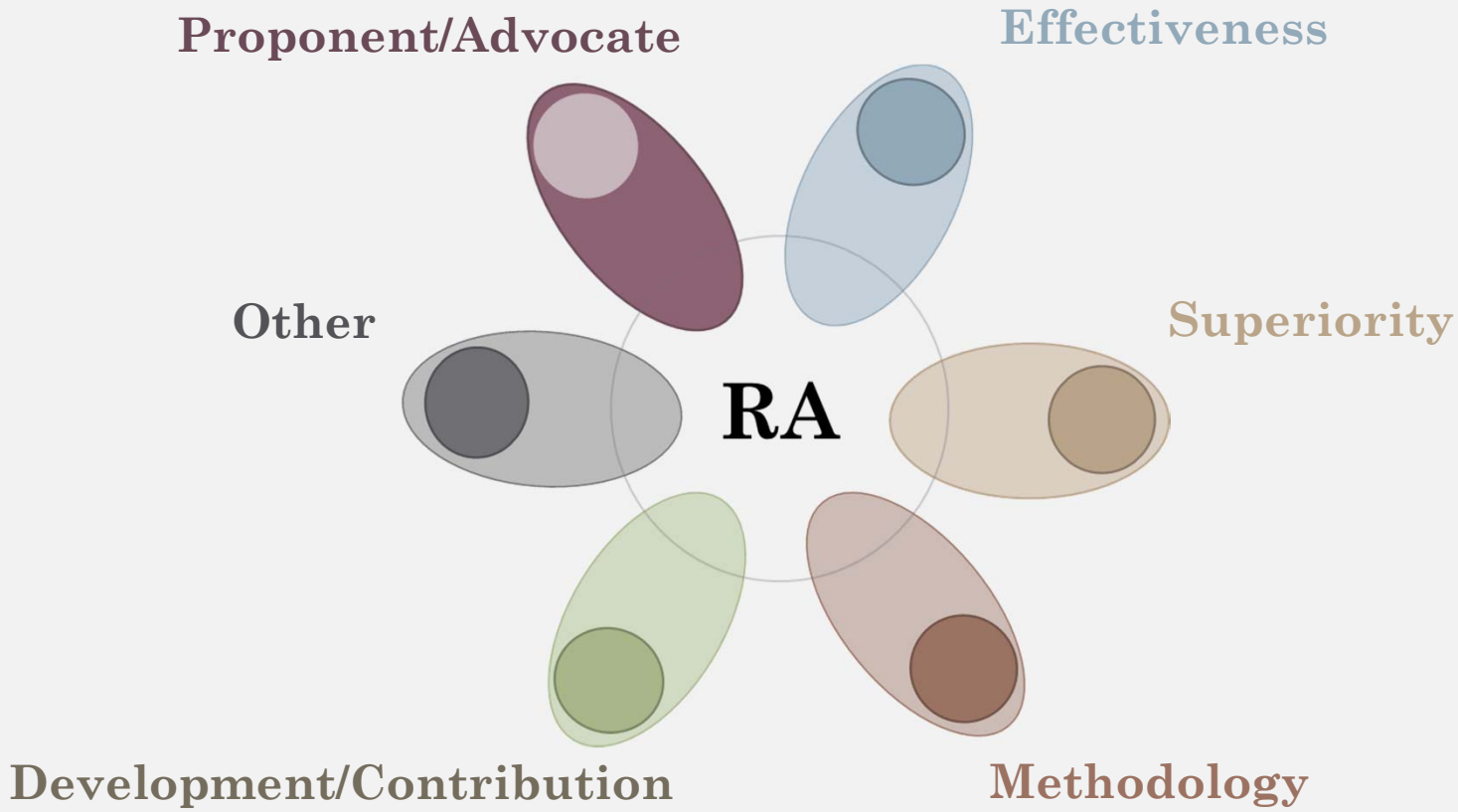

Proponent/Advocate
Effectiveness
Other
RA
Superiority
Development/Contribution
Methodology

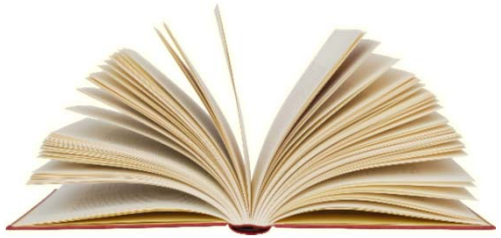
Research Aim

There is a need in the field for a **reliable** and **valid** method for assessing RA.

Develop a checklist based on common indicators of the **reprint method** that measures RA in psychotherapy trials

Validate the RA checklist by surveying authors about their career history and beliefs related to psychotherapy

Methods



Searched the literature

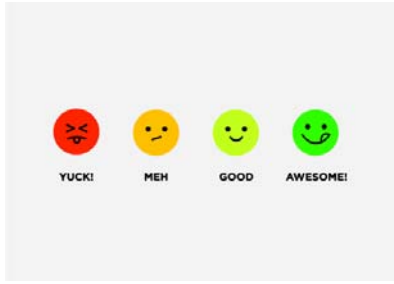
Developed and piloted RA checklist

Developed and piloted an author survey

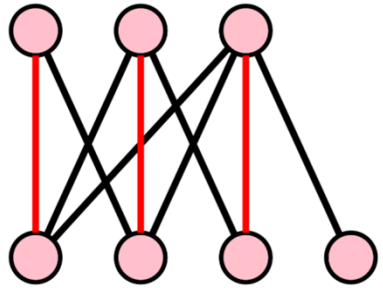
Revised checklists and author survey

Randomly selected 100 depression trials from our database (50 HTH and 50 Control)

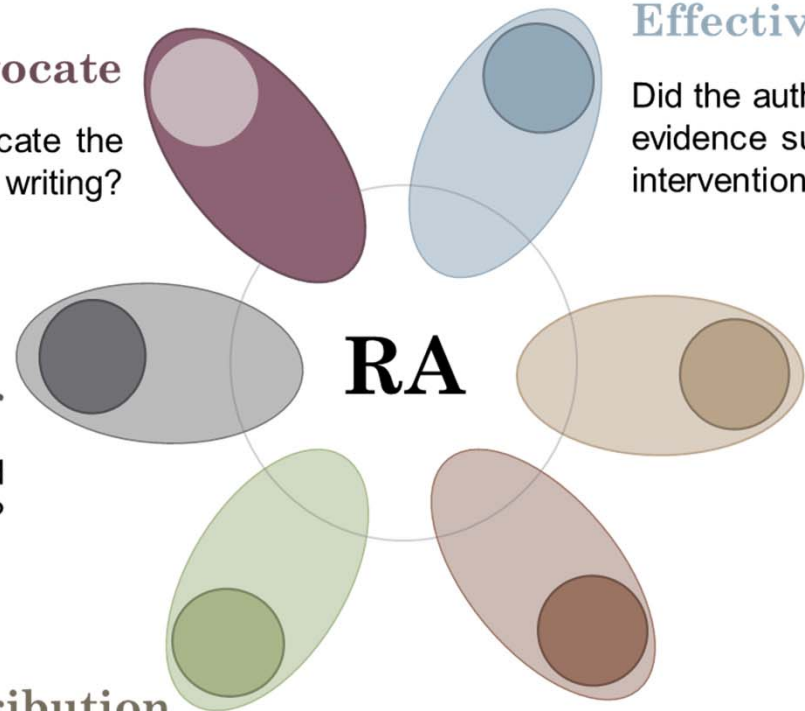
Sent author survey to 1st, 2nd, and last authors until we received 100 responses



Used RA checklist to rate papers associated with the respondent



Matched and scored author survey and RA checklist scores for analyses



Proponent/Advocate

Did the author advocate the intervention through their writing?

Effectiveness

Did the author previously publish evidence supporting the efficacy of the intervention?

Superiority

★ Did the author provide an extensive amount of information about one intervention?

★ Was there an explicit hypothesis or study aim in one direction?

Did the author refer to previous research showing superiority of one intervention?

Other

Was the intervention mentioned in the title of the paper?

Development/Contribution

Did the author develop or adapt the intervention?

Did the author contribute to an etiological model of the disorder that is consistent with the intervention?

Methodology

Was the author involved in supervision/training of therapists

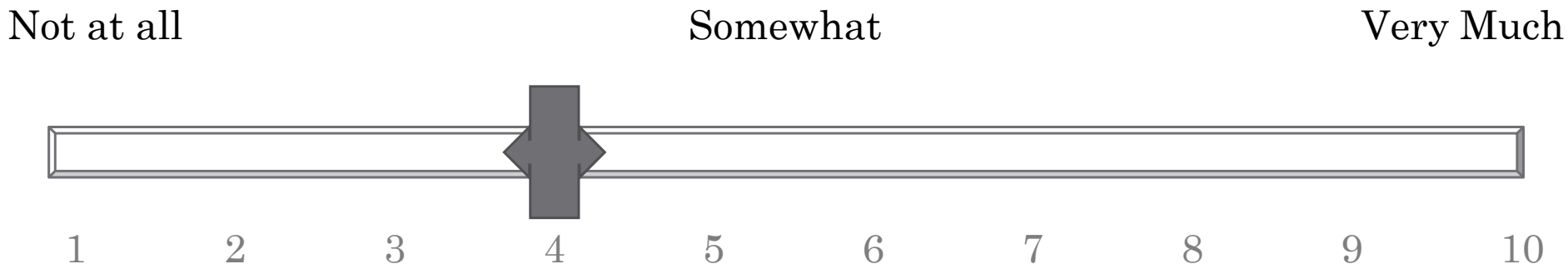
Did the author take on the role as a therapist?

★ Was it explicitly stated that the intervention was used as a credible control/minimal therapy?

Author Survey

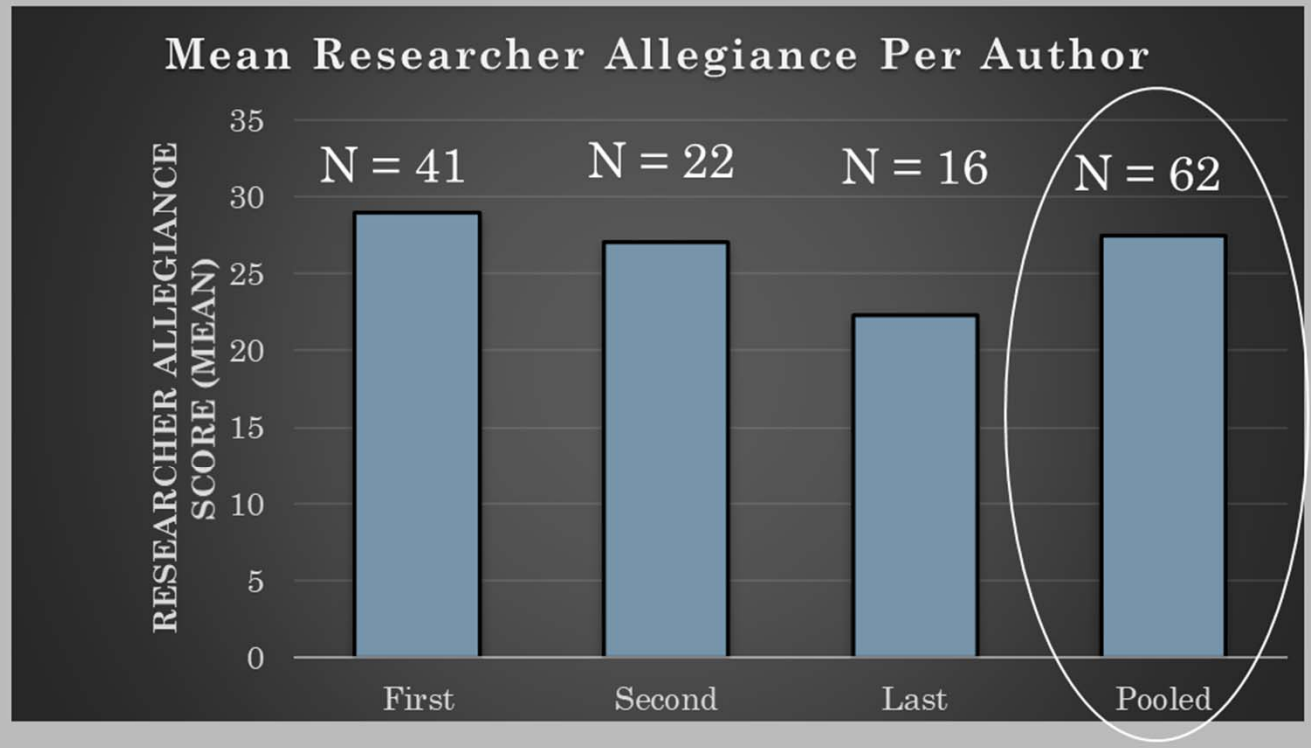
To what extent do you believe each of the following interventions are **EFFECTIVE** in the treatment of **depression**?

Cognitive Behavioral Therapy

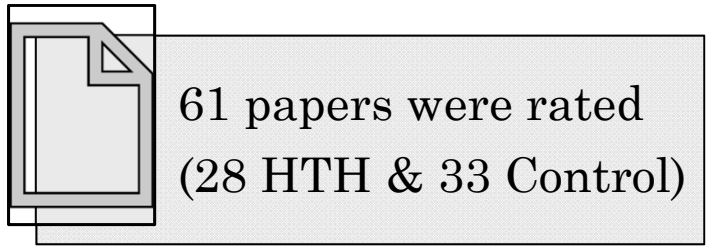


Author Survey

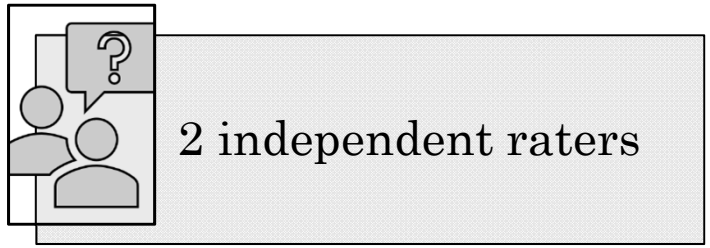
When more than one author responded to the survey, we took the **average** of their scores



Rating Depression Studies

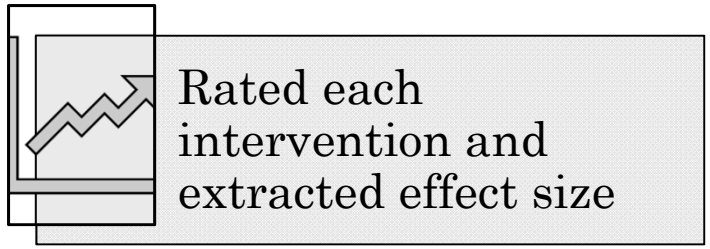


61 papers were rated
(28 HTH & 33 Control)



2 independent raters

Raters were blinded to results



Rated each intervention and extracted effect size

	Intervention A CBT	Intervention B IPT
1	1	0
2	1	1
3	0	0
4	0	0
5	0	0
6	1	0
7	1	1
8	0	0
9	1	1
10	1	0
11	0	1
SUM	6	4

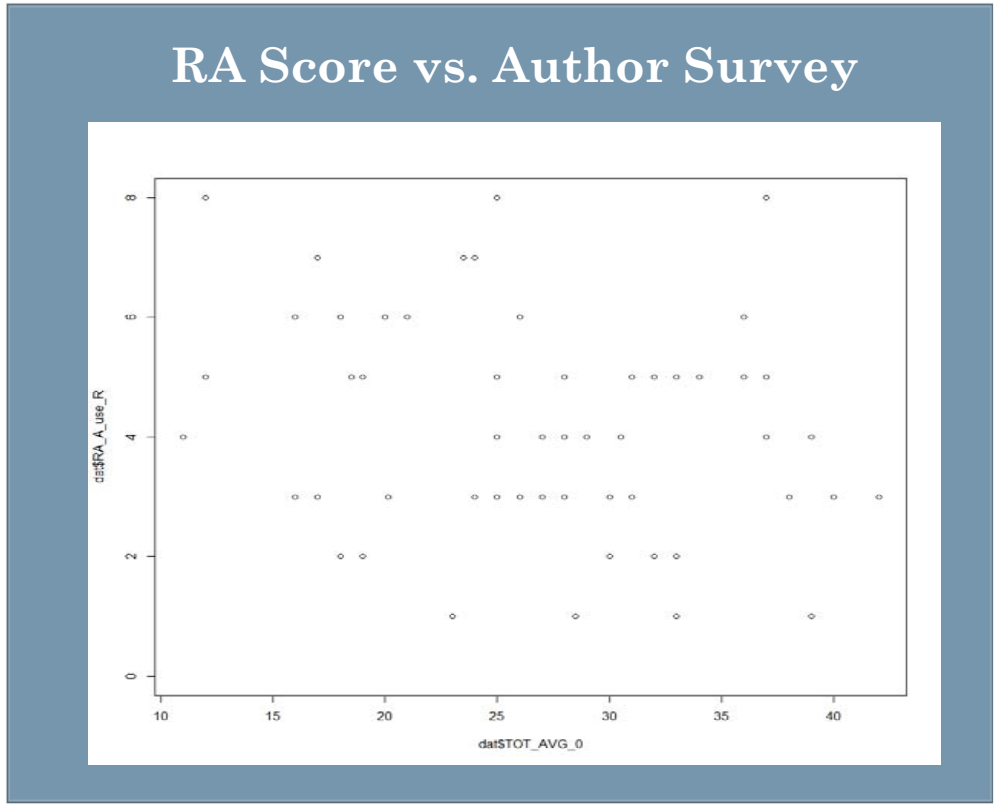
Researcher allegiance towards Intervention A

RA = 2

Difference

Validation Results

	Checklist	Survey	Effect Size
Checklist	-	**-0.24**	0.28*
Survey	-	-	0.30*
Effect Size	-	-	-



What came first?
The chicken or the egg?

Conclusion

The chicken or the egg problem

It remains unclear as to how positive trial results influence the presence of these common indicators of RA in a published paper.

Bias

In this case, the reprint method may lead to the identification of RA for whichever of the interventions had been found to be superior in the study (Leykin & DeRubeis, 2009)

Debunked?

We did not find a relationship between the author survey and the reprint method. Is this a valid measure which should continue to be used?




Thank you!

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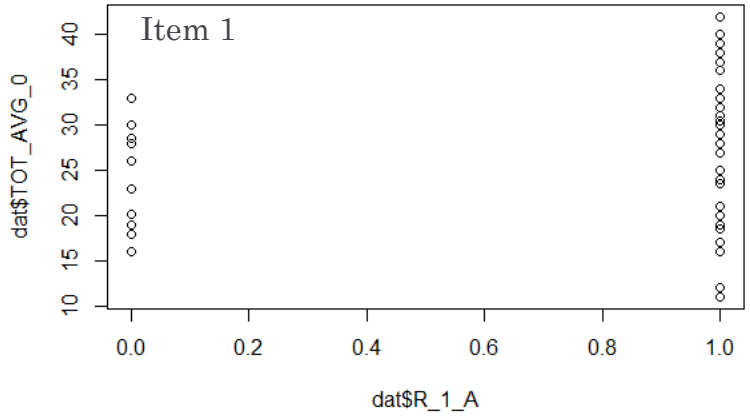
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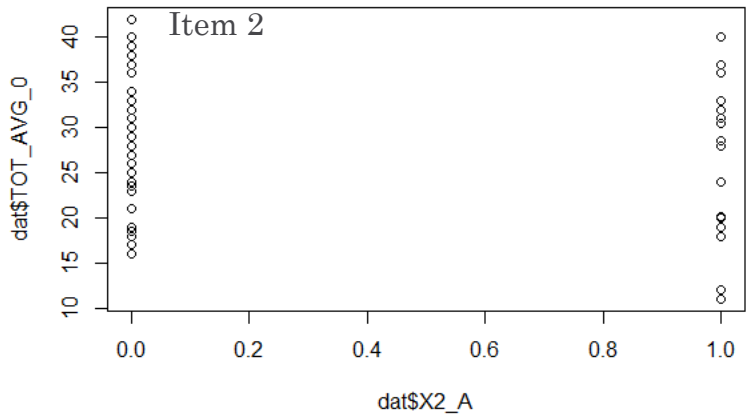
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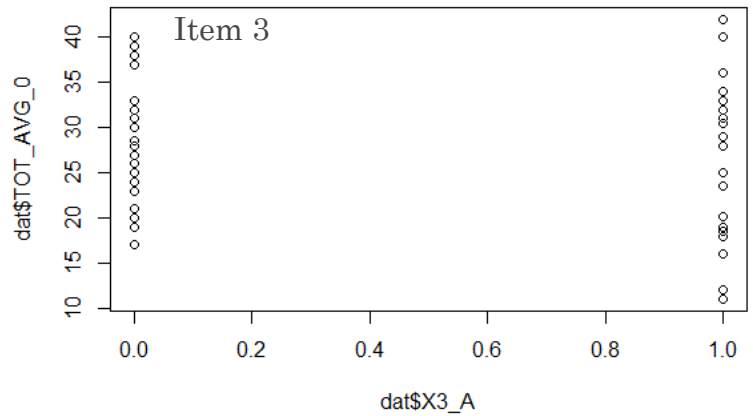
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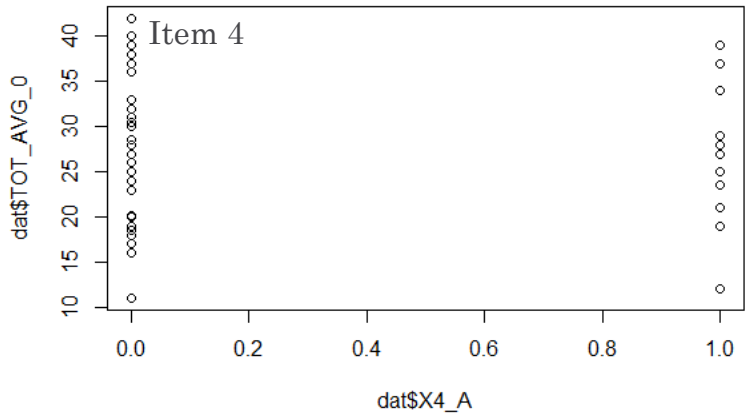
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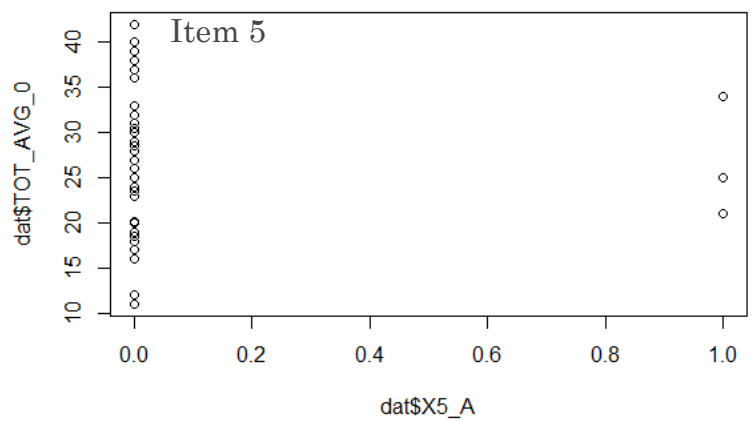
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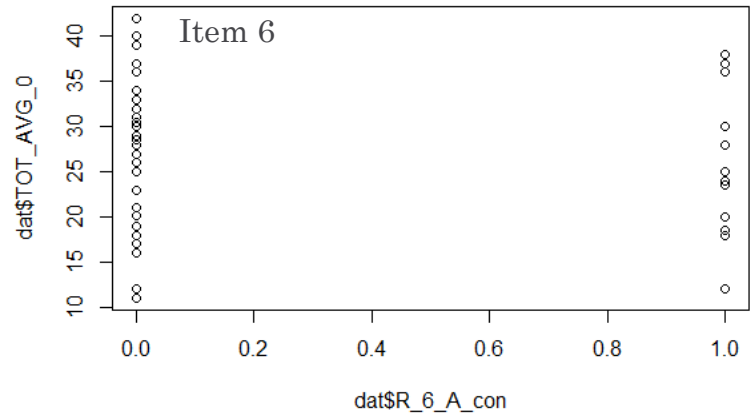
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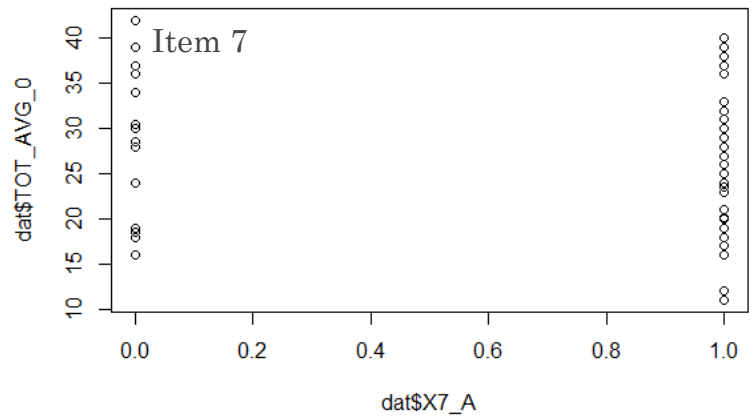
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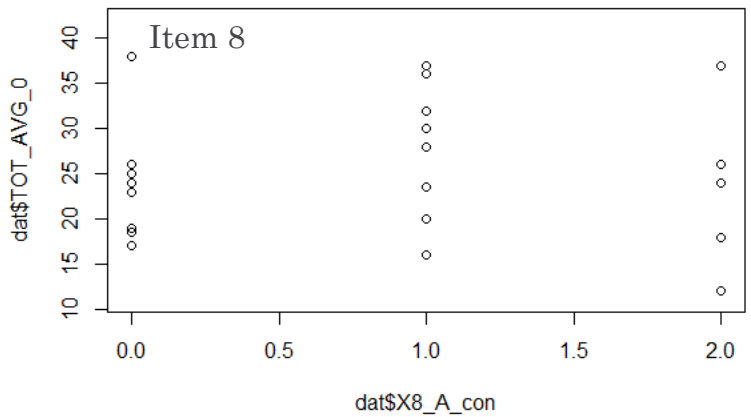
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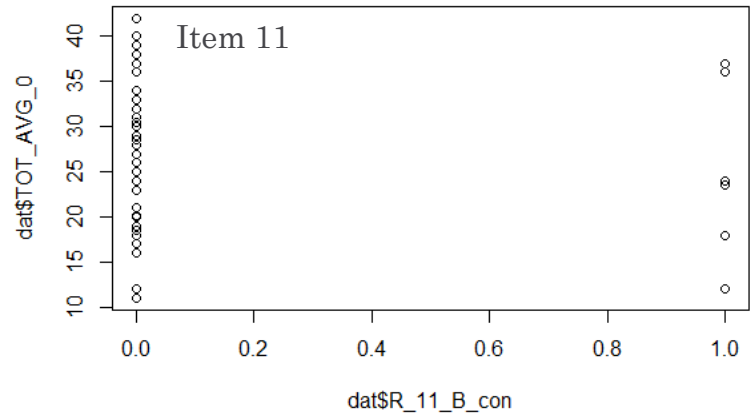

Item 11
dat$TOT_AVG_0
dat$R_11_B_con

RA items

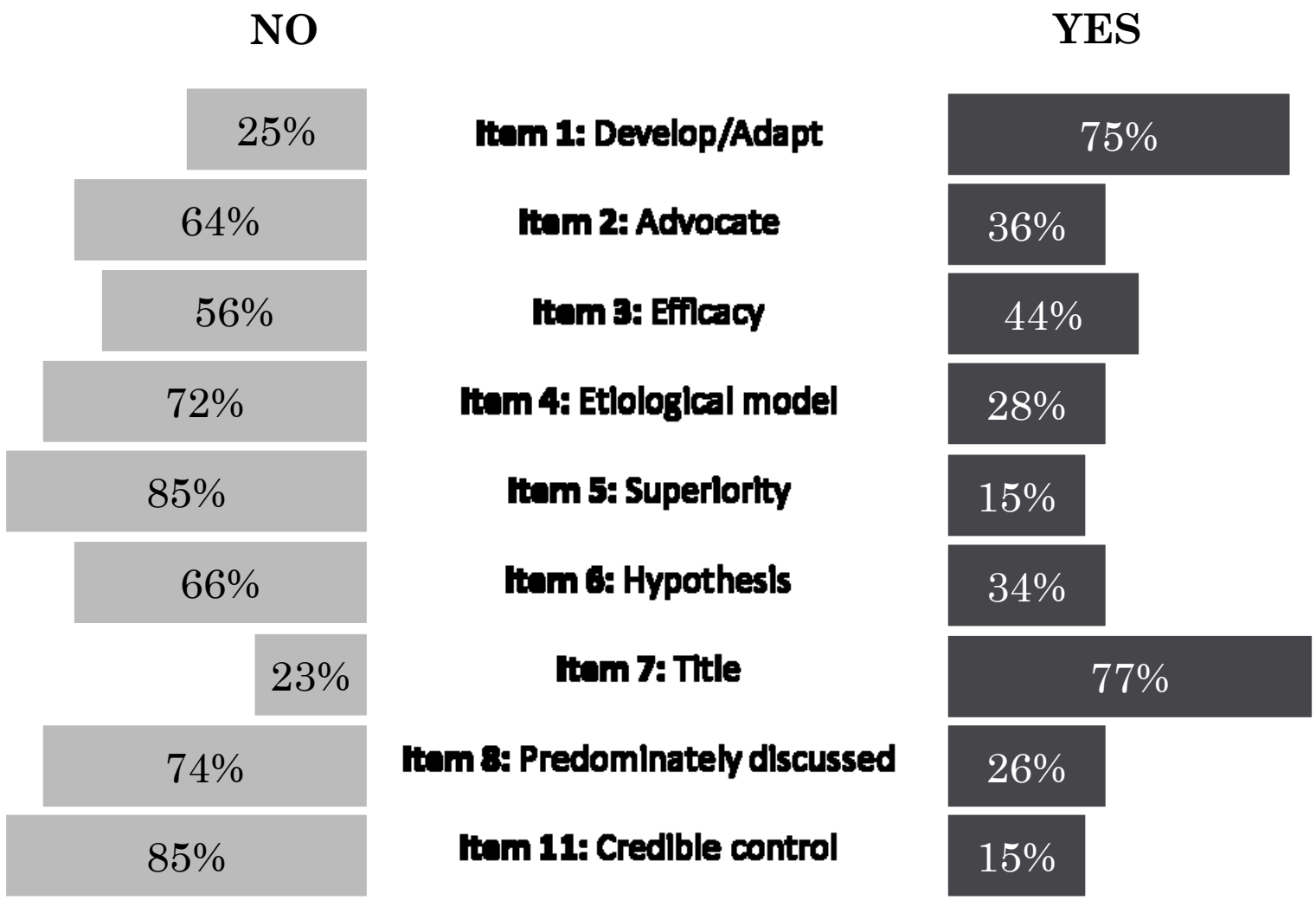
- Problem items that included many **"not reported"** and **"not applicable"** answers
  - Item 9: **Did the author participate in training/supervision?**
  - Item 10: **Did the author take the role of a therapist**

- NA was recoded to zero
- NR was kept as NR to avoid assumption

	No	Yes	NR
Item 9	10	20	32
Item 10	9	7	46

Decided to exclude these items from analysis

RA items (intervention A; n = 61)



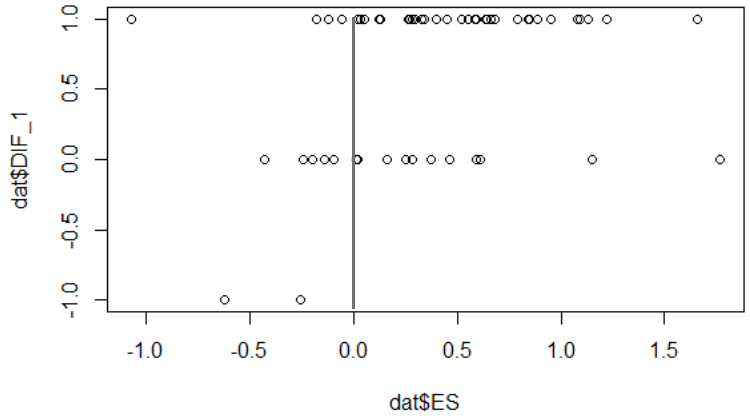
Interitem correlations

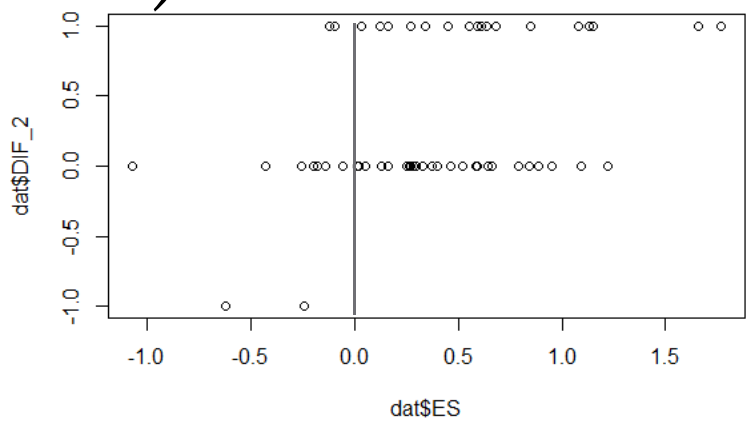
	1	2	3	4	5	6	7	8	11
1	1.00								
2	0.19	1.00							
3	0.36*	0.29*	1.00						
4	0.27*	0.14	0.18	1.00					
5	-0.08	-0.12	0.09	0.26*	1.00				
6	0.01	0.11	0.05	0.01	-0.01	1.00			
7	0.14	0.17	-0.06	0.17	0.01	-0.18	1.00		
8	0.08	0.02	0.07	0.13	0.17	0.59*	-0.12	1.00	
11	0.24+	0.07	0.28*	0.15	-0.04	0.48*	-0.10	0.59*	1.00

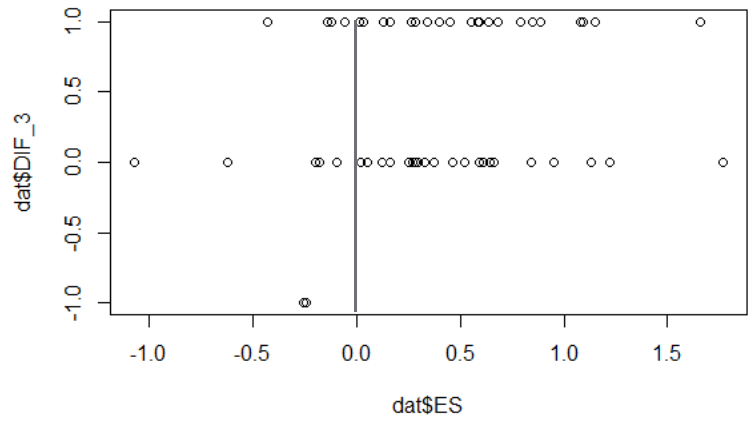
* $p \leq 0.05$, + $p \leq 0.1$

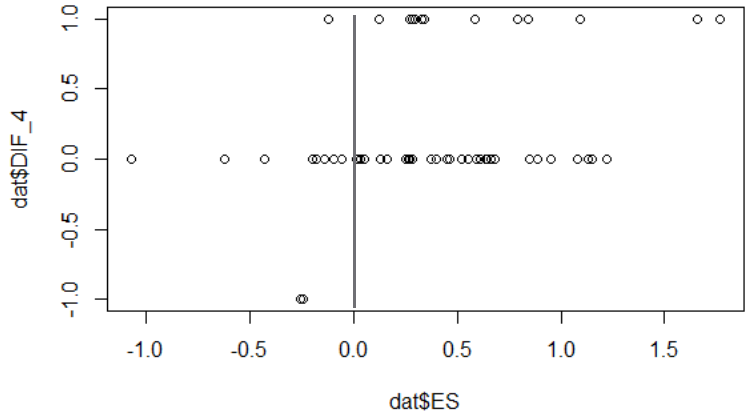
1 = Develop/Adapt
2 = Advocates
3 = Efficacy
4 = Etiological model
5 = Superiority
6 = Hypothesis
7 = Title
8 = Predominately discussed
11 = Credible control

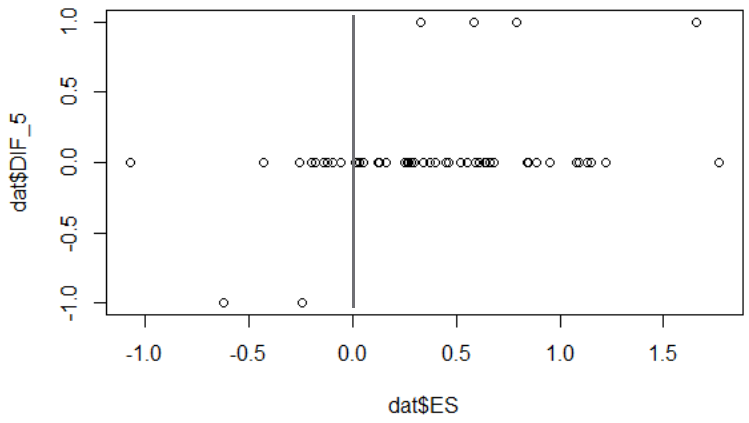
Checklist Items (DIF) vs. ES

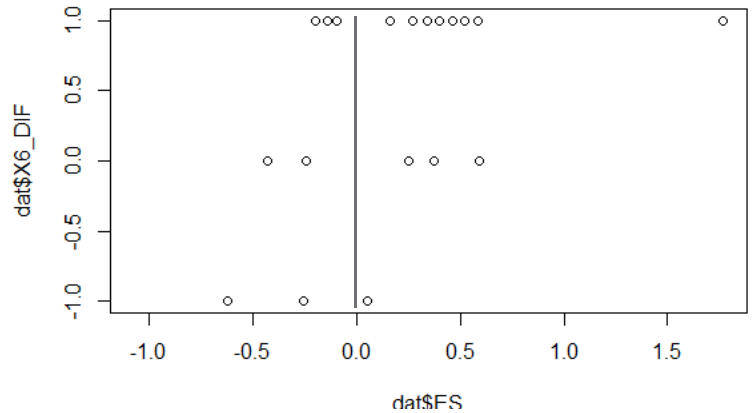


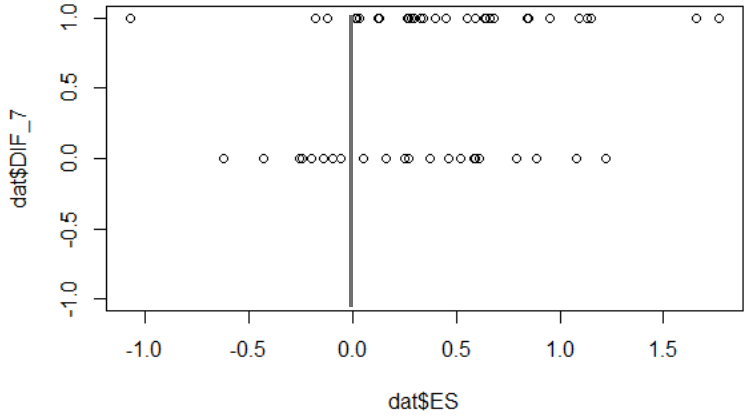


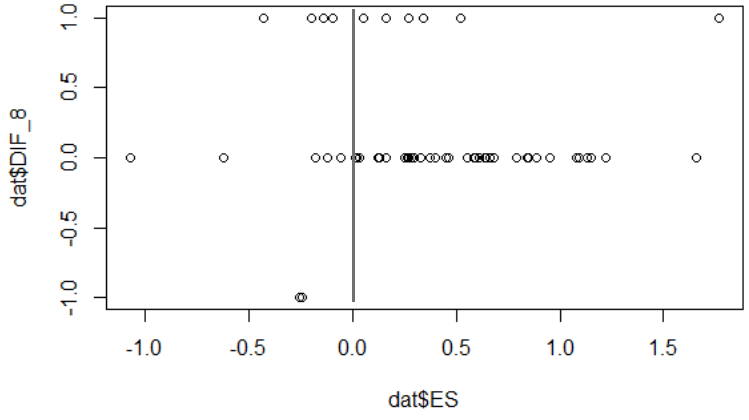


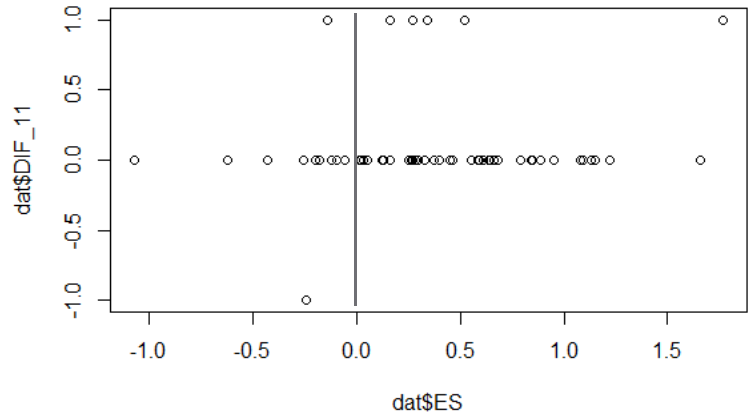




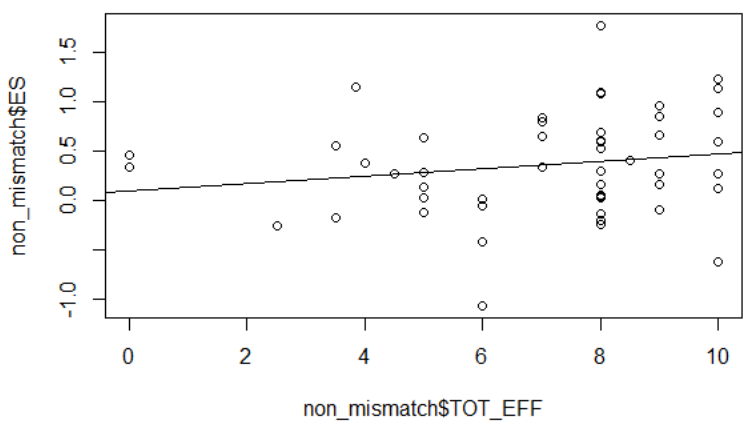


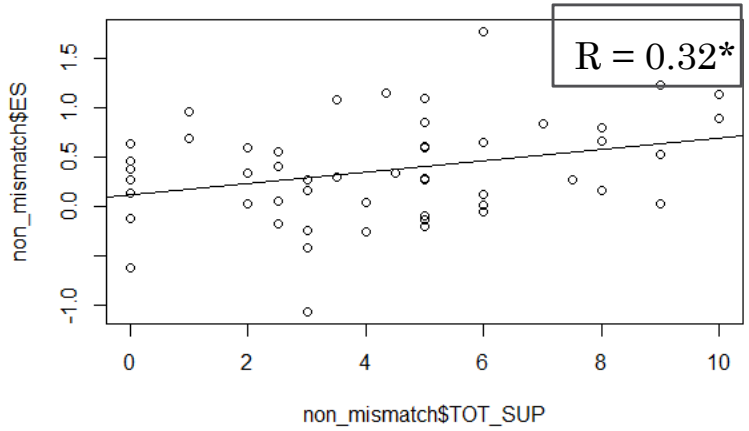


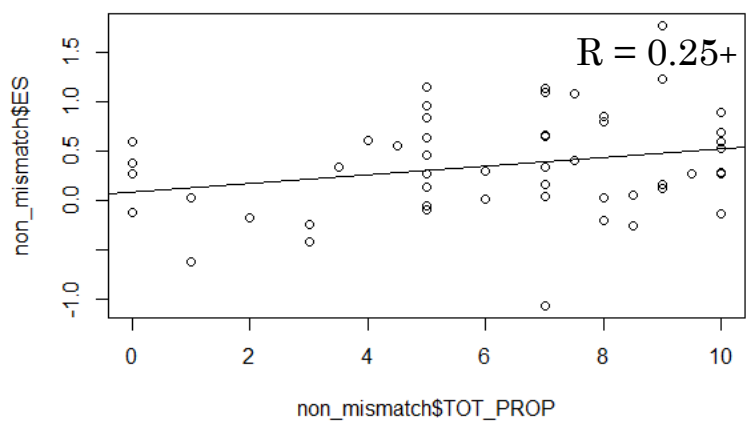


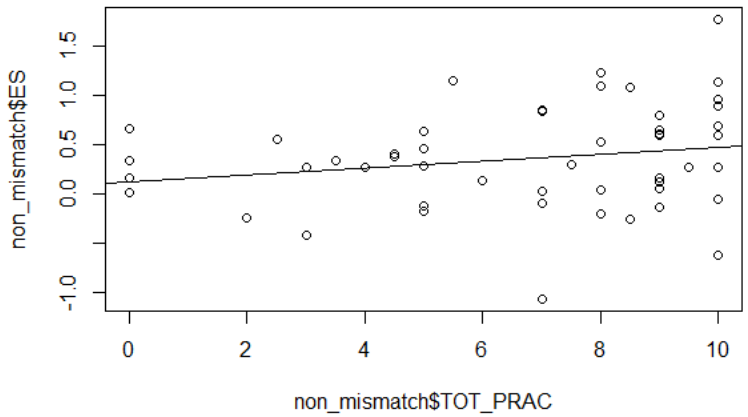


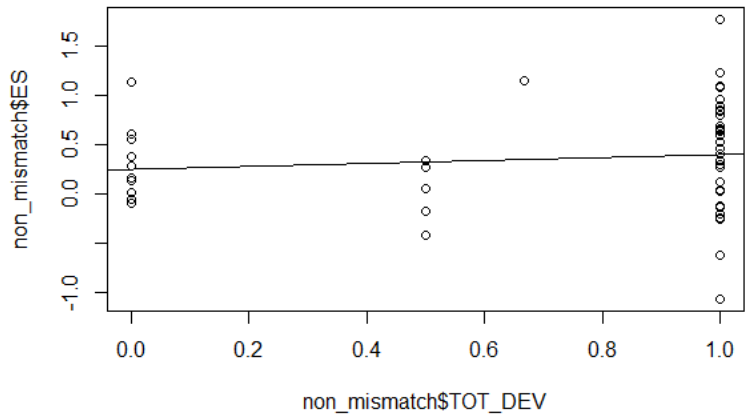
Exploration: Author Responses vs ES

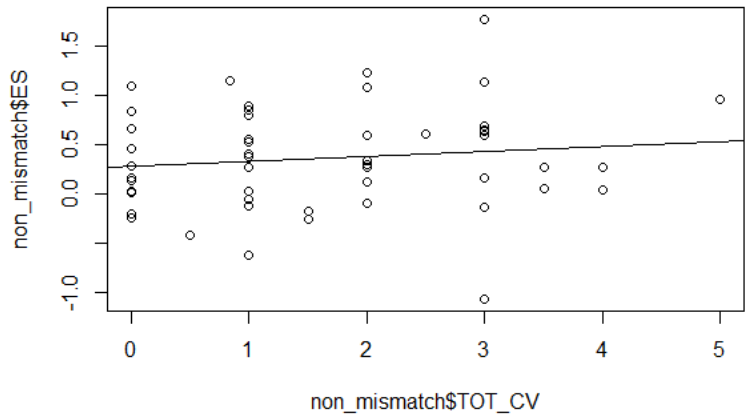




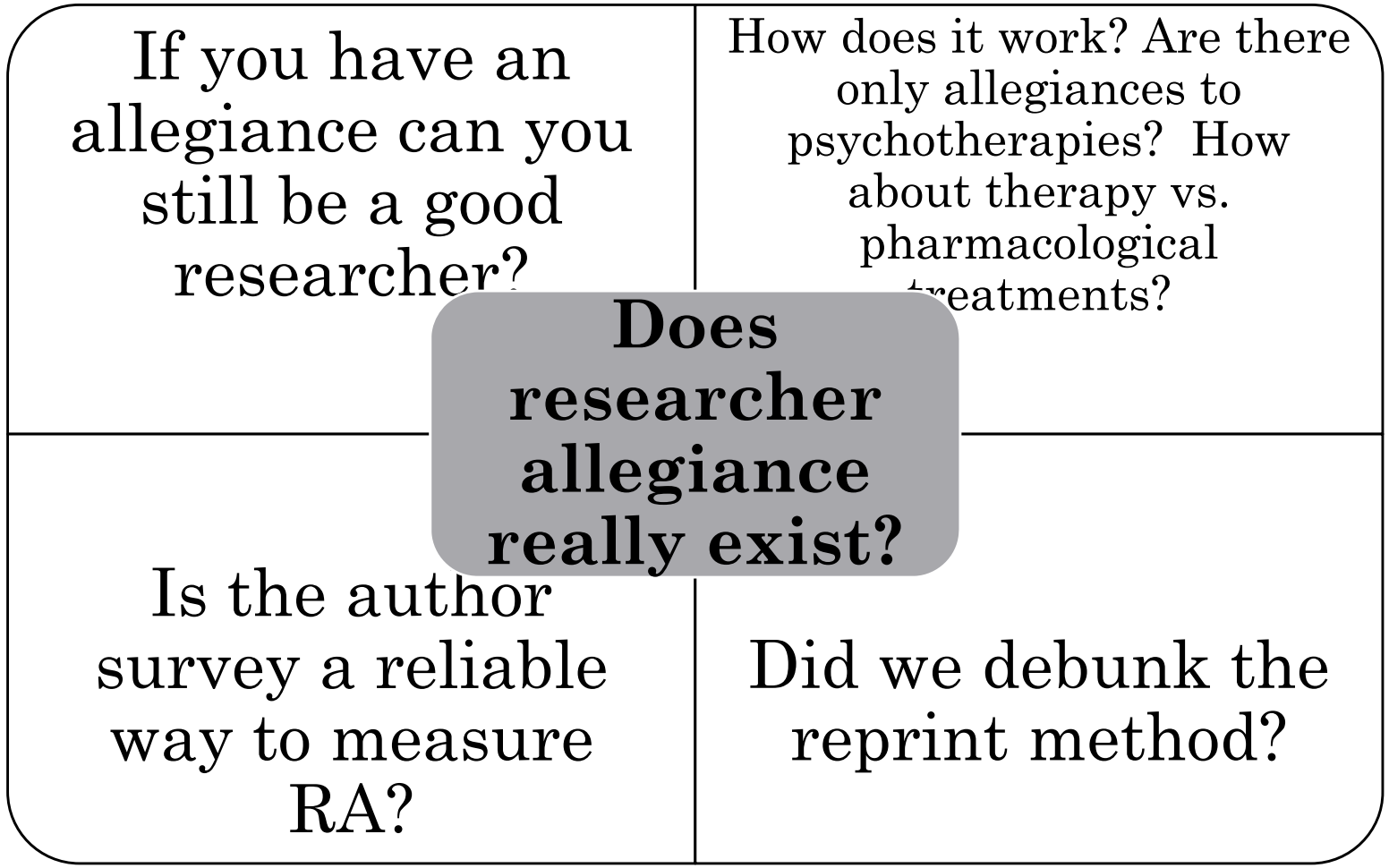








Overall Discussion points



Author Survey (n = 78)

1. There are two ways to participate in this survey:

- 53% — Send CV
- 47% — Answer few more questions

2. What is the field you most identify with? (select all that apply)

- N = 50 — Clinical/health/counseling
- N = 29 — Psychiatry/other medical field
- N = 5 — Statistics/epidemiology
- N = 6 — Other (related to psychology
- N = 1 — Other (not related to psychology)

3. Which of the following schools of psychotherapy do you most identify with? (select all that apply)

- N = 63 — Cognitive and Behavioral Therapies
- N = 26 — Third Wave Psychotherapies
- N = 16 — Psychoanalytical/Psychodynamic Therapy
- N = 5 — Client-Centered Therapy/Gestalt Therapy
- N = 12 — Interpersonal Psychotherapy
- N = 2 — Systems Therapy
- N = 8 — Other _____
- N = 3 — None

4. Which of the following psychological disorders do you focus your research and/or clinical efforts on? (select all that apply)

- N = 78 — Depression Disorders
- N = 39 — Anxiety Disorders
- N = 3 — None

Author Survey (cont.)

Category	Question
Effectiveness	1.To what extent do you believe each of the following interventions are **effective** in the treatment of depression? (Not at all, somewhat, very much)
Superiority	2. To what extent do you believe each of the following interventions to be **more effective** than other psychotherapies in the treatment of depression? (Not at all, somewhat, very much)
Proponent/ Advocate	3. To what extent do you identify yourself as a **proponent** of each of the following interventions for the treatment of depression? (Not at all, somewhat, very much)
Proponent/ Advocate	4. If you ever **practiced** psychotherapy during your career, how often do/did you use each of the following interventions for the treatment of depression (when appropriate)? (Never, sometimes, always, NA)
Contribution/ Development	5. Have you **developed or contributed to the development** of any of the following interventions for the treatment of depression? (yes, no)
Contribution/ Development	6. Can you please provide a **brief explanation** about how you contributed to the development of the intervention(s) selected?

Author Survey (cont.)

Additional CV questions
Do you have a **patent or copyright** related to the any of the following treatments for depression (or have you ever applied for one)? (yes, no)
Have you received **extensive training or supervision** in any of the following psychotherapies for the treatment of depression? (yes, no)
Have you ever **trained therapists** or **taught courses/workshops** on any of the following interventions for the treatment of depression? (yes, no)
Have you ever **supervised therapists** in any of the following interventions for the treatment of depression? (yes, no)
Have you ever/do you currently serve on a **board of directors as a coordinator or committee chair** of a professional society related to any of the following psychotherapies? (yes, no)

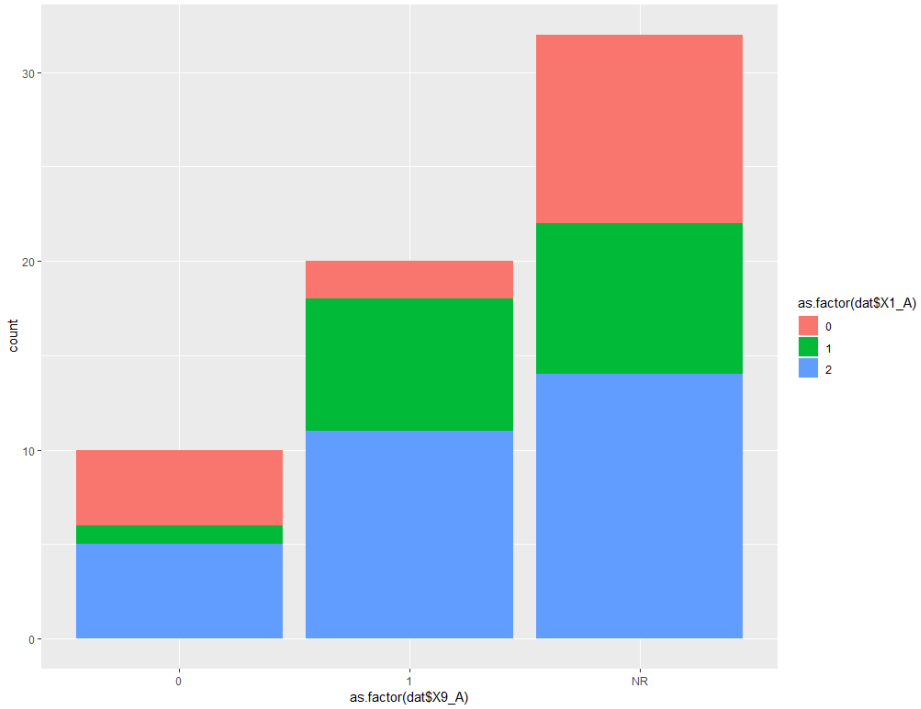
Frequencies

	RA_A	RA_B	RA_DIF
Min	0	0	-3.00
Max	7	5	6.00
Median	3	0	3
Mean	3.4	0.7	2.64

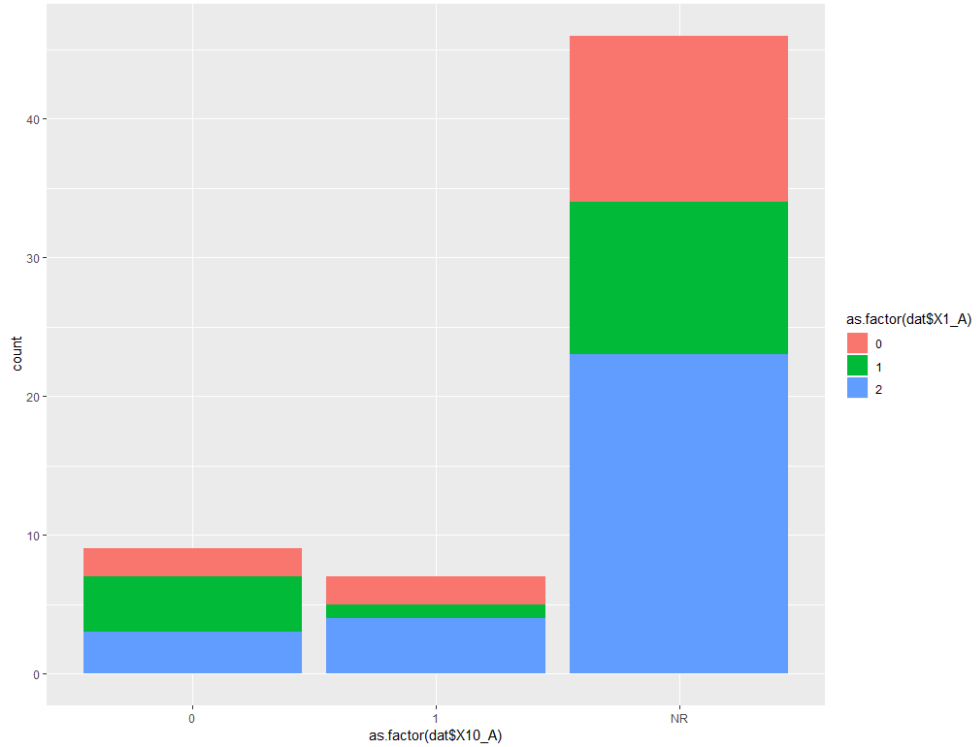
Items 9 & 10 (cont.)

Since this would be excluded from our analysis due to lack of information, we wanted to understand if there were any differences between these groups and their relationship to development of the scale and/or ES.

Item 9



Item 10

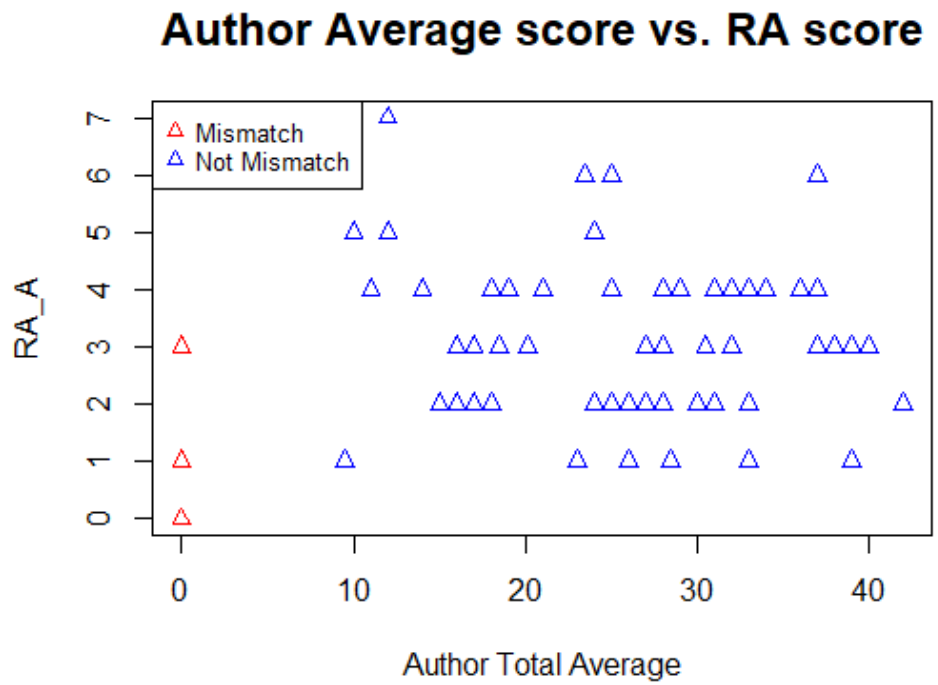


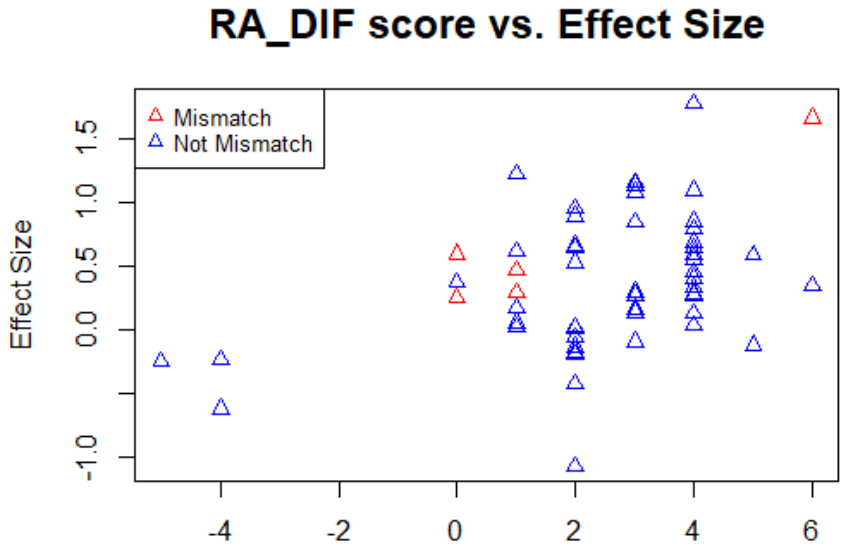
Mismatch data

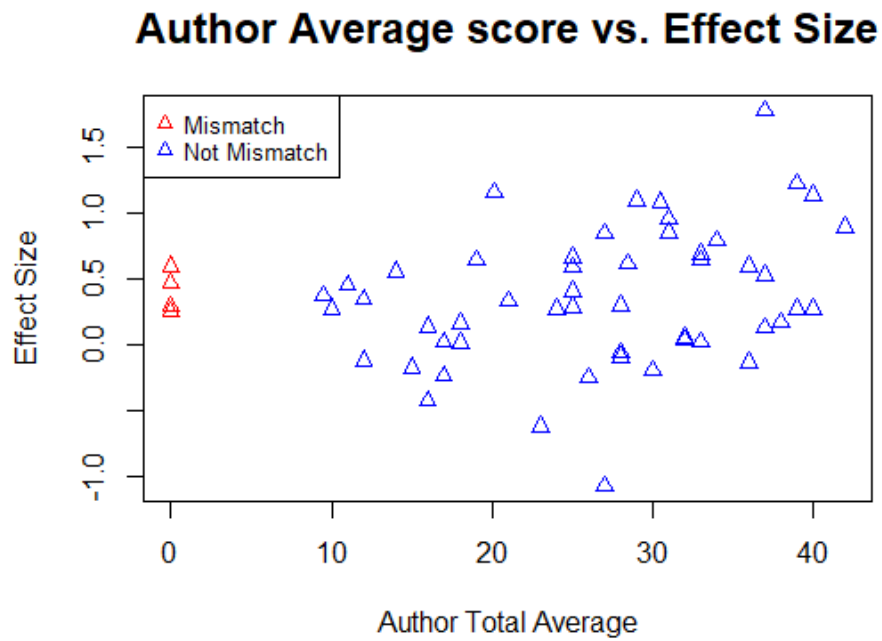
- - 7 studies with mismatch data
- - Exclude or assume survey score to be 0?

	Intervention A	Category A	Intervention B	Category B	Comparison	AUT_1	1_MIS	AUT_2	2_MIS	AUT_3	3_MIS
1	Adaptation of the coping with stress program	CBT	Control: TAU	TAU	Control	1	N	2	N	-	-
2	Automated depression internet training program (ITP)	OTH (CBT/IPT)	Internet support group (ISG)	OTH	HTH	1	N	-	-	3	N
3	Skills training	OTH	Control: TAU	TAU	Control	-	-	-	-	3	Y
4	Mothers' and babies' course	CBT	Control: TAU	TAU	Control	-	N	2	N	-	-
5	Self-help emails: mood memos	OTH	Control: control emails	OTH	Control	1	Y	-		-	-
6	Manualized individualized i-CBT	CBT	Control: TAU	TAU	Control	-		2	N	-	-
7	Therapist delivered cognitive behavioral therapy session (CB-education)	CBT	CBM	OTH	HTH	-	-	-	-	3	N
8	Alles Onder Controle AOC-TR	CBT	Control (wait-list)	WL	Control	1	N	-	-	-	-

Mismatch data (cont.)







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