NKR 29. PICO 7: Mindfulness som tilbagefaldsprofylakse.

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Bieling 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** Inclusion criteria were a DSM-IV diagnosis of Major Depressive Disorder (MDD), a scoreof ≥ 16 on the Hamilton Depression Rating Scale (HRSD-17), two or more previousdepressive episodes, and between 18 and 65 years in age **Excluded criteria:** Patients were excluded if they had a current diagnosis of Bipolar Disorder, Substance Abuse Disorder, Schizophrenia or Borderline Personality Disorder or a trial of ECT within the past six months, or currently practiced meditation more than once per week or yoga more than twice per week. A full description of inclusion and exclusion criteria, treatment fidelity, and can be found in Segal et al., (2010). **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: Patients in MBCT attended 8 weekly 2 hour groups and a 6 hour retreat day in week 6.Details of the treatment protocol and fidelity are provided in Segal et al. (2010) Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: maintenance antidepressant medication (ADM)
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome ● **Direction**: Higher is better ● **Data value**: Endpoint *Recidiv, Længste follow-up (min. ½ år)*

	● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This study was funded by Grant #066992 (R01: Dr. Segal) from the National Institute of Mental Health, Bethesda,MD. **Country:** Canada **Setting:** **Comments:** **Authors name:** Bieling, 2012 **Institution:** **Email:** **Address:**
Notes	*Birgitte Holm Petersen* on 01/11/2015 10:10 **Included** Hører til flg. hovedstudie: Segal, Z. V., Bieling, P., Young, T., MacQueen, G., Cooke, R., Martin, L., ... & Levitan, R. D. (2010). Antidepressant monotherapy vs sequential pharmacotherapy and mindfulness-based cognitive therapy, or placebo, for relapse prophylaxis in recurrent depression. Archives of General Psychiatry, 67(12), 1256-1264.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Unclear risk	Judgement Comment: The study protocol was approved by institutional review boardsat the Centre for Addiction and Mental Health (CAMH),Toronto, and St Joseph's Healthcare, Hamilton. No clinicaltrials.gov reference
Incomplete outcome data	Low risk	Judgement Comment: Attrition was evenly distributed across the 18-month follow-up interval,with 50% of dropouts occurring by the ninthmonth
Sequence Generation	Low risk	Judgement Comment: Info hentet fra det originale studie: Segal, Z. V., Bieling, P., Young, T., MacQueen, G., Cooke, R., Martin, L., ... & Levitan, R. D. (2010). Antidepressant monotherapy vs sequential pharmacotherapy and mindfulness-based cognitive therapy, or placebo, for relapse prophylaxis in recurrent depression. Archives of General Psychiatry, 67(12), 1256-1264.Block randomization, with a block size of 4, wasperformed at CAMH by an independent

		statistician usingcomputer-generated quasi-random numbers.
Other sources of bias	Low risk	Judgement Comment: None detected
Allocation concealment	Low risk	Judgement Comment: Details of group assignment were contained in sealed envelopes that wereopened by the statistician and communicated to the coordinatoronce a patient was deemed suitable for study entry
Blinding of participants and personnel	High risk	Judgement Comment: Not blinded
Blinding of outcome assessors	Low risk	Judgement Comment: Evaluators were blind to treatment allocation.

Bondolfi 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: **Included criteria:** Inclusion criteria were as follows: historyof recurrent majordepression according to DSM-IV (Diagnostic and StatisticalManual of Mental Disorders;American Psychiatric Association,1994) assessed with the Structured Clinical Interview for DSM-IV (First et al.,1996); at least three past depressive episodes (2episodes in thepast5 years and atleastoneinthe past 2 years);remission for at least 3 months at time of enrolment. TheMontgomery−Asberg Depression Rating Scale score (MADRS;Montgomery and Asberg, 1979)hadtobe≤ 13, correspondingto the baseline score of 10 (Zimmerman et al., 2004)ontheHamilton Rating Scale for Depression 17-items (HRSD;Hamil-ton, 1960), which was the cut-off score used as inclusioncriterion in the two previous MBCT trials (Ma and Teasdale,2004; Teasdale et al., 2000). Participants were required to havea history of treatment with antidepressants but to currently beoff medication forat least 3 months before enrolment. As it wasnot possible to determine the adequacy of treatment byantidepressant medication this criterion was used as anindicator that in the naturalistic course of service deliverypatients had been judged as appropriate for pharmacotherapyby their treating physician. **Excluded criteria:** Patients with the following conditions were excluded:history of schizophrenia or schizoaffective disorder; current substance abuse, eating disorder, or obsessive compulsivedisorder; organic mental disorder, pervasive developmentaldisorder or borderline personality disorder; dysthymia withonset before age 20; more than four sessions of CBT ever;current psychotherapy or counselling more frequently thanonce per month; current practice of meditation more thanonce per week or yoga more than twice per week.

	Pretreatment: Not signifcant, see table 1
Interventions	**Intervention Characteristics** Mindfulness Treatment as usual (farmakologisk behandling)
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This study was supported by a grant of the Swiss NationalScience Foundation (Grant no. 3200BO-108432 to GuidoBondolfi, Gilles Bertschy, Jean-Michel Aubry and Martial Vander Linden **Country:** Switzerland **Setting:** The study was conducted by a single research team at twodifferent sites separated by 60 km (Geneva and LausanneUniversity Hospitals) to enable people living within a largegeographic area to participate. Participants were recruitedthrough media announcements and mailings to psychiatristsand general practitioners in the French speaking region ofSwitzerland. **Comments:** **Authors name:** **Institution:** **Email:** **Address:**
Notes	*Birgitte Holm Petersen* on 30/09/2015 22:36 **Select** Inklusion: remission for at least 3 months at time of enrolment! *Karsten JøRgensen* on 27/04/2016 22:58 **Interventions** BCT plus TAU, witheight weekly 2-hour training sessions. The French translationof the MBCT manual was used in this study (Segal et al.,2006). At least four MBCT sessions were considered as theminimal dose of MBCT in accordance with previous MBCTtrials (Ma and Teasdale, 2004; Teasdale et al., 2000). FourMBCT groups were instructed by three senior CBT psycholo-gists and a senior CBT psychiatrist. All therapists had under-gone at least one training program taught and supervised byone of the developers of MBCT (Z. Segal) and two instructorsattended 9 day professional trainings in Mindfulness-BasedStress Reduction at the University of Massachusetts MedicalSchool (UMASS). Prior to this trial, they had all led at leastthree supervised MBCTgroups. All instructors

	had an ongoingpersonal mindfulness practice. All trial groups were audio-taped in order to enable an independent rating of adherenceto the program. Twenty-one audiotaped MBCT sessions wereevaluated using the MBCT adherence scale (MBCT-AS;Segalet al., 2002a), by two psychologists who were familiar withMBCT but independent from the research team. Ratings in-dicated that there was a high degree of adherence of theinstructors to the MBCT protocol (mean ratings indicated that93.33% of items were rated as meeting“definite evidence ofadherence”, 4.29% showing“slight evidence”and 2.38% show-ing“no evidence”of adherence across sessions) TAU, participants were told to seek help from their familydoctor of other sources as they normally would, should theyencounter symptomatic deterioration or other difficultiesover the course of the study. The treatment that patientsreceived was monitored at each follow-up interview and isdescribed in theResultssection;

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: Not detected
Incomplete outcome data	Unclear risk	Judgement Comment: 4/31 (MBCT) versus 1/29 (TAU) completed
Sequence Generation	Low risk	Quote: "A stratified block randomization procedure was implemented."
Other sources of bias	Low risk	Judgement Comment: Not detected
Allocation concealment	Unclear risk	Quote: "intervention was assigned to patients through sealed envelopes."
Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible
Blinding of outcome assessors	Unclear risk	Judgement Comment: Unclear whether this would ensure blinded outcome assessment.

Geschwind 2011

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** adults with residual symp-tomatology after at least one episode of major depressive disorderwere recruited from outpatient mental health care facilities inMaastricht (the Netherlands) and through posters in public spaces. Residual symptoms were defined as ascore of seven or higher on the 17-item Hamilton DepressionRating Scale (HDRS; Hamilton, 1960) at the time of screening.

	Excluded criteria: Exclusion criteria included the following: fulfilling criteria for acurrent depressive episode, schizophrenia, or psychotic episodes inthe past year, and recent (past 4 weeks) or upcoming changes inongoing psychological or pharmacological treatment. **Pretreatment:** At baseline, there were no large or significant differencesbetween treatment groups with respect to sociodemographic andclinical characteristics. Table 2 shows baseline and postassessmentscores of variables used in the analyses, stratified by treatmentgroup. Again, there were no large or significant differences be-tween groups at baseline.
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: Content of MBCT training sessions followed the protocol ofSegal et al. (2002). Trainings consisted of eight weekly meetingslasting 2.5 hr and were run in groups of 10–15 participants (thusoccasionally larger than the usual 10–12 participants per group).Assessment periods for control participants were matched to thoseof MBCT participants. Sessions included guided meditation, ex-periential exercises, and discussions. In addition to the weeklygroup sessions, participants received CDs with guided exercisesand were assigned daily homework exercises (30–60 min daily).Trainings were given by experienced trainers in a center special-ized in mindfulness trainings. All trainers were supervised by anexperienced health care professional who had trained with Teas-dale and Williams, the co-developers of MBCT (Teasdale et al.,1995) Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: Waitlist
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Marieke Wichers was supported by the Dutch Organisation for ScientificResearch (NWO, VENI Grant Nr. 916.76.147). **Country:** Holland **Setting:** recruited from outpatient mental health care facilities inMaastricht (the Netherlands) and through posters in public spaces **Comments:** **Authors name:** **Institution:**

	Email: **Address:**
Notes	*Karsten JøRgensen* on 26/04/2016 19:56 **Outcomes** Funktionsniveau: Pleasantness of function *Karsten JøRgensen* on 26/04/2016 19:59 **Interventions** add on to usual treatment

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	High risk	Judgement Comment: No assessment of relapse rate or medication use.
Incomplete outcome data	Low risk	Judgement Comment: Only one participant of 130 randomised dropped out
Sequence Generation	Low risk	Quote: "An independent researcher not involved in the project generated the randomization sequence in blocks of five (using the"
Other sources of bias	Low risk	Judgement Comment: Not detected Not detected
Allocation concealment	High risk	Quote: "the researcher allocated participants to their treatment condition based on the randomization code in the sealed envelope (opened in order of sequence). No masking of treatment condition took place."
Blinding of participants and personnel	High risk	Judgement Comment: Open-label trial
Blinding of outcome assessors	High risk	Judgement Comment: Open-label trial

Godfrin 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: 6.65 Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: 7.24 **Included criteria:** **Excluded criteria:**

	Pretreatment:
Interventions	**Intervention Characteristics** Mindfulness Treatment as usual (farmakologisk behandling)
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome ● **Direction**: Higher is better *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Supported by the Flemish Ministry ofWelfare, Health and Family, Belgium. **Country:** Belgien **Setting:** **Comments:** **Authors name:** Godfrin 2010 **Institution:** **Email:** **Address:**
Notes	*Birgitte Holm Petersen* on 05/10/2015 07:44 **Population** Min. moderat dep. *Jens Aaboe* on 12/10/2015 20:30 **Population** Dep. sværhedsgrad: BDI score mean (SD)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Unclear risk	Judgement Comment: No protocol
Incomplete outcome data	Low risk	Judgement Comment: Attrition well described
Sequence Generation	Low risk	Judgement Comment: Computer generated
Other sources of bias	Low risk	Judgement Comment: None detected

Allocation concealment	Low risk	Judgement Comment: Allocation information was concealed until assignment.
Blinding of participants and personnel	High risk	Judgement Comment: Not described
Blinding of outcome assessors	Unclear risk	Judgement Comment: Not described

Huijbers 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** Inclusioncriteria were a history of at least three depressive episodesaccording to the Diagnostic and Statistical Manual of Mental Disorders-4thedition (DSM-IV); in full or partial remission, defined asnot currently meeting the DSM-IV criteria for MDD; currentlytreated with ADM for at least 6 months; 18 years of age or older;and Dutch speaking **Excluded criteria:** Exclusion criteria were: bipolar disorder; anyprimary psychotic disorder (current and previous); clinically relevantneurological/somatic illness; current alcohol or drug dependency;high dosage of benzodiazepines (42 mg lorazepamequivalents daily); recent electroconvulsive therapy (o3 monthsago); previous MBCT and/or extensive meditation experience (i.e.retreats); current psychological treatment with a frequency ofmore than once per three weeks; and inability to complete interviewsand self-report questionnaires. **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: The intervention consisted of 8 weeklysessions of 2.5 (instead of 2) h and one day of silent practice betweenthe 6th and 7th session (which originates from the MBSRcurriculum (Kabat-Zinn, 1990) and is suggested in the most recentversion of the MBCT protocol (Segal et al., 2012)). It was deliveredin groups of 8–12 participants. MBCT included both formal meditationexercises, such as the body scan, sitting meditation, walkingmeditation and mindful movement, and informal exercises,such as bringing present-moment awareness to everyday activities.Cognitive-behavioural techniques included education, monitoringand scheduling of activities, identification of negative automaticthoughts, and devising a relapse prevention plan. Participantswere encouraged to practise meditation at home for aboutan hour a day using CDs Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: Patients attended at least one visit with study psychiatrists fora review of their mADM. A protocol for optimisation was developedby two

	experts in pharmacological treatment of MDD (WNand MB) (Huijbers et al., 2012). Psychiatrists were instructed tomaintain or reinstate an adequate dose of mADM, and recommendationsto manage side effects were provided. Adherenceto the study protocol was defined as using a therapeutic dose ofmADM at each follow-up contact during the observed time period(using last observation carried forward for participants who didnot complete all assessments) and not attending MBCT.
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** None described **Country:** Netherlands **Setting:** **Comments:** **Authors name:** Huijbers **Institution:** **Email:** **Address:**
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: ClinicalTrials.gov: NCT00928980
Incomplete outcome data	Low risk	Judgement Comment: Attrition described, approx. equal between groups.
Sequence Generation	Low risk	Judgement Comment: Randomisation was performed using a website-based application, developed specifically for this study by an independent statistician, with a minimisation procedure for research centre, full versus partial remission, number of past episodes, prior CBT (yes/no), and gender. Allocation was performed with a 1:1 ratio.
Other sources of bias	Low risk	Judgement Comment: None detected

Allocation concealment	Unclear risk	
Blinding of participants and personnel	High risk	Judgement Comment: Not blinded
Blinding of outcome assessors	High risk	Judgement Comment: Not blinded

Kuyken 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder*: 6 ● *Dep. sværhedsgrad*: 5.62 Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder*: 6 ● *Dep. sværhedsgrad*: 5.76 **Included criteria:** three ormore previous episodes of depression meeting criteria for depressionaccording to the Diagnostic and Statistical Manual of MentalDisorders (4th ed.; DSM–IV; American Psychiatric Association,1994); 18 years of age or older; and on a therapeutic **Excluded criteria:** comorbiddiagnoses of current substance dependence; organic braindamage; current/past psychosis; bipolar disorder; persistent antisocialbehavior; persistent self-injury requiring clinical management/therapy;unable to engage with MBCT for physical, prac **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness ● *Beskrivelse*: MBCT and antidepressant tapering/discontinuation. MBCT isa manualized, group-based skills training program designed toenable patients to learn skills that prevent the recurrence of depression(Segal, Williams, & Teasdale, 2002). It is derived frommindfulness-based stress reduction, a program with proven efficacyin ameliorating distress in people suffering chronic disease(Baer, 2003; Kabat-Zinn, 1990), and cognitive– behavioral therapyfor acute depression (Beck, Rush, Shaw, & Emery, 1979), whichhas demonstrated efficacy in preventing depressive relapse/recurrence (Hollon et al., 2005). MBCT is intended to enablepeople to learn to become more aware of the bodily sensations,thoughts, and feelings associated with depressive relapse and torelate constructively to these experiences. Treatment as usual (farmakologisk behandling) ● *Beskrivelse*: Maintenance antidepressant treatment. The m-ADM relapseprevention intervention comprised maintenance of the ADM treatmentthat was an inclusion criterion for the study. Patients weremonitored and treated by their physicians in primary care settings.During the maintenance phase, physicians were asked to

	managem-ADM in line with standard clinical practice and the BritishNational Formulary. Primary care physicians were asked to meetwith patients regularly to review their medication treatment.Changes in medication sometimes occurred during the maintenancetreatment stage, but physicians and patients were asked toensure the dose remained within therapeutic limits.
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome ● **Direction**: Higher is better ● **Data value**: Endpoint *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome ● **Direction**: Higher is better ● **Data value**: Endpoint *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better ● **Data value**: Endpoint *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** No financial or other conflicts of interest exist. This trial was registered(ISRCTN12720810) and was funded by the UK Medical Research Council(TP 72167). **Country:** UK **Setting:** **Comments:** **Authors name:** Kuyken 2008 **Institution:** **Email:** **Address:**
Notes	*Jens Aaboe* on 12/10/2015 21:57 **Population** Depression: BDI-II score: M (SD)antal episoder: median *Jens Aaboe* on 12/10/2015 22:26 **Outcomes** Funktionsevne: Data fra physical quality of life tabel 2 er brugt.Recidiv: Data fra relapse i tekst: In the PPT sample, 46% (24/52) of the MBCT patients had a relapse/recurrence, compared with 60% (31/52) of the m-ADM patients, log-rank 2 (1) 3.32, p .07.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: This trial was registered (ISRCTN12720810).
Incomplete outcome data	Low risk	
Sequence Generation	Low risk	Judgement Comment: computer-generated
Other sources of bias	Low risk	Judgement Comment: None detected
Allocation concealment	Unclear risk	Judgement Comment: Not described
Blinding of participants and personnel	High risk	
Blinding of outcome assessors	Low risk	Judgement Comment: Outcome assessors were blinded

Kuyken 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** Inclusion criteria were a diagnosis of recurrent major depressive disorder in full or partial remissionaccording to the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV); three or more previousmajor depressive episodes; age 18 years or older; and on a therapeutic dose of maintenance antidepressant drugs inline with the British National Formulary (BNF)13 and NICE guidance. **Excluded criteria:** Exclusion criteria were a current majordepressive episode, comorbid diagnoses of currentsubstance misuse; organic brain damage; current or pastpsychosis, including bipolar disorder; persistent antisocialbehaviour; persistent self-injury needing clinical managementor therapy; and formal concurrent psychotherapy.All participants gave written informed consent. **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: The programme consists of eight 2·25 h group sessions,normally over consecutive weeks, with four refreshersessions off ered roughly every 3 months for the followingyear. Four therapists delivered 21 MBCT-TS groups invarious settings including research clinical facilities,hospital sites, and the community. Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: Patients in the maintenance antidepressant groupreceived support from their GPs to maintain a therapeuticlevel of antidepressant

	medication in line with BNF13 andNICE guidelines for the 2-year follow-up period.
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Kuyken, 2015 **Country:** UK **Setting:** **Comments:** **Authors name:** Kuyken, 2015 **Institution:** **Email:** **Address:**
Notes	*Jens Aaboe* on 02/11/2015 20:59 **Outcomes** Livskvalitet ved 9 måneders FU.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: Current Controlled Trials, ISRCTN26666654
Incomplete outcome data	Low risk	
Sequence Generation	Low risk	Judgement Comment: Participants were randomly assigned to eitherMBCT-TS or maintenance antidepressants (in a 1:1 ratio) with a computer-generated random number sequence
Other sources of bias	Low risk	Judgement Comment: None detected
Allocation concealment	Low risk	Judgement Comment: Allocation was undertakenusing a password-protected website maintained by thePeninsula Clinical Trials Unit, independent of the trial.The trial administrator informed participants of theoutcome of randomisation via a letter; research assessorsremained masked to treatment allocation for the durationof

		the follow-up period
Blinding of participants and personnel	High risk	Judgement Comment: Not blinded
Blinding of outcome assessors	Low risk	Judgement Comment: Assessors were blinded

Ma 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder, Median (interquartile range)*: 3.0 (2.0) ● *Dep. sværhedsgrad BDI, mean (SD)*: 13.49 (7.16) ● *Dep. sværhedsgrad Ham-d, mean (SD)*: 5.70 (3.02) Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder, Median (interquartile range)*: 3.0 (2.0) ● *Dep. sværhedsgrad BDI, mean (SD)*: 15.13 (9.51) ● *Dep. sværhedsgrad Ham-d, mean (SD)*: 5.68 (2.97) **Included criteria:** **Excluded criteria:** **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness ● *Beskrivelse*: MBCT is a manualized group skills-training program (Segal et al., 2002)based on an integration of aspects of CBT for depression (Beck et al.,1979) with components of the MBSR program developed by Kabat-Zinn(1990). It is designed to teach patients in remission from recurrent majordepression to become more aware of, and to relate differently to, theirthoughts, feelings, and bodily sensations—for example, relating tothoughts and feelings as passing events in the mind, rather than identifyingwith them or treating them as necessarily accurate readouts on reality. Theprogram teaches skills that allow individuals to disengage from habitual(“automatic”) dysfunctional cognitive routines, in particular depressionrelatedruminative thought patterns, as a way to reduce future risk ofrelapse and recurrence of depression Treatment as usual (farmakologisk behandling) ● *Beskrivelse*: Patients were told to seek help from their family doctor or other sourcesas they normally would if they encountered symptomatic deterioration orother difficulties over the course of the study
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome

	Arbejdsfastholdelse, Længste follow-up (min. ½ år) ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** No information on funding resources. **Country:** UK **Setting:** **Comments:** **Authors name:** Ma 2004 **Institution:** **Email:** **Address:**
Notes	*Jens Aaboe* on 12/10/2015 23:57 **Outcomes** Data er desværre opdelt på deltagere med hhv. >3 episoder vs. 2 episoder målt ved baseline, hvorfor data for de to treatment grupper ikke er rapporteret. Ingen data er derfor tilgængelige. *Birgitte Holm Petersen* on 01/11/2015 08:38 **Included** Kan bruges v at addere de to mbct gr.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Unclear risk	Judgement Comment: No protocol available
Incomplete outcome data	Unclear risk	Judgement Comment: Not described groupwise.
Sequence Generation	Low risk	
Other sources of bias	Low risk	Judgement Comment: No information on funding resources, however not expected to bias the results.
Allocation concealment	Unclear risk	
Blinding of participants and personnel	High risk	
Blinding of outcome assessors	Unclear risk	

Meadows 2014

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** Enrolled participants met DSM-IV criteria for >2MDEs with a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of MDD (recurrent) or bipolar disorder (BD) I or II (assessed from 1 to 3 above), were aged between 18 and 75 years, and able to speak and read English fluently. **Excluded criteria:** Diagnostic exclusions included current MDE (1–3); current symptoms of a psychotic disorder or a past diagnosis of a psychotic disorder where the treating clinician believes the therapy may be contraindicated (1); organic mental disorder or pervasive developmental delay (1); current eating disorder or obsessive-compulsive disorder (1, 3); current borderline orantisocial personality disorder (1); current alcohol or drug dependency other than tobacco (1, 3); current benzodiazepine intake of more than 20 mg diazepam equivalent (1, 3); and inability to give informed consent (3). **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: After an initial individual orientation session, theMBCT program was delivered by an instructor in eightweekly 2-hour group training sessions involving up to 10participants. As per previous trials, four sessions was consideredthe minimal treatment dose. Sessions incorporatedmindfulness practices and CBT-based exercises (Segalet al., 2002b). Homework included formal daily meditationpractices and exercises for the development of everydaymindful awareness. In 3-monthly ‘booster sessions’,optional for MBCT participants, an experienced MBCTpractitioner led mindfulness practices over a 5-hour period. Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: Depression Relapse Active Monitoring (DRAM). DRAM wasdesigned as an alternative to TAU-only control with considerationsincluding seeking to equalise treatment expectancyacross treatment conditions and attenuate the risk ofresentful demoralisation in participants allocated to thecontrol group. DRAM comprised training on self-managementof depression and supported monthly self-monitoringusing the Patient Health Questionnaire-2
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)*

	● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This research was supported by a grant from the National Healthand Medical Research Council of Australia (grant number 436897). **Country:** Australia **Setting:** **Comments:** **Authors name:** Meadows, 2014 **Institution:** **Email:** **Address:**
Notes	*Jens Aaboe* on 02/11/2015 21:33 **Outcomes** Frafald for kontrolgruppen er ikke angivet efter de 8 ugers intervention, men først efter 14 måneder, hvorfor dette tidspunkt er valgt som frafald. Recidiv data er angivet i tabel 3 og 4 som %(n), men det er ikke angivet om n er antallet med relapse svarende til procentangivelsen eller om n egentlig er N.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Unclear risk	Judgement Comment: No protocol
Incomplete outcome data	Low risk	Judgement Comment: Missing data were unrelated to treatmentcondition in either year 1 or year 2.
Sequence Generation	Low risk	Judgement Comment: Enrolled participants were randomised independently by a statistician.
Other sources of bias	Low risk	Judgement Comment: None detected
Allocation concealment	Unclear risk	Judgement Comment: Not described
Blinding of participants and personnel	High risk	
Blinding of outcome assessors	Low risk	Judgement Comment: Rater-blindness to intervention was maintainedfor 94% of assessment interviews; raters' selection of thetreatment condition was not above statistical expectationbased on chance.

R 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** patients with three or more previous depressive episodes according toDSM-IV criteria. Patients using antidepressant medi-cation were required to be on a stable dose for at least6 weeks and were asked to maintain this dosage forthe study period. **Excluded criteria:** Exclusion criteria for the study were:(1) one or more previous (hypo)manic episodes ac-cording to DSM-IV criteria; (2) current alcohol and/ordrug abuse; (3) urgent need for psychiatric treatment,for example, suicidality or psychotic symptoms; (4)problems impeding participating in a group, such assevere borderline personality disorder; (5) problemsimpeding completing the questionnaires, such as cog-nitive dysfunctions **Pretreatment:** There were no baseline differences between thegroups with regard to age [MBCT: mean=47.3 (S.D.=11.5) years; TAU: mean=47.7 years (S.D.=11.1)] orother sociodemographic or clinical characteristics(see Table 1)
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: MBCT was delivered according to the guidelines ofSegalet al. (2002). Training consisted of eight weeklysessions of 2.5 h and a silent day of 6 h meditation. Inaddition to the group sessions, participants were in-structed to practise 6 days per week for approximately45 min per day. Compliance was assessed by attend-ance and weekly homework diaries. To support homepractice, patients received CDs with guided medi-tations and exercises. Group size varied between eightand 14 participants. After completing MBCT, par-ticipants were invited to attend monthly 1-h boostersessions and silent days of consecutive MBCT groups.Three different MBCT instructors participated inthe study: (1) a psychiatrist and cognitive behaviouraltherapist; (2) a clinical psychologist; (3) an occu-pational therapist. All had received at least 1.5 years oftraining in MBCT and were experienced in workingwith patients with a wide range of psychiatric prob-lems and groups. Trainers were also experiencedmeditators, with meditation practice ranging between2 and 20+years. Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: TAU
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)*

	● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** The corresponding author is financial supported byFonds Psychische Gezondheid; Grant Number: 20056028 and part of the Spinoza prize 2002 of ProfessorH. P. Barendregt. **Country:** Holland **Setting:** General practise **Comments:** **Authors name:** **Institution:** **Email:** **Address:**
Notes	*Henning Keinke Andersen* on 22/10/2015 21:20 **Select** Forfatterne angiver at 1 års follow-up vil blive beskrevet senere, men protokollen angiver follow-up efter 3, 6, 9, og 12 måneder. Check dette inden vurdering. *Birgitte Holm Petersen* on 02/11/2015 07:23 **Included** Kun omk halvdelen i mindfulness gr modtager antidep. medicin. ingen sub gr analyser. studiet skal derfor ekskluderes. *Karsten JøRgensen* on 26/04/2016 20:26 **Outcomes** QoL: Psychological component of WHOQOL-Bref.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	High risk	Judgement Comment: Relapse and medication use not assessed.
Incomplete outcome data	Low risk	Judgement Comment: 9/111 and 5/108 dropped out
Sequence Generation	Unclear risk	Quote: "A list of random numbers was generated for both groups."
Other sources of bias	Low risk	Judgement Comment: Not detected
Allocation concealment	Low risk	Quote: "Assignment to groups was conducted by an independent researcher."

Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible
Blinding of outcome assessors	High risk	Judgement Comment: Blinding not possible

Segal 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder*: ● *Dep. sværhedsgrad*: **Included criteria:** Inclusion criteria were: (1) diagnosis of Major Depressive Disorder (MDD) according toDSM-IV criteria, (2) a score of ≥ 16 on the Hamilton Depression Rating Scale (HRSD-17),(3) ≥ 2 previous episodes of MDD [to ensure that those randomized would have a minimumof 3 past episodes], (4) between 18 and 65 years of age and (5) English speaking and theability to provide informed consent. **Excluded criteria:** Exclusion criteria were: (1) a current diagnosis ofBipolar Disorder, Substance Abuse Disorder, Schizophrenia or Borderline PersonalityDisorder, (2) a trial of ECT within the past six months (3) depression secondary to aconcurrent medical disorder, (4) current or planned pregnancy within the 6 months of acutephase treatment, (5) current practice of meditation more than once per week or yoga morethan twice per week. **Pretreatment:** Table 3 shows that there were no differences inbaseline characteristics between the three prevention arms, with the only exception being agreater percentage of Axis II comorbidity in MBCT (P<.05)
Interventions	**Intervention Characteristics** Mindfulness Treatment as usual (farmakologisk behandling)
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Frafald/ All-cause discontinuation, Ved interventionens afslutning* ● **Outcome type**: DichotomousOutcome

	Recidiv, Længste follow-up (min. ½ år) ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This study was funded by Grant #066992 (R01: Dr. Segal) from the National Institute of Mental Health, Bethesda,MD **Country:** USA **Setting:** Outpatient clinics at the Centre for Addiction and Mental Health, Toronto and St.Joseph's Healthcare, Hamilton **Comments:** **Authors name:** **Institution:** **Email:** **Address:**
Notes	*Birgitte Holm Petersen* on 30/09/2015 23:35 **Select** Flot studie, desværre ikke MBCT som add-on til farma. *Karsten JøRgensen* on 27/04/2016 23:18 **Interventions** MBCT was delivered according to the protocol described in Segal et al.,24. Patients attended8 weekly group meetings of 2 hours duration and a retreat day held between sessions 6 and7. In addition, patients had the option of attending a monthly one hour mindfulnessmediation class that was offered throughout the maintenance phase. Control: maintenance antidepressant medication

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: Not detected
Incomplete outcome data	High risk	Judgement Comment: 25% dropped out
Sequence Generation	Low risk	Quote: "MBCT, medication taper plus PLA. Block randomization, utilizing a block size of 4 was performed at CAMH by an independent statistician (TB) using computer generated quasi-random numbers. Details of group assignment were"
Other sources of bias	Low risk	Judgement Comment: Not detected
Allocation concealment	Low risk	Quote: "using computer generated quasi-random numbers. Details of group assignment were contained in sealed envelopes which were opened by the statistician and communicated to the coordinator once a patient was deemed suitable for Segal et al. Page 4"
Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible

Blinding of outcome assessors	Unclear risk	Quote: "Patients were assessed by clinical evaluators blind to treatment allocation at randomization,"

Teasdale 2000

Methods	**Study design:** **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness ● *Antal dep. episoder, median (interquartil range)*: 3.5 (2.0) ● *Dep. sværhedsgrad BDI, median (interquartil range)*: 10.0 (10.0) Treatment as usual (farmakologisk behandling) ● *Antal dep. episoder, median (interquartil range)*: 3.0 (3.8) ● *Dep. sværhedsgrad BDI, median (interquartil range)*: 10.0 (10.0) **Included criteria:** **Excluded criteria:** **Pretreatment:**
Interventions	**Intervention Characteristics** Mindfulness ● *Beskrivelse*: MBCT is a manualized group skills-training program (Segal,Williams, & Teasdale, in press). MBCT is based on an integration ofaspects of CBT for depression (Beck et al., 1979) wilh components of IheMBSR program developed by Kabat-Zinn and colleagues (e.g., KabatZinn,1990). It is designed to teach patients in remission from recurrentmajor depression to become more aware of, and to relate differently to,their thoughts, feelings, and bodily sensations (e.g., relating to thoughts andfeelings as passing events in the mind rather than identifying with them ortreating them as necessarily accurate readouts on reality). The programteaches skills that allow individuals to disengage from habitual ("automatic")dysfunctional cognitive routines, in particular depression-relatedruminative thought patterns, as a way to reduce future risk of relapse andrecurrence of depression Treatment as usual (farmakologisk behandling) ● *Beskrivelse*: TAU. Patients were instructed to seek help from their family doctor, orother sources, as they normally would, should they encounter symptomaticdeterioration or other difficulties over the course of the study
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome

	Frafald/ All-cause discontinuation, Ved interventionens afslutning ● **Outcome type**: DichotomousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This research was supported in part by Grant RA 013 from the Wales Office of Research and Development for Health and Social Care and by Grant MH53457 from the National Institute of Mental Health. **Country:** UK **Setting:** **Comments:** **Authors name:** Teasdale 2000 **Institution:** **Email:** **Address:**
Notes	*Jens Aaboe* on 13/10/2015 00:08 **Population** Inclusion criteria were (a) 18 to 65 years of age; (b) meeting enhanced Diagnostic and Statistical Manual of Mental Disorders (3rd ed.; DSMIII-R; American Psychiatric Association, 1987) criteria for a history of recurrent major depression (these normally require a history of two or more previous episodes of DSM-1H-R major depression in the absence of a history of mania or hypomania; in addition, we required that at least two episodes of major depression occurred within the past 5 years and that at least one of those episodes was within the past 2 years); (c) a history of treatment by a recognized antidepressant medication, but off antidepressaiit medication, and in recovery /remission, at the time of baseline assessment and for at least the preceding 12 weeks (it was not possible to determine rhe adequacy of treatment by antidepressant medication; rather, this criterion was used as an indicator that, in the naturalistic course of service delivery, patients had been judged as appropriate for pharmacotherapy by a treating physician); and (d) at baseline assessment, a 17-item Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960) score of less than 10.Exclusion criteria were (a) history of schizophrenia or sehizoaffective disorder; (b) current substance abuse, eating disorder, or obsessivecompulsive disorder (OCD); (c) organic mental disorder, pervasive developmental delay, or borderline personality disorder (BPD); (d) dysthymia before age 20; (e) more than four sessions of cognitive-behavioral treatment ever; (f) current psychotherapy or counseling more frequently than once per month; and (g) current practice of meditation more than once per week or yoga more than twice per week. Patients with eating disorders were excluded because they frequently experience depression secondary to those disorders and the MBCT program was not designed to deal with the primary eating disorder. Patients with OCD were excluded because the obsessional quality of their thoughts might have rendered the implementation of mindfulness strategies particularly difficult. Patients with dysthymia before the age of 20 were excluded because of the possible characterological nature of their depression. Patients who currently practiced yoga more than twice a week were excluded because yoga overlaps considerably with mindfulness training and is, indeed, a component of the MBCT program.

	Jens Aaboe on 13/10/2015 00:30 **Outcomes** Data er igen opdelt i deltagere med >3 episoder vs. 2 episoder, og der er derfor kun recidiv data tilgængelig.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Unclear risk	Judgement Comment: No protocol
Incomplete outcome data	Unclear risk	Judgement Comment: Not described
Sequence Generation	Unclear risk	
Other sources of bias	Low risk	Judgement Comment: No information on funding resources, however not expected to bias the results.
Allocation concealment	High risk	
Blinding of participants and personnel	High risk	
Blinding of outcome assessors	Unclear risk	Judgement Comment: Not described

Williams 2014

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Mindfulness-træning som add-on Vanlig behandling/ treatment as usual (farmakologisk behandling) **Included criteria:** Inclusion criteria atbaseline assessment were (a) age between 18 and 70 years; (b)history of at least three episodes of major depression meetingDSM–IV, text revision (DSM–IV–TR) criteria (American Psychi-atric Association, 2000), of which two must have occurred withinthe last 5 years, and one within the last 2 years; (c) remission forthe previous 8 weeks (with potential trial participants deemednotto be in recovery or remission, and henceineligible, if theyreported that at least 1 week during the previous 8 they experi-encedeithera core symptom of depression (depressed mood,anhedonia)orsuicidal feelings and at least one other symptom ofdepression, which together were not attributable to bereavement,substances, or medical condition, but were impairing functioning);and (d) informed consent from participants and their primary carephysicians. **Excluded criteria:** Exclusion criteria were (a) history of schizophrenia, schizoaf-fective disorder, bipolar disorder, current abuse of alcohol or othersubstances, organic mental disorder, pervasive developmental de-lay,

	primary diagnosis of obsessive-compulsive disorder or eatingdisorder, or regular nonsuicidal self-injury; (b) positive continuingresponse to cognitive behavior therapy (CBT), that is, no relapse todepression since treatment with CBT, due to the known effects ofCBT in reducing risk of relapse; (c) current psychotherapy orcounseling more than once a month; (d) regular meditation prac-tice (meditating more than once per month); or (e) inability tocomplete research assessments through difficulty with English,visual impairment, or cognitive difficulties **Pretreatment:** The 19 participants lost to follow-upwere significantly youngerthan those who provided follow-up data, by5.6 years (95% CI [1.5, 9.7]). There were no other significant differ-ences between the groups.
Interventions	**Intervention Characteristics** Mindfulness-træning som add-on ● *description*: MBCT is a manualized group skills training program(Segal et al., 2002) that integrates psychological educational as-pects of CBT for depression with meditation components ofmindfulness-based stress reduction developed byKabat-Zinn(1990). It stems from experimental research showing that relapseis more likely when, in periods of low mood, patterns of negativethoughts and feelings associated with previous episodes of depres-sion recur (Lau, Segal, & Williams, 2004). The program teachesskills that enable participants to disengage from these habitualdysfunctional cognitive routines and thus reduce the risk of relapseinto depression. In this study, MBCT comprised an individualpreclass interview followed by eight weekly 2-hr classes, includingtraining in meditation skills such as sustained attentional focus onthe body and breath and adopting a decentered view of thoughts aspassing mental events. The program followed the original MBCTmanual (Segal et al., 2002) except for greater emphasis on patternsof thoughts and feelings that might be associated with suicidalplanning, factors that maintain and exacerbate such patterns, andpreparation of explicit action plans for suicidal crises. Participantswere also invited to follow-up classes taking place 6 weeks and 6months posttreatment, respectively. Each follow-up class lasted for2 hr and included meditation, discussion of discoveries and diffi-culties since the course ended, and how these were being dealt withby participants. Vanlig behandling/ treatment as usual (farmakologisk behandling) ● *description*: TAU
Outcomes	*Livskvalitet, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Recidiv, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome *Arbejdsfastholdelse, Længste follow-up (min. ½ år)* ● **Outcome type**: DichotomousOutcome *Rumination, Længste follow-up (min. ½ år)* ● **Outcome type**: ContinuousOutcome

	Frafald/ All-cause discontinuation, Ved interventionens afslutning ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** This study was funded by Wellcome Trust Grant GR067797, awarded toJ. Mark G. Williams and Ian T, Russell (Trial Registration Number:ISRCTN97185214). All authors declare financial support for the submittedwork from the Wellcome Trust; **Country:** UK **Setting:** referrals from primary careand mental health clinics in Oxford, England, and Bangor, NorthWales, and advertisements in the community **Comments:** **Authors name:** **Institution:** **Email:** **Address:**
Notes	*Henning Keinke Andersen* on 22/10/2015 21:29 **Select** Er ikke helt klar over betydningen af 'dismantling trial' - skal lige vendes inden en evt inklusion *Birgitte Holm Petersen* on 02/11/2015 07:38 **Included** Mindre end halvdelen af ptt. i mindfulness gr var i medicinsk beh var start. Bør på denne bagrund ekskluderes.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Selective outcome reporting	Low risk	Judgement Comment: Not detected
Incomplete outcome data	Low risk	Judgement Comment: Less than 10% drop out.
Sequence Generation	Low risk	Judgement Comment: By central unit.
Other sources of bias	Low risk	Judgement Comment: Not detected
Allocation concealment	Low risk	Quote: "Randomization was by e-mail to the North Wales Organisation for Randomised Trials in Health, which used dynamic allocation (Russell, Hoare, Whitaker, Whita- ker, & Russell, 2011) to stratify by two variables in addition to site and recruitment cohort: antidepressant medication in last 7 days and history of suicidality."
Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible
Blinding of outcome assessors	High risk	Judgement Comment: Blinding not possible

Footnotes

References to studies

Included studies

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Godfrin, K. A.; van Heeringen, C.. The effects of mindfulness-based cognitive therapy on recurrence of depressive episodes, mental health and quality of life: A randomized controlled study. Behaviour Research and Therapy 2010;48(8):738-746. [DOI: 10.1016/j.brat.2010.04.006]

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Kuyken 2015

Kuyken W.; Hayes R.; Barrett B.; Byng R.; Dalgleish T.; Kessler D.; Lewis G.; Watkins E.; Brejcha C.; Cardy J.; Causley A.; Cowderoy S.; Evans A.; Gradinger F.; Kaur S.; Lanham P.; Morant N.; Richards J.; Shah P.; Sutton H.; Vicary R.; Weaver A.; Wilks J.; Williams M.; Taylor RS.; Byford S.. Effectiveness and cost-effectiveness of mindfulness-based cognitive therapy compared with maintenance antidepressant treatment in the prevention of depressive relapse or recurrence (PREVENT): a randomised controlled trial.. Lancet (London, England) 2015;386(9988):63-73. [DOI: 10.1016/S0140-6736(14)62222-4]

Ma 2004

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Data and analyses

1 Mindfulness vs Treatment as usual (farmakologisk behandling)

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Livskvalitet, Længste follow-up (min. ½ år)	4	553	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.32, 0.02]
1.1.1 Længste follow-up (min. ½ år)	4	553	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.32, 0.02]
1.2 Funktionsevne (aktivitet og deltagelse), Længste follow-up (min. ½ år)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

1.3 Rumination, Længste follow-up (min. ½ år)	3	296	Std. Mean Difference (IV, Fixed, 95% CI)	-0.36 [-0.59, -0.13]
1.4 Arbejdsfastholdelse, Længste follow-up (min. ½ år)	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.5 Frafald/ All-cause discontinuation, Ved interventionens afslutning	11	1604	Risk Ratio (IV, Fixed, 95% CI)	1.25 [0.94, 1.66]
1.5.1 Ved interventionens afslutning	11	1604	Risk Ratio (IV, Fixed, 95% CI)	1.25 [0.94, 1.66]
1.6 Recidiv, Længste follow-up (min. ½ år)	9	1012	Risk Ratio (IV, Fixed, 95% CI)	0.77 [0.67, 0.88]
1.6.1 Længste follow-up (min. ½ år)	9	1012	Risk Ratio (IV, Fixed, 95% CI)	0.77 [0.67, 0.88]

Figures

Figure 1 (Analysis 1.1)

	Mindfulness			Treatment as usual (farmakologisk behandling)				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% C**
1.1.1 Længste follow-up (min. ½ år)								
Godfrin 2010	-4.88	7.47	34	-11.02	10.18	41	0.2%	6.14 [2.14, 10.1
Huijbers 2015	3.8	0.8	26	4	0.5	24	21.5%	-0.20 [-0.57, 0.1
Kuyken 2015	3.7	0.9	151	3.9	0.8	141	76.0%	-0.20 [-0.40, -0.0
R 2012	20.2	3.3	68	18.9	3.3	68	2.3%	1.30 [0.19, 2.4
Subtotal (95% CI)			**279**			**274**	**100.0%**	**-0.15 [-0.32, 0.02**
Heterogeneity: Chi² = 16.38, df = 3 (P = 0.0009); I² = 82%								
Test for overall effect: Z = 1.77 (P = 0.08)								
Total (95% CI)			**279**			**274**	**100.0%**	**-0.15 [-0.32, 0.02**
Heterogeneity: Chi² = 16.38, df = 3 (P = 0.0009); I² = 82%								
Test for overall effect: Z = 1.77 (P = 0.08)								
Test for subgroup differences: Not applicable								

Risk of bias legend
(**A**) Selective outcome reporting
(**B**) Incomplete outcome data
(**C**) Sequence Generation
(**D**) Other sources of bias
(**E**) Allocation concealment
(**F**) Blinding of participants and personnel
(**G**) Blinding of outcome assessors

Forest plot of comparison: 1 Mindfulness vs Treatment as usual (farmakologisk behandling), outcome: 1.1 Livskvalitet, Længste follow-up (min. ½ år).

Figure 2 (Analysis 1.3)

	Mindfulness			Treatment as usual (farmakologisk behandling)				Std. Mean Differe
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 9**
Bieling 2012	19.05	3.36	17	17.73	3.91	15	10.9%	0.35 [-0.35,
Geschwind 2011	34.4	9.8	63	37.9	10	65	43.7%	-0.35 [-0.70, -
R 2012	21.3	8.6	68	26.4	10.4	68	45.5%	-0.53 [-0.87, -
Total (95% CI)			**148**			**148**	**100.0%**	**-0.36 [-0.59, -**

Heterogeneity: Chi² = 4.97, df = 2 (P = 0.08); I² = 60%
Test for overall effect: Z = 3.03 (P = 0.002)

Risk of bias legend
(**A**) Selective outcome reporting
(**B**) Incomplete outcome data
(**C**) Sequence Generation
(**D**) Other sources of bias
(**E**) Allocation concealment
(**F**) Blinding of participants and personnel
(**G**) Blinding of outcome assessors

Forest plot of comparison: 1 Mindfulness vs Treatment as usual (farmakologisk behandling), outcome: 1.3 Rumination, Længste follow-up (min. ½ år).

Figure 3 (Analysis 1.5)

	Mindfulness		Treatment as usual (farmakologisk behandling)			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**IV, Fixed, 95% CI**
1.5.1 Ved interventionens afslutning						
Bieling 2012	5	26	7	28	7.9%	0.77 [0.28, 2.12]
Bondolfi 2010	4	31	1	29	1.8%	3.74 [0.44, 31.55]
Geschwind 2011	1	63	0	65	0.8%	3.09 [0.13, 74.55]
Godfrin 2010	7	52	4	54	5.9%	1.82 [0.57, 5.84]
Huijbers 2015	5	33	5	35	6.2%	1.06 [0.34, 3.33]
Kuyken 2008	9	62	10	61	11.8%	0.89 [0.39, 2.03]
Kuyken 2015	26	212	28	212	32.6%	0.93 [0.56, 1.53]
Meadows 2014	25	102	7	102	12.9%	3.57 [1.62, 7.88]
R 2012	9	111	5	108	7.2%	1.75 [0.61, 5.06]
Segal 2010	5	26	7	28	7.9%	0.77 [0.28, 2.12]
Williams 2014	9	108	3	56	5.1%	1.56 [0.44, 5.52]
Subtotal (95% CI)		**826**		**778**	**100.0%**	**1.25 [0.94, 1.66]**
Total events	105		77			

Heterogeneity: Chi² = 12.84, df = 10 (P = 0.23); I² = 22%
Test for overall effect: Z = 1.51 (P = 0.13)

Total (95% CI)		**826**		**778**	**100.0%**	**1.25 [0.94, 1.66]**
Total events	105		77			

Heterogeneity: Chi² = 12.84, df = 10 (P = 0.23); I² = 22%
Test for overall effect: Z = 1.51 (P = 0.13)
Test for subgroup differences: Not applicable

0.1

Risk of bias legend
(**A**) Selective outcome reporting
(**B**) Incomplete outcome data
(**C**) Sequence Generation
(**D**) Other sources of bias
(**E**) Allocation concealment
(**F**) Blinding of participants and personnel
(**G**) Blinding of outcome assessors

Forest plot of comparison: 1 Mindfulness vs Treatment as usual (farmakologisk behandling), outcome: 1.5 Frafald/ All-cause discontinuation, Ved interventionens afslutning.

Figure 4 (Analysis 1.6)

	Mindfulness		Treatment as usual (farmakologisk behandling)			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**IV, Fixed, 95% CI**
1.6.1 Længste follow-up (min. ½ år)						
Bondolfi 2010	9	31	10	29	3.4%	0.84 [0.40, 1.77]
Godfrin 2010	12	40	32	47	7.1%	0.44 [0.26, 0.74]
Huijbers 2015	12	33	13	35	4.8%	0.98 [0.52, 1.83]
Kuyken 2015	70	153	80	162	34.6%	0.93 [0.73, 1.17]
Ma 2004	14	36	23	37	8.1%	0.63 [0.39, 1.01]
Meadows 2014	13	42	31	56	7.2%	0.56 [0.34, 0.93]
Segal 2010	10	26	13	28	4.7%	0.83 [0.44, 1.55]
Teasdale 2000	22	55	33	50	13.0%	0.61 [0.41, 0.89]
Williams 2014	46	99	28	53	17.1%	0.88 [0.63, 1.22]
Subtotal (95% CI)		**515**		**497**	**100.0%**	**0.77 [0.67, 0.88]**
Total events	208		263			
Heterogeneity: Chi² = 12.04, df = 8 (P = 0.15); I² = 34%						
Test for overall effect: Z = 3.83 (P = 0.0001)						
Total (95% CI)		**515**		**497**	**100.0%**	**0.77 [0.67, 0.88]**
Total events	208		263			
Heterogeneity: Chi² = 12.04, df = 8 (P = 0.15); I² = 34%						
Test for overall effect: Z = 3.83 (P = 0.0001)						
Test for subgroup differences: Not applicable						

Risk of bias legend
(**A**) Selective outcome reporting
(**B**) Incomplete outcome data
(**C**) Sequence Generation
(**D**) Other sources of bias
(**E**) Allocation concealment
(**F**) Blinding of participants and personnel
(**G**) Blinding of outcome assessors

Forest plot of comparison: 1 Mindfulness vs Treatment as usual (farmakologisk behandling), outcome: 1.6 Recidiv, Længste follow-up (min. ½ år).