NKR_38_opdat_Rehabilitering af patienter med proststakræft: Systematisk vurdering for depression - metaanalyse. København: Sundhedsstyrelsen, 2021.

Review information

Authors

Sundhedsstyrelsen[1]

[1][Empty affiliation]

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Characteristics of studies

Characteristics of included studies

Arving 2019

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Number (percentages) of patients with prostate cancer*: 61 (42%) ● *Number (percentages) of men*: 53 % ● *Age in years, mean (SD)*: 68 (47%) Control ● *Number (percentages) of patients with prostate cancer*: 63 (43%) ● *Number (percentages) of men*: 53 % ● *Age in years, mean (SD)*: 69 (47%) Overall ● *Number (percentages) of patients with prostate cancer*: 43% ● *Number (percentages) of men*: 53% ● *Age in years, mean (SD)*: 61 **Included criteria:** Those who were over the age of 18, had Stage I-III disease and were scheduled for neo/adjuvant or curative treatment were considered for inclusion (n= 1923). **Excluded criteria:** Exclusion criteria were previous cancer diagnosis (n= 593), ongoing psychiatric condition as determined by medical chart review (n= 19), or language deficiencies (n= 631)

Interventions	**Intervention Characteristics** Intervention ● *Description*: The intervention included the same topics as in an earlier study described by Rissanen et al (2014). The fidelity of treatment was checked in the supervision. It proved that the HPs followed the manuals and were similar in their administration of the intervention. All sessions, in both Step 1 and Step 2, lasted 45 to 60 minutes.The intervention started a mean 27 days after inclusion and the start of neo/adjuvant/curative therapy, and was completed within 26 weeks of inclusion (M = 70 days, standard deviation = 66 days) for both Step 1 and Step 2. Step 1: All patients (n= 145) received one counseling session whenthey started their neo/adjuvant/curative therapy at the Departmentof Oncology, and a follow-up session face-to-face (or over the telephone [n= 48, 34%] if the patient had been discharged from the hospital or lived at a great distance from it). At the counseling session, the patient received oral and written information about the causes and symptoms of stress, self-care measures to influence stress such as the daily registration of events and behaviors, and scheduled behavioral and physical exercises, along with brief relaxation training. Six weeks post inclusion and after having received acounseling session, participants were screened. Patients who didnot report clinically significant levels of cancer-related stress reactions or psychological distress (cut-off scores described elsewhere) participated in only one counseling session and a follow-up but were followed regularly for 2 years (Figure 1). Step 2: Patients (n= 66, 48%) who reported clinically significant levels of intrusive thoughts/avoidance behavior (≥9) and/or anxiety and depression (≥8) were offered additional sessions by the same HP who had conducted the first counseling session. Step 2 includes a higher-intensity stress-management intervention, with an additional three to eight sessions. At the end of each session, it was jointly decided whether further sessions were warranted.The main reason for continuation was presence of problems covered by the intervention that the individual wanted to address ● *Screening instrument*: Hospital Anxeity and Depression Scale (HADS) and the Impact of Event Scale (IES). ● *Follow-up treatment after screening*: Alle patienter der rapporrterede klinisk relevante symptomer (>7 på HADS eller >8 på IES) blev tilbudt 3-8 opfølgende sessioner. Control ● *Description*: This condition included the care offered to all patients, eg, all study participants and non-study participants at the Department of Oncology. It consisted of regular contact with the patient's own doctor and hospital staff, as well as the opportunity to take part in the common rehabilitation program, including patient education and physical training. ● *Screening instrument*: N/A ● *Follow-up treatment*: N/A
Outcomes	*HADS depression, 17 weeks, mean, 95% CI* ● **Outcome type**: Continuous Outcome ● **Reporting**: Partially reported ● **Scale**: Hospital anxiety and depression scale ● **Range**: 0-21 ● **Unit of measure**: Points ● **Direction**: Lower is better ● **Data value**: Endpoint *HADS depression, 104 weeks, mean, 95% CI* ● **Outcome type**: Continuous Outcome ● **Reporting**: Partially reported ● **Scale**: Hospital anxiety and depression scale ● **Range**: 0-21

	● **Unit of measure**: Points ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Norwegian Cancer Society; Grieg Foundation **Country:** Norway **Setting:** Department of Oncology and Medical Physics, Haukeland University Hospital,Bergen. **Authors name:** Cecilia Arving **Institution:** Department of Oncology and MedicalPhysics, Haukeland University Hospital,Bergen, Norway **Email:** cecilia.arving@pubcare.uu.se **Address:** Cecilia Arving, Department of Public Healthand Caring Sciences, Uppsala University, Box564, SE-751 22 Uppsala, Sweden.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "patients were randomized to either intervention or control, using block randomization (block size 4) stratified for cancer types." Judgement Comment: Presume the allocation sequence was generated by a computer.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information of allocation concealment.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information. Not possible to blind participants or personnel.
Blinding of outcome assessment (detection bias)	High risk	Quote: "The results are based only on self-reported measures." Judgement Comment: No information, patients were not blinded and outcomes were self-reported.
Incomplete outcome data (attrition bias)	Low risk	Quote: "Outcome data were analyzed according to the “intention to treat” principle." Judgement Comment: Completion rates: Intervention 85%, control 88%. No information on reasons for attrition. Low and equal numbers of dropoutds, intention to treat analysis
Selective reporting (reporting bias)	High risk	Quote: "(ClinicalTrials.gov Identifier: NCT 01588262)" Judgement Comment: HADS were stated in the methods section and reported in the publication. But this outcome were not stated in the protocol.
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Hollingworth 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Number (percentages) of patients with prostate cancer*: Urological cancer 27 (24.1) ● *Number (percentages) of men*: 36 (32.1%) ● *Age in years, mean (SD)*: 61 (12.2) Control ● *Number (percentages) of patients with prostate cancer*: Urological cancer 33 (30.6) ● *Number (percentages) of men*: 44 (40.7%) ● *Age in years, mean (SD)*: 62 (11.5) **Included criteria:** Eligibility criteria were as follows: age 18 and less than 85 years; primary solid tumor diagnosis within previous 12 months; outpatient external radiotherapy over a period of 2 weeks or outpatient chemotherapy of two cycles; ability to read and communicate in English; not receiving neoadjuvant chemotherapy; and not diagnosed with ductal carcinoma in situ or skin carcinoma **Excluded criteria:** Se above.
Interventions	**Intervention Characteristics** Intervention ● *Decription*: During approximately the second week of radiotherapy or second cycle of chemotherapy, patients in the DT&PL arm completed the DT&PL in a face-to-face meeting with a radiographer/nurse. At the discretion of the patient, a second DT&PL meeting could be arranged toward the end of therapy.The DT&PL is a quick method for screening for distress and identifying needs among people with cancer. Patients rate their distress in the last week on a 0 to 10 visual analog scale. The Distress Thermometer (DT) accurately identifies clinically significant levels of distress and is used in conjunction with a Problem List (PL) of physical, practical, family, emotional, and spiritual concerns to identify needs and the causes of distress. We refined the PL for United Kingdom patients, resulting in the 42-item list used in this RCT. The DT&PL forms the basis of a therapeutic conversation where concerns arei dentified and potential solutions are discussed including immediate staff actions (eg, pro-viding information), patient actions (eg, using a self-help resource), and referral (eg, psychological counseling). These action plans were recorded on the DT&PL. In our study, the DT&PL was predominantly used as a needs assessment tool, enabling patients to discuss concerns that might be addressed through immediate staff and patient actions. Although use of the DT&PL might prompt referral for specialist support, it was not primarily used as a screening tool, and therefore, no formal triage criteria were implemented. All staff attended a training session including an audiovisual example of DT&PL administration, role playing, and advice on dealing with strong emotions. We developed a resource directory providing information on self-management techniques, information sources, and support groups and guidance for staff on when to refer patients. Referrals were at the discretion of the clinician. ● *Screening instrument*: Distress Termometer (DT) and Problem list (PL) ● *Follow-up treatment after screening*: Ved en terapuetisk samtale blev resultatet og mulige løsninger herunder videre henvisning til psykologisk behandling diskuteret. Control ● *Decription*: The group assigned to usual care received chemotherapy or radiotherapy as normal. If patients expressed concerns about physical or psychosocial issues, then staff discussed these issues as normal, offering advice or making a referral. No formal time was set aside to monitor patient distress using the DT, elicit problems using the PL, or develop a plan of action. ● *Screening instrument*: N/A

	● *Follow-up treatment*: If patients expressed concerns about physicalor psychosocial issues, then staff discussed these issues as normal, offering advice or making a referral.
Outcomes	*Livskvalitet, diagnosespecifik, EORTC QLQ-C30, mean, SD, 6 måneder* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: EORTC QLQ-C30 ● **Range**: 0-100 ● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Endpoint *Livskvalitet, diagnosespecifik, EORTC QLQ-C30, mean, SD, 12 måneder* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: EORTC QLQ-C30 ● **Range**: 0-100 ● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Endpoint *Livskvalitet, helbredsrelateret, EQ-5D, mean, SD, 6 måneder* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: EQ-D5 ● **Range**: 0-100 ● **Direction**: Higher is better ● **Data value**: Endpoint *Livskvalitet, helbredsrelateret, EQ-5D, mean, SD, 12 måneder* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: EQ-5D ● **Range**: 0-100 ● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Endpoint *Antal i depressionsbehandling, antal henviste til psykologisk behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint

Identification	**Sponsorship source:** Supported by the National Institute forHealth Research, Research for PatientBenefit (Grant No. PB-PG-0807-13387). **Country:** UK **Setting:** two sites , outpatient chemotherapy or outpatient external radiotherapy **Authors name:** William Hollingworth **Institution:** School of Social and Community Medicine, Canynge Hall **Email:** e-mail:william.hollingworth@bristol.ac.uk **Address:** William Hollingworth, PhD, School of Social and Community Medicine, Canynge Hall, 39Whatley Rd, University of Bristol, Bris-tol, BS8 2PS, United Kingdom
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The random assignment list was computer generated with a 1:1 allocation, stratified by recruitment site, using random block sizes of two, four, or six."
Allocation concealment (selection bias)	Low risk	Quote: "The random assignment list was computer generated with a 1:1 allocation, stratified by recruitment site, using random block sizes of two, four, or six. Encryption concealed allocation until the patient’s details had been logged. Patients"
Blinding of participants and personnel (performance bias)	High risk	Quote: "Patients and therapists were aware of the allocated treatment."
Blinding of outcome assessment (detection bias)	High risk	Quote: "Outcomes were collected at baseline and 1, 6, and 12 months after random assignment by a researcher, unaware of the random assignment, using telephone-administered questionnaires." Judgement Comment: Outcomes were collected by blinded researcher, but outcomes were self-reported and participants were not blinded.
Incomplete outcome data (attrition bias)	Low risk	Quote: "The primary analysis was based on intention to treat" Judgement Comment: Low and equal number of dropouts, intention to treat analyses.
Selective reporting (reporting bias)	Low risk	Quote: "Clinical trial information: NCT00960466." Judgement Comment: All outcomes of interest that were stated in the protocol are reported in the publication.
Other bias	Low risk	Quote: "The author(s) indicated no potential conflicts of interest." Judgement Comment: The study appears to be free of other sources of bias

Singer 2017

Methods	**Study design:** Cluster randomized controlled trial **Study grouping:** Parallel group

Participants	**Baseline Characteristics** Intervention ● *Number (percentages) of patients with prostate cancer*: 43 (7.5) ● *Number (percentages) of men*: 317 (55.6) ● *Age in years, mean (SD)*: 63.4 (12.9) Control ● *Number (percentages) of patients with prostate cancer*: 81 (18.3) ● *Number (percentages) of men*: 361 (81.7) ● *Age in years, mean (SD)*: 64.1 (11.1) ● *Time since diagnosis*: **Included criteria:** Cluster level: Wards of the University Medical Centre Leipzig were randomly allocated to either“stepped care” or “standard care. ”Wards were eligible for this study if they treated cancer patients and if psychooncological care followed the standard model; ie, a consultation psychooncologist was called ifa doctor or nurse felt this was needed for a patient. Wards with a liaison service, ie, where a psychooncologist visited every patient, could not participate. Patient level: The eligibility criterion for patients was age greater than or equal to 18 years. **Excluded criteria:** Patient exclusion criteria were insufficient command of German and no written informed consen.
Interventions	**Intervention Characteristics** Intervention ● *Decription*: The stepped care had 3 steps.Step 1: each patient was screened for distress (including depression, anxiety, pain, fatigue, and financial difficulties). The results were electronically computed, graphically visualized, and fed back to the clinician in charge. Each patient's distress level was visualized by colors (green = no or little distress andred = severe distress) Step 2: during routine clinical consultation, the clinician talked to patients with severe distress about the screening results and explored their wishes for support. All doctors were trained to interpret the screening results and how to incorporate them into their daily clinical care. They were also trained to address distress in their consultations and how to consider the patient's wishes and needs for support. The training was done on each ward, first with all residents and consultants together and then with each doctor separately again. A team member (HD) was always available for questions via email and telephone, and he visited and supervised the doctors regularly on the wards. Step 3: if the patient and doctor agreed that further support was needed, the patient was referred to the hospital's services. ● *Screening instrument*: In the intervention arm, the patients were screened at baseline regarding depression with the Patient Health Questionnaire Short Form (PHQ-9) and regarding anxiety with the Generalized Anxiety Screener. ● *Follow-up treatment after screening*: Step 3: If the patient and doctor agreed that further support was needed, the patient was referred to the hospital's services. Control ● *Decription*: Standard care was provided to patients on the control wards. That is, doctors could call CL services when ever they felt it was necessary. They did not receive specific training to detect distress or to talk with the patients about emotional problems. ● *Screening instrument*: N/A ● *Follow-up treatment*: doctors could call CL services whenever they felt it was necessary.They did not receive specific training to detect distress or to talk withthe patients about emotional problems.

Outcomes	*Livskvalitet, weelbeeing målt med HADS, 6 måneder, mean, SD* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: HADS ● **Range**: 0-21 ● **Unit of measure**: Points ● **Direction**: Lower is better ● **Data value**: Endpoint *Antal i depressionsbehandling, antal henviste til psykologisk behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Funding information: Bundesministerium für Gesundheit (German Federal Ministry of Health), Grant/Award Number: NKP-332-026 **Country:** Germany **Setting:** wards of the Universitiy medical Centre Leipzig **Authors name:** Susanne Singer **Institution:** Institute of Medical Biostatistics, Epidemiology, and Informatics (IMBEI), University Medical Centre Mainz, Mainz, Germany **Email:** singers@uni-mainz.de **Address:** Susanne Singer, Institute of Medical Biostatistics, Epidemiology and Informatics, University Medical Centre Mainz, Obere Zahlbacher Straße 69, 55131 Mainz,Germany
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The Centre for Clinical Trials (Interdisziplinäres Zentrum Klinische Studien) performed the randomization of wards externally. The wards were concealed for the randomization by using pseudonyms (random numbers). Only the project manager (HD) knew which number belonged to which ward. He was not involved in the randomization. The Interdisziplinäres Zentrum Klinische Studien performed the ran- domization independently, and the project manager then unsealed the ward numbers for each arm."
Allocation concealment (selection bias)	Low risk	Quote: "The Centre for Clinical Trials (Interdisziplinäres Zentrum Klinische Studien) performed the randomization of wards externally. The wards were concealed for the randomization by using pseudonyms (random numbers). Only the project manager (HD) knew which number belonged to which ward. He was not involved in the randomization. The Interdisziplinäres Zentrum Klinische Studien performed the ran- domization independently, and the project manager then unsealed the ward numbers for each arm."

Blinding of participants and personnel (performance bias)	High risk	Quote: "The patients were not told to which group they had been randomized. However, the intervention itself obviously could not be blinded. The doctors could not be blinded because they had to change their consultation behavior in the intervention arm. The study nurses collected data either always on intervention wards or always on control wards. They did not change trial arms."
Blinding of outcome assessment (detection bias)	High risk	Quote: "The study nurses collected data either always on intervention wards or always on control wards. They did not change trial arms." Judgement Comment: Patients in both trial arms were assessed at the beginning (t1) and the end (t2) of their hospital stay, and then 3 months (t3) and 6 months (t4) after baseline. At t1 and t2, data collection was done via tablet com- puters with the help of study nurses who were not treating the patients but were employed only for data collection in this trial. Patients in both arms underwent the same assessments. Self-reported outcomes.
Incomplete outcome data (attrition bias)	High risk	Quote: "dropout was 40% in stepped care and 47% in standard care" Judgement Comment: High number of dropouts, but equal in the two groups. 217/570 in the stepped care intervention vs 195/442 in the standard care intervention. Reasons not stated. Dropouts are excpected in this population, 84 deceased in the intervention group and 63 in the control.
Selective reporting (reporting bias)	High risk	Quote: "NCT01859429," Judgement Comment: Protocol available at clinicaltrials.gov.Role Functioning Subscale, EORTC QLQ-C30 is stated in the protocol but not reported in the publication
Other bias	High risk	Judgement Comment: 7,5 % with prostate cancer in the intervention group and 18,3 % i the control group. Other imbalances between the two groups (sex, type of cancer, stage of cancer) a consequenc of a low number of clusters. 7,5 % with prostate cance rin the intervention group and 18,3 % i the control group. Other imbalances between the two groups (sex, type of cancer, stage of cancer) a consequenc of a low number of clusters.

Velikova 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Number (percentages) of patients with prostate cancer*: 0% ● *Number (percentages) of men*: 36 (25%) ● *Age in years, mean (SD)*: 55.1 (13.02) Attention control ● *Number (percentages) of patients with prostate cancer*: 0% ● *Number (percentages) of men*: 21 (30 %) ● *Age in years, mean (SD)*: 54.8 (12.49) Control ● *Number (percentages) of patients with prostate cancer*: 0% ● *Number (percentages) of men*: 19 (26%) ● *Age in years, mean (SD)*: 54.7 (11.67)

	Included criteria: Patients attending the Leeds Cancer Centre Medical Oncol-ogy Clinic at St James's Hospital (Leeds, UK) were eligible if they were commencing treatment, expected to attend the clinic at least three times, fluent in English, not taking part in HRQL studies, and not exhibiting overt psychopathology. Patients were invited to participate in the study after a medical decision had been made during their initial consultation to start cytotoxic or biologic treatment. **Excluded criteria:** Se above
Interventions	**Intervention Characteristics** Intervention ● *Decription*: The intervention questionnaires used were the European Organization for Research and Treatment of Cancer–Core Quality of Life Questionnaire, version 3.0 (EORTC QLQ-C30), and the Hospital Anxiety and Depression Scale (HADS). EORTC QLQ-C30 is a 30-item questionnaire including five functional scales (physical, emotional, cognitive, social, and role), three symptom scales (fatigue, pain, and nausea/vomiting), a global HRQL scale, and six single items on common symptoms. The EORTC QLQ-C30 was chosen as intervention questionnaire because it is widely used in clinical trials and is likely to be familiar tomany oncologists. The questionnaire measures common cancer-related symptoms—a feature considered desirable by participating oncologists. It has a published developmental history, and reference data were available in a non cancer population to aid interpretation of results. HADS is a 14-item instrument with two subscales for anxiety and depression. Scores range from 0 to 21 on each scale, with higher scores indicating more distress. Scores above 11 suggest probable cases of anxiety or depressive illness, and scores between 8 and 10 indicate borderline cases.Touch-screen computers were used, with graphic printouts of results. Physicians were trained in interpretation of the questionnaires. A manual was prepared, with description of scales, interpretation of scores, and explanation of the graphs. Structured meetings were conducted individually, with each physicianto discuss the study and review examples of HRQL and clinical details of real patients. Posters with interpretative information were displayed in clinics. The physicians were asked to review and use the HRQL results during all intervention encounters, unless totally inappropriate. No recommendations for specific responseswere made. After seeing each patient, the physicians completed a check-list assessing the clinical usefulness of the HRQL results for the individual encounter. Physicians indicated whether they found the data clinically useful and in what way. ● *Screening instrument*: Hospital Anxiety and Depression Scale (HADS) og European Organization for Research and Treatment and Cancer-Core Quality of Life Questionnaire (EORTC QLQ-C30) ● *Follow-up treatment after screening*: No reccomendations for specific responses were made. Attention Control ● *Decription*: ; attention-control group (group 2; completion of HRQL questionnaires on touch-screen computer, but no feedback to physicians); ● *Screening instrument*: Hospital Anxiety and Depression Scale (HADS) og European Organization for Research and Treatment and Cancer-Core Quality of Life Questionnaire (EORTC QLQ-C30) ● *Follow-up treatment*: Control ● *Decription*: (group 3, no touch-screen measurement of HRQL before clinicencounters). ● *Screening instrument*: N/A ● *Follow-up treatment*:
Outcomes	*Livskvalitet, diagnosespecifik, FACT-G* ● **Outcome type**: Continuous Outcome ● **Reporting**: Partially reported ● **Scale**: *FACT-G* ● **Range**: 0-108

	● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** Supported by grants from Cancer Re-search UK (formerly Imperial CancerResearch Fund; G.V., A.B.S., L.B., P.L.,and P.J.S.), the National Lotteries Chari-ties Board (G.V.), and National HealthService Research and Development(J.M.B., P.M.B. **Country:** UK **Setting:** Oncology clinics **Authors name:** Galina Velikova **Institution:** the Cancer Research UK ClinicalCentre–Leeds, Cancer Medicine Re-search Unit, St James's University Hospital; and Northern and Yorkshire Clini-cal Trials and Research Unit, Leeds,United Kingdom **Email:** g.velikova@cancermed.leeds.au.uk
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The random assignment was unbalanced 2:1:1 in favor of the intervention group, and stratified by site of cancer in random permuted blocks (block size was 8). Random assignment was carried out by telephone, by the Administrative Office at Cancer Research UK Centre (Leeds)." Judgement Comment: Presume the sequence was generated by a computer.
Allocation concealment (selection bias)	Low risk	Quote: "Random assignment was carried out by telephone, by the Administrative Office at Cancer Research UK Centre (Leeds)."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: introduction of the atttention control group somewhat blinded the patients for the intervention. The physicians were not blinded.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: FACT-G is a self-reported measure. High risk of bias for the control vs intervention group. Participants in the attention group vs. intervention group was somewhat blinded.
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "An attrition rate of above 30% was observed, which is not dissimilar to other longitudinal studies. The missing data problem was addressed to some extent in the analysis by the mixed- effects model, which assumes that drop-out is not related to intervention. This assumption was checked using logistic regression with drop-out as outcome and study arm was not found to influence attrition" Judgement Comment: Dropouts unevenly distribuited between groups, 3 months: 27/144 (19%) in the intervention group, 19/70 (27%) in the attention control group and 11/72 in the control group (15 %), 6 months: 46/144 (32%), 29/70 (41%) and 23/72 (325).
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No reference to a protocol. Reports on the outcomes stated in the methods section. Only FACT-G is reported. No reference to a protocol. Reports on the outcomes stated in the methods section. Only FACT-G is reported.
Other bias	Low risk	Judgement Comment: The study appears to be free of other sources of bias

Footnotes

Characteristics of excluded studies

Anna 2020

Reason for exclusion	Wrong study design

Bergholdt 2012

Reason for exclusion	Wrong intervention

Bergholdt 2013

Reason for exclusion	Wrong intervention

Braeken 2009

Reason for exclusion	Wrong intervention

Braeken 2011

Reason for exclusion	Wrong intervention

Braeken 2013

Reason for exclusion	Wrong intervention

Braeken 2013a

Reason for exclusion	Wrong intervention

Butow 2018

Reason for exclusion	Wrong study design

Butow 2018a

Reason for exclusion	Wrong study design

Desjardins 2018

Reason for exclusion	Wrong study design

Detmar 2002

Reason for exclusion	Wrong intervention

doCarmo 2017

Reason for exclusion	Wrong intervention

Dvorak 2018

Reason for exclusion	Wrong comparator

ElAlili 2020

Reason for exclusion	Wrong study design

Fraguell Hernando 2020

Reason for exclusion	Wrong study design

Geerse 2017

Reason for exclusion	Wrong patient population

Giesler 2005

Reason for exclusion	Wrong intervention

Given 2004

Reason for exclusion	Wrong intervention

Hahn 2019

Reason for exclusion	Wrong patient population

Hahn 2020

Reason for exclusion	Wrong patient population

Hansen 2011

Reason for exclusion	Wrong intervention

Harrison 2011

Reason for exclusion	Wrong patient population

Igelstrom 2020

Reason for exclusion	Wrong study design

Jayani 2019

Reason for exclusion	Wrong study design

Kutner 1999

Reason for exclusion	Wrong intervention

Lazenby 2019

Reason for exclusion	Wrong study design

Livingston 2010

Reason for exclusion	Wrong intervention

Matsuda 2019

Reason for exclusion	Wrong intervention

Maunsell 1996

Reason for exclusion	Wrong intervention

McCarter 2018

Reason for exclusion	Wrong study design

McCarter 2018a

Reason for exclusion	Wrong study design

Nimako 2017

Reason for exclusion	Wrong patient population

OHea 2020

Reason for exclusion	Wrong intervention

Olesen 2018

Reason for exclusion	Wrong patient population

Peeters 2020

Reason for exclusion	Wrong patient population

Richards 2019

Reason for exclusion	Wrong patient population

Roick 2018

Reason for exclusion	Wrong study design

Rosenbloom 2007

Reason for exclusion	Wrong intervention

Schofield 2013

Reason for exclusion	Wrong patient population

Schofield 2016

Reason for exclusion	Wrong intervention

Schuurhuizen 2018

Reason for exclusion	Wrong patient population

Schuurhuizen 2019

Reason for exclusion	Wrong patient population

Shreders 2019

Reason for exclusion	Wrong study design

Singer 2019

Reason for exclusion	Wrong study design

vanderDonk 2019

Reason for exclusion	Wrong study design

vanderMeulen 2018

Reason for exclusion	Wrong patient population

vanNuenen 2020

Reason for exclusion	Wrong study design

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Arving 2019

Arving C.; Assmus J.; Thormodsen I.; Berntsen S.; Nordin, K.. Early rehabilitation of cancer patients-An individual randomized stepped-care stress-management intervention.. Psycho-oncology 2019;28(2):301-308. [DOI:]

Hollingworth 2013

Hollingworth, W.; Metcalfe, C.; Mancero, S.; Harris, S.; Campbell, R.; Biddle, L.; McKell-Redwood, D.; Brennan, J.. Are needs assessments cost effective in reducing distress among patients with cancer? A randomized controlled trial using the Distress Thermometer and Problem List. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2013;31(29):3631-3638. [DOI: 10.1200/JCO.2012.48.3040 [doi]]

Singer 2017

Singer, S.; Danker, H.; Briest, S.; Dietrich, A.; Dietz, A.; Einenkel, J.; Papsdorf, K.; Lordick, F.; Meixensberger, J.; Mossner, J.; Niederwieser, D.; Prietzel, T.; Schiefke, F.; Stolzenburg, J. U.; Wirtz, H.; Kersting, A.. Effect of a structured psycho-oncological screening and treatment model on mental health in cancer patients (STEPPED CARE): study protocol for a cluster randomized controlled trial. Trials 2014;15(Journal Article):482-6215-15-482. [DOI: 10.1186/1745-6215-15-482 [doi]]

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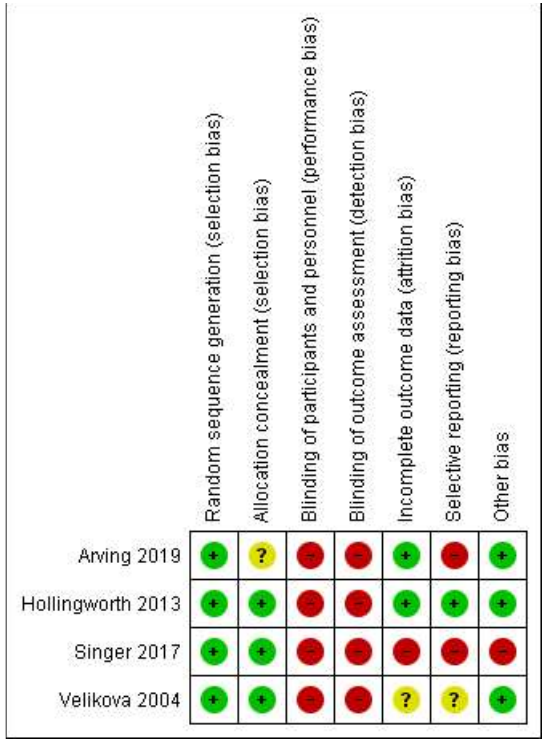
Data and analyses

1 Systematisk vurdering for depression vs Ingen systematisk vurdering

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Diagnosespecifik livskvalitet (disease related quality of life) Tidlig opfølgning	2	423	Std. Mean Difference (IV, Random, 95% CI)	-0.22 [-0.61, 0.18]
1.2 Diagnosespecifik livskvalitet (disease related quality of life) Længste follow-up	2	425	Std. Mean Difference (IV, Random, 95% CI)	-0.04 [-0.24, 0.16]
1.3 Helbredsrelateret livskvalitet (health related quality of life) tidlig opfølgning	1	209	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.06, 0.07]
1.4 Helbredsrelateret livskvalitet (health related quality of life) længste follow-up	1	209	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.03, 0.12]
1.5 Depressive symptomer (depressive symptoms) tidlig opfølgning	2	473	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.25, 0.11]
1.6 Depressive symptomer (depressive symptoms) Længste follow-up	2	460	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.23, 0.33]
1.7 Diagnosespecifik livskvalitet (disease related quality of life) Tidlig opfølgning, antal med klinisk relevant forbedring	1	216	Risk Ratio (M-H, Fixed, 95% CI)	1.71 [1.08, 2.70]

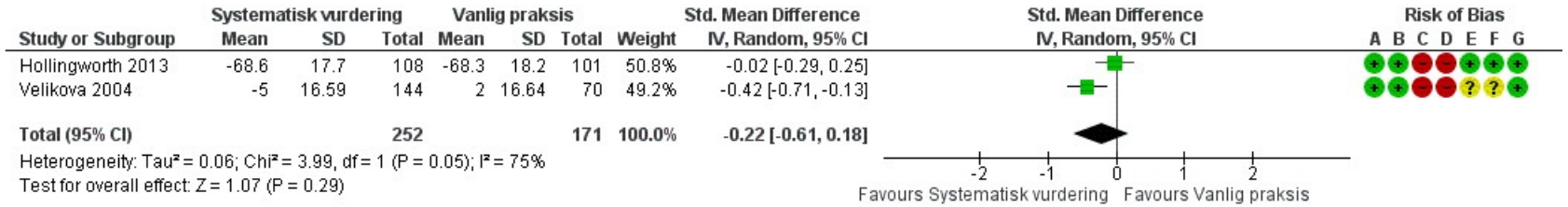
Figures

Figure 1



Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

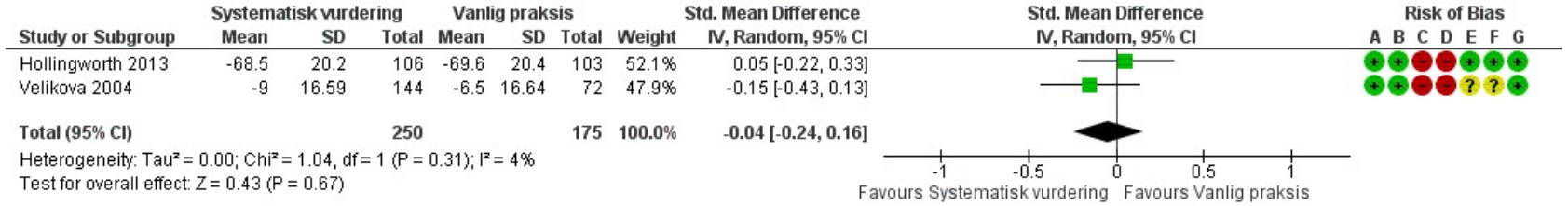
Figure 2 (Analysis 1.1)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.1 Diagnosespecifik livskvalitet (disease related quality of life) Tidlig opfølgning.

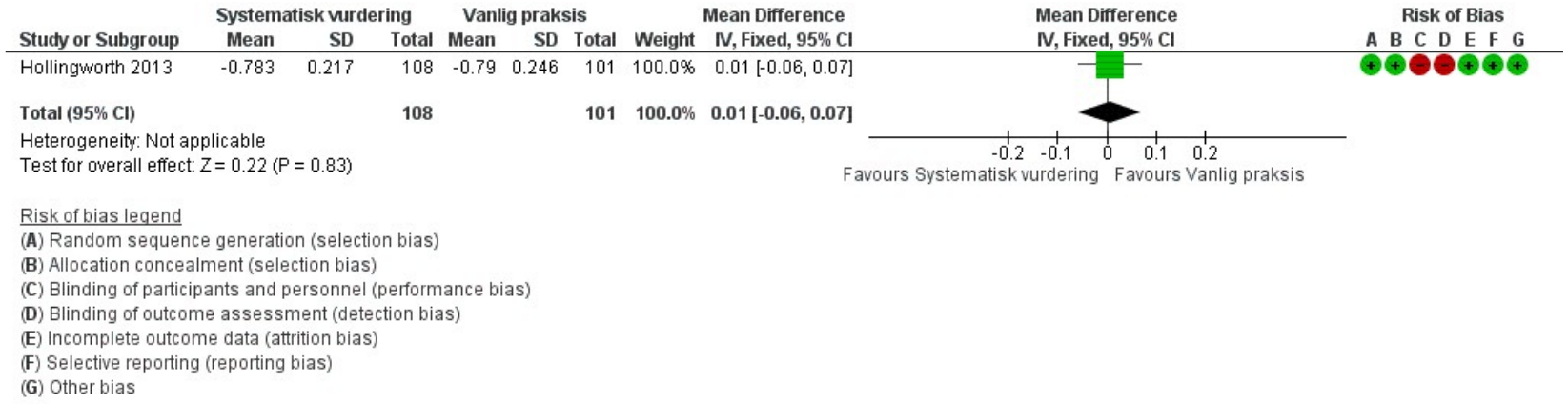
Figure 3 (Analysis 1.2)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

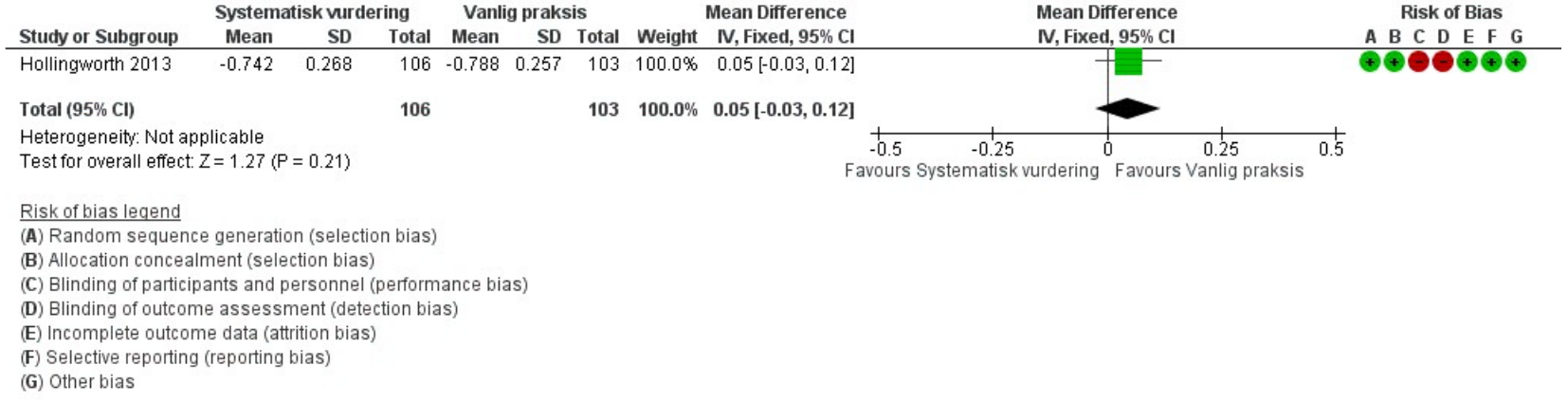
Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.2 Diagnosespecifik livskvalitet (disease related quality of life) Længste follow-up.

Figure 4 (Analysis 1.3)



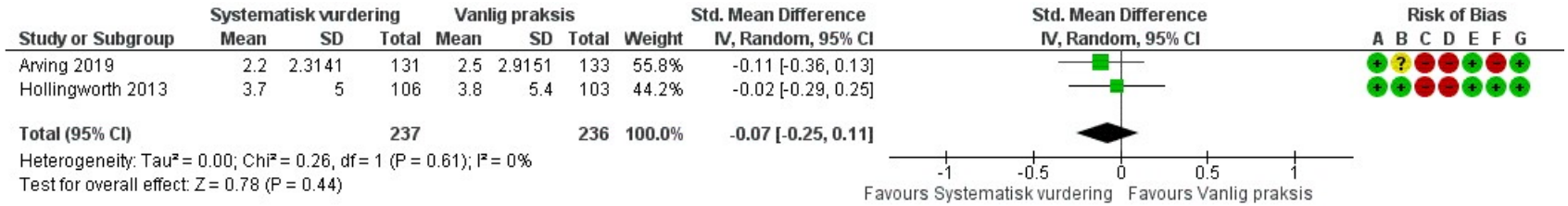
Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.3 Helbredsrelateret livskvalitet (health related quality of life) tidlig opfølgning.

Figure 5 (Analysis 1.4)



Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.4 Helbredsrelateret livskvalitet (health related quality of life) længste follow-up.

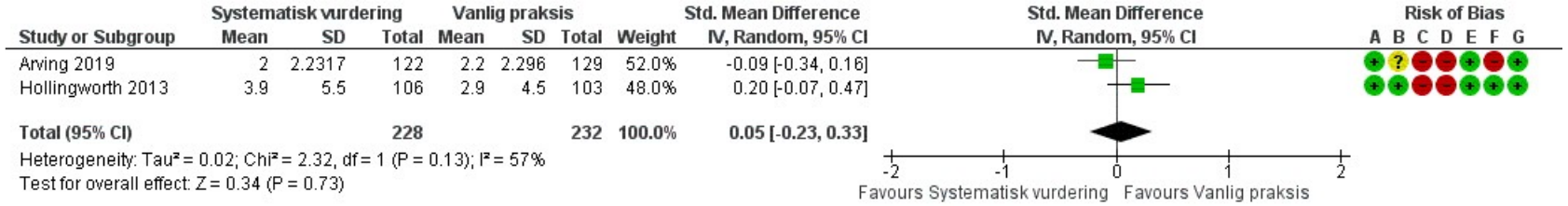
Figure 6 (Analysis 1.5)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.5 Depressive symptomer (depressive symptoms) tidlig opfølgning.

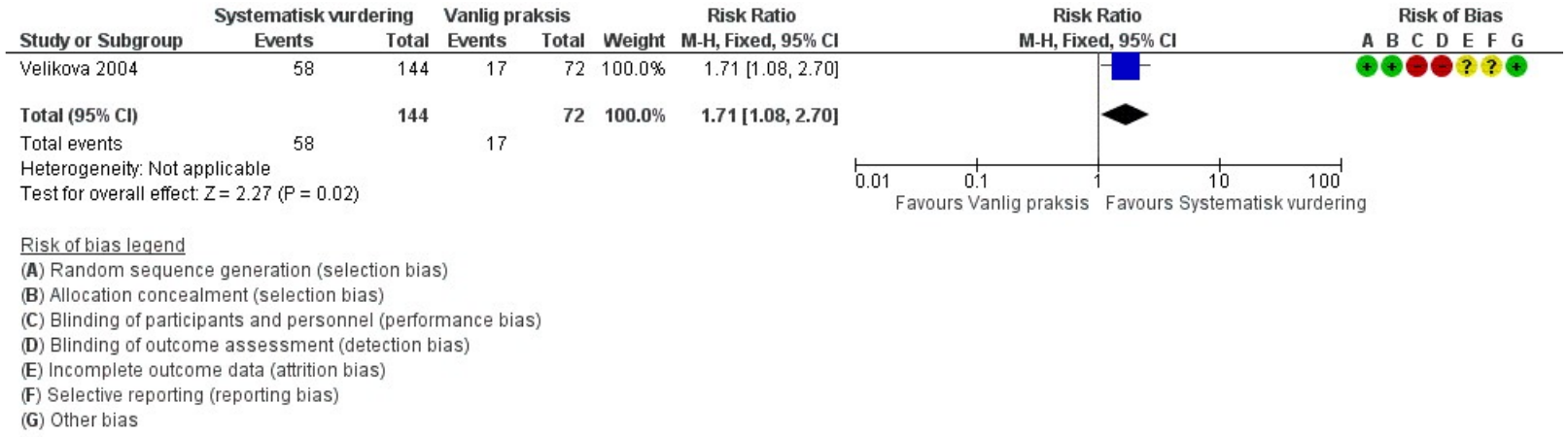
Figure 7 (Analysis 1.6)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.6 Depressive symptomer (depressive symptoms) Længste follow-up.

Figure 8 (Analysis 1.7)



Forest plot of comparison: 1 Systematisk vurdering for depression vs Ingen systematisk vurdering, outcome: 1.7 Diagnosespecifik livskvalitet (disease related quality of life) Tidlig opfølgning, antal med klinisk relevant forbedring.