NKR 58 PICO 5c Unified Protocol for generaliseret angst

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Barlow 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Mean age in years (SD)*: 31.0 (11.6) ● *Number of females (%)*: 48 (54.5) Control ● *Mean age in years (SD)*: 30.4 (10.0) ● *Number of females (%)*: 51 (56%) **Included criteria:** Individuals were eligible for the study if they were (1) assigned a principal (most interfering and severe) diagnosis of panic disorder with or without agoraphobia (PD/A), generalized anxiety disorder, obsessive-compulsive disorder (OCD), or social anxiety disorder; (2) 18 years or older; and (3) fluent in English. Following long-standing procedures in our clinical trials, individuals taking psychotropic medications at the time of enrollment were required to be stable on the same dose for at least 6 weeks prior to enrolling in the study and were requested to maintain these medications and dosages during treatment. **Excluded criteria:** Exclusion criteria consisted primarily of conditions that required prioritization for immediate or simultaneous treatment: specifically, a current diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, or organic mental disorder; current high risk of suicide; or recent (within 3 months) history of substance use disorder, with the exception of nicotine (1 patient), marijuana (0 patients), and caffeine (0 patients). Individuals were also excluded if they received at least 8 sessions of cognitive behavioral therapy within the past 5 years. Anyone receiving non-cognitive behavioral therapy focused on an emotional disorder agreed to discontinue that treatment **Pretreatment:** No baseline differences in demografic and diagnostic baseline charateristics

Interventions	**Intervention Characteristics** Intervention ● *Description*: Unified Protocol (UP). The UP contains strategies similar to those in the SDPs, including cognitive reappraisal and exposure, but the focus is on there actions to the experience of emotion itself, such as autonomic arousal, rather than situational factors, such as crowds.The UP consists of the following 5 core treatment modules: (1) mindful emotion awareness, (2) cognitive flexibility, (3) identifying and preventing patterns of emotion avoidance, (4) increasing awareness and tolerance of emotion-related physical sensations, and (5) interoceptive and situational emotion-focused exposures. The 5 core modules are preceded by a module focused on enhancing motivation as well as an introductory module on the adaptive nature of emotions that provides a framework for understanding emotional experiences situational emotion-focused exposures. The 5 core modules are preceded by a module focused on enhancing motivationas well as an introductory module on the adaptive nature of emotions that provides a framework for understanding emotional experiences ● *Dose*: Patients with a principal diagnosis of social anxiety disorder, generalized anxiety disorder, or OCD received 16 sessions of treatment and patients with a principal diagnosis of PD/A received 12 sessions. Treatment sessions were approximately 50 to 60 minutes. ● *Duration*: 16-21 weeks Control ● *Description*: Standard cognitive behavioral therapy for each disorder: Single-Disorder Protocols (SDP). The SDPs included: Managing Social Anxiety: A Cognitive-Behavioral Therapy Approach. Mastery of Your Anxiety and Panic Mastery of Your Anxiety and Worry andTreating Your Obsessive-Compulsive Disorder With Exposure and Response (Ritual) Prevention Therapy As recommended by the protocol developers, patients with a principal diagnosis of social anxiety disorder, generalized anxiety disorder, or OCD received 16 sessions of treatment and patientswith a principal diagnosis of PD/A received 12 sessions. Treatment sessions were approximately 50 to 60 minutes, except for patients with a principal diagnosis of OCD, for whom treatment sessions were 80 to 90 minutes. ● *Dose*: Patients with a principal diagnosis of social anxiety disorder, generalized anxiety disorder, or OCD received 16 sessions of treatment and patients with a principal diagnosis of PD/A received 12 sessions. Treatment sessions were approximately 50 to 60 minutes. ● *Duration*: 16-21 weeks
Outcomes	*Grad af angst, HAM-A, mean final, SD, alle angstlidelser* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: HAM-A ● **Range**: 0-56 ● **Direction**: Lower is better ● **Data value**: Endpoint *Grad af angst, GAD ADIS CSR, mean change, 95% CI, kun GAD patienter* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: GAD ADIS CSR ● **Direction**: Lower is better ● **Data value**: Change from baseline *Grad af angst, Generalized Anxiety Disorder Severioty Scale (GADSS), mean change, 95% CI, Kun GAD patienter* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported

	● **Scale**: Generalized Anxiety Disorder Severioty Scale (GADSS) ● **Data value**: Change from baseline *Funktion, The overall anxiety severity and impairment scale, mean (SD), alle angstlidelser* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: The overall anxiety severity and impairment scale ● **Range**: 0-20 ● **Direction**: Lower is better ● **Data value**: Endpoint *Funktion, The Work and Social adjustment Scale, mean, SD, alle angstlidelser* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: The Work and Social adjustment Scale ● **Range**: 0-40 ● **Direction**: Lower is better ● **Data value**: Endpoint *Bedring, number of patients no longer meeting diagnostic criteria at ADIS* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Scale**: Anxiety Disorder Interwiev Schedule (ADIS) ● **Direction**: Higher is better ● **Data value**: Endpoint *Fraflad, alle årsager* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** This study was funded by grant R01 MH090053 from the National Institute of Mental Health. **Country:** USA **Setting:** Outpatient clinic **Authors name:** David H. Barlow **Institution:** Center for Anxiety and Related Disorders, Boston University **Email:** dhbarlow@bu.edu **Address:** David H. Barlow, PhD, Center for Anxiety and Related Disorders, Boston University, 648 Beacon St, Sixth Floor, Boston, MA 02215
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "a research assistant who was not involved in those evaluations randomized patients by principal diagnosis (PD/A, generalized anxiety disorder, OCD, and social anxiety disorder) using a computerized block randomization with a 2:2:1 allocation ratio to the UP, SDP, and WLC study conditions, respectively." Judgement Comment: The allocation sequence was computer generated
Allocation concealment (selection bias)	Low risk	Quote: "The project coordinator (T.J.F.) who was re-sponsible for final determination of study eligibility was blinded to the randomization sequence." Judgement Comment: The allocation sequence was concealed for the project coordinator enrolling the participants
Blinding of participants and personnel (performance bias)	High risk	Quote: "Participants were unaware of the study hyopothesis and were instructed not to reveal their randomization status to raters prior to each assessment. To further protect blinding, raters were located separately from therapists and a new rater was assigned in the event of an unintentional unblinding." Judgement Comment: The participants were unaware of the study hyopothesis, thus the researchers tried to blind the participants receiving the two active interventions. Personels not blinded. Project coordinator likely blinded and participants unaware of study hypotheses and instructed not to reveal allocation to blinded assessors.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Participants were unaware of the study hyopothesis and were instructed not to reveal their randomization status to raters prior to each assessment. To further protect blinding, raters were located separately from therapists and a new rater was assigned in the event of an unintentional unblinding." Judgement Comment: Participants unaware of study hypotheses and instructed not to reveal allocation to blinded assessors. The Work and Social adjustment Scale and The overall anxiety severity and impairment scale were self-reported. HAM-A, ADIS were clinician rated. CGI was clinician rated. Diagnosis specific outcomes GADSS og LSAS were clinician rated.
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "analyses were conducted with Mplus 7.2 47 on the intent- to-treat sample that included all randomized patients (ie, 88 patients for the UP, 91 for the SDP, and 44 for the WLC condition). Missing data were accommodated using multiple imputation (10 000 imputed data sets) and robust maximum likelihood methods under a missing at random assumption." Judgement Comment: 12,5% (UP) vs 30% (SDP) did not complete treatment as randomized. Balanced incomplete posttreatment assessment between groups. Appropriate ITT analysis but with possible moderate risk of attrition bias.
Selective reporting (reporting bias)	Low risk	Quote: "clinicaltrials.gov Identifier: NCT01243606" Judgement Comment: Protocol available, the study reports on all the pre-specified outcomes
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Footnotes

Characteristics of excluded studies

Ellard 2017

Reason for exclusion	Wrong comparator

Farchione 2012

Reason for exclusion	Wrong comparator

Mennin 2007

Reason for exclusion	Wrong study design

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Barlow 2017

Barlow, D. H.; Farchione, T. J.; Bullis, J. R.; Gallagher, M. W.; Murray-Latin, H.; Sauer-Zavala, S.; Bentley, K. H.; Thompson-Hollands, J.; Conklin, L. R.; Boswell, J. F.; Ametaj, A.; Carl, J. R.; Boettcher, H. T.; Cassiello-Robbins, C.. The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders Compared With Diagnosis-Specific Protocols for Anxiety Disorders: A Randomized Clinical Trial. JAMA psychiatry 2017;74(9):875-884. [DOI: 10.1001/jamapsychiatry.2017.2164 [doi]]

Excluded studies

Ellard 2017

Ellard, K. K.; Bernstein, E. E.; Hearing, C.; Baek, J. H.; Sylvia, L. G.; Nierenberg, A. A.; Barlow, D. H.; Deckersbach, T.. Transdiagnostic treatment of bipolar disorder and comorbid anxiety using the Unified Protocol for Emotional Disorders: A pilot feasibility and acceptability trial. Journal of affective disorders 2017;219(Journal Article):209-221Netherlands Elsevier B.V 2017.

Farchione 2012

Farchione, T. J.; Fairholme, C. P.; Ellard, K. K.; Boisseau, C. L.; Thompson-Hollands, J.; Carl, J. R.; Gallagher, M. W.; Barlow, D. H.. Unified protocol for transdiagnostic treatment of emotional disorders: a randomized controlled trialBehavior therapy. 2012;43(3):666-678England . Published by Elsevier Ltd 2012.

Mennin 2007

Mennin, D. S.; Holaway, R. M.; Fresco, D. M.; Moore, M. T.; Heimberg, R. G.. Delineating components of emotion and its dysregulation in anxiety and mood psychopathology. Behavior therapy 2007;38(3):284-302. [DOI: S0005-7894(07)00020-2 [pii]]

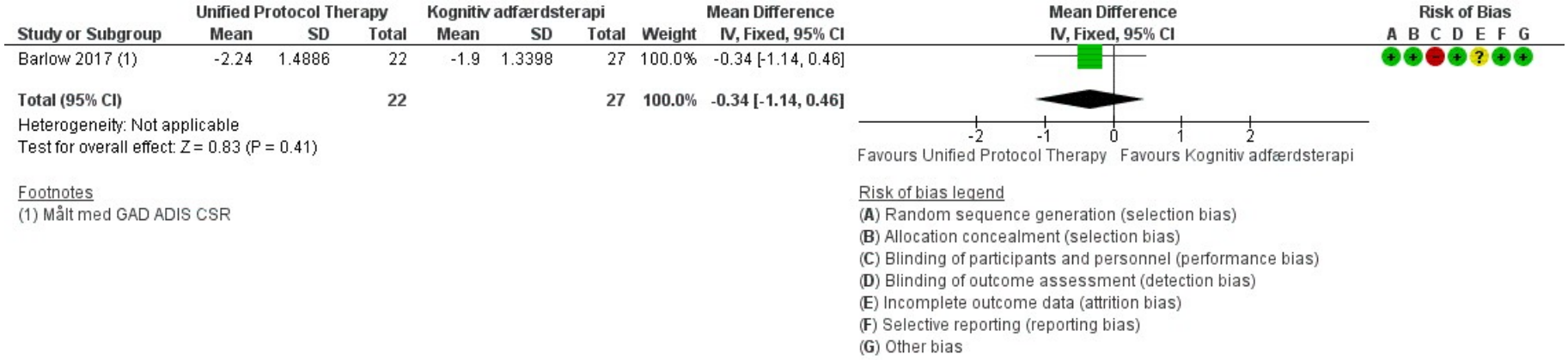
Data and analyses

1 Unified Protocol terapi vs kognitvi adfærdsaterapi

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Grad af angst (severity of anxiety)	1	49	Mean Difference (IV, Fixed, 95% CI)	-0.34 [-1.14, 0.46]
1.2 Grad af angst (severity of anxiety)	1	49	Mean Difference (IV, Fixed, 95% CI)	-1.05 [-3.51, 1.41]
1.3 Funktion (function)	1	179	Mean Difference (IV, Fixed, 95% CI)	-0.12 [-2.36, 2.12]
1.4 Bedring (response)	1	179	Risk Ratio (IV, Fixed, 95% CI)	1.11 [0.88, 1.41]
1.5 Frafald, alle årsager (dropouts all causes)	1	179	Risk Ratio (IV, Fixed, 95% CI)	0.41 [0.22, 0.76]

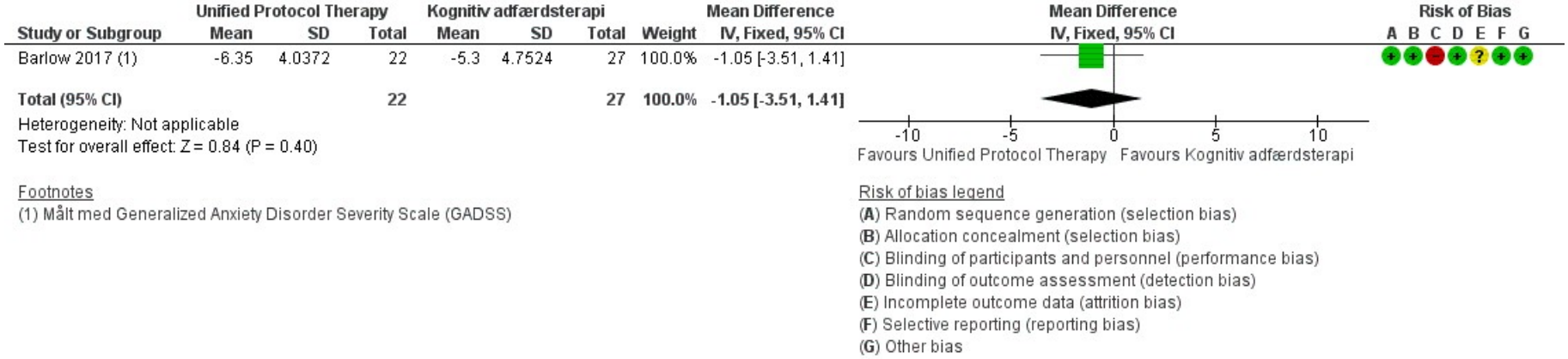
Figures

Figure 1 (Analysis 1.1)



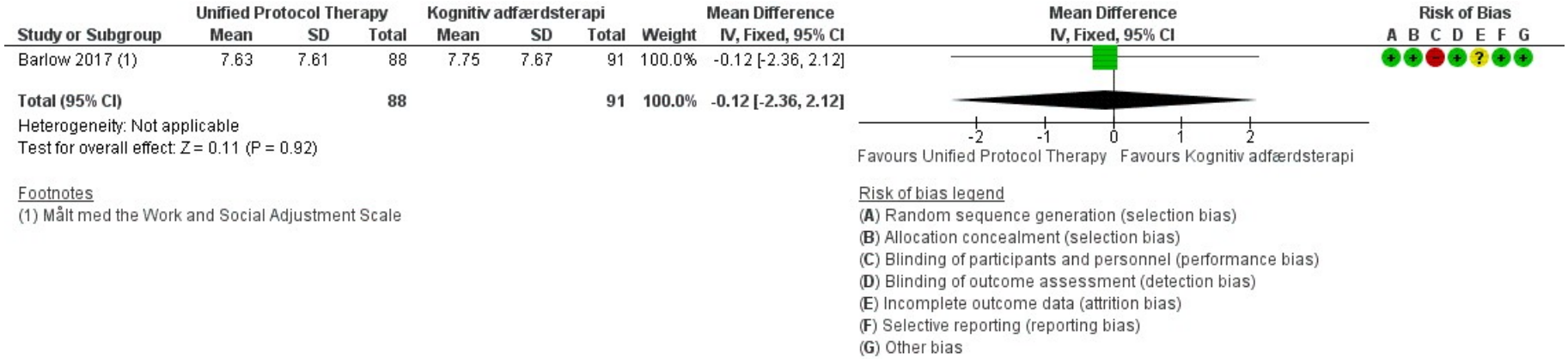
Forest plot of comparison: 1 Unified Protocol terapi vs kognitvi adfærdsaterapi, outcome: 1.1 Grad af angst (severity of anxiety).

Figure 2 (Analysis 1.2)



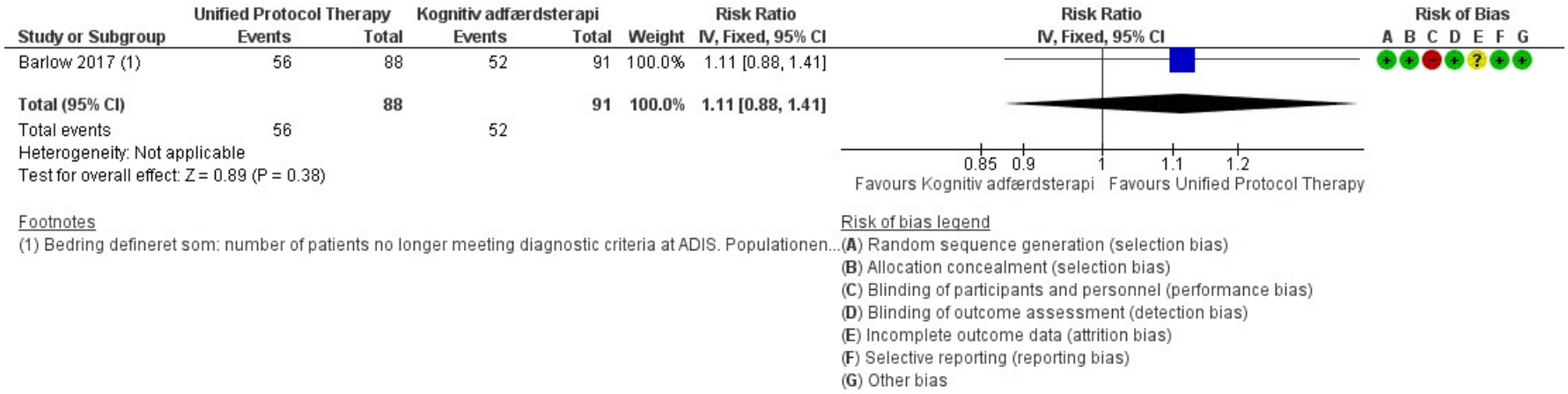
Forest plot of comparison: 1 Unified Protocol terapi vs kognitvi adfærdsaterapi, outcome: 1.2 Grad af angst (severity of anxiety).

Figure 3 (Analysis 1.3)



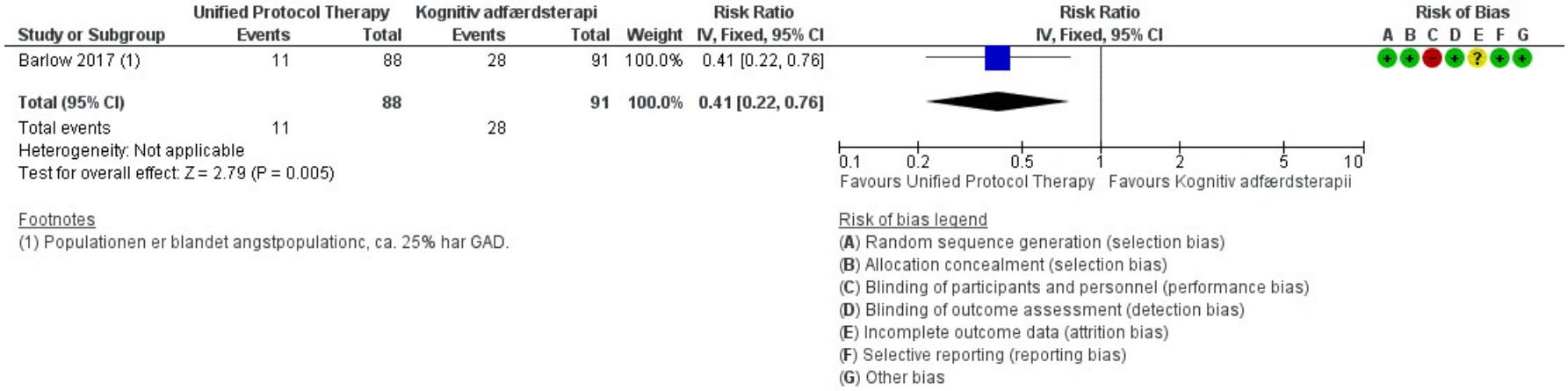
Forest plot of comparison: 1 Unified Protocol terapi vs kognitvi adfærdsaterapi, outcome: 1.3 Funktion (function).

Figure 4 (Analysis 1.4)



Forest plot of comparison: 1 Unified Protocol terapi vs kognitvi adfærdsaterapi, outcome: 1.4 Bedring (response).

Figure 5 (Analysis 1.5)



Forest plot of comparison: 1 Unified Protocol terapi vs kognitvi adfærdsaterapi, outcome: 1.5 Frafald, alle årsager (dropouts all causes).