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Supplemental online content for:

Screening and Stepped Care Targeting Psychological Distress in Patients With Metastatic Colorectal Cancer: The TES Cluster Randomized Trial

Claudia S.E.W. Schuurhuizen, MD; Annemarie M.J. Braamse, PhD; Aartjan T.F. Beekman, PhD; Pim Cuijpers, PhD; Mecheline H.M. van der Linden, PhD; Adriaan W. Hoogendoorn, PhD; Hans Berkhof, PhD; Dirkje W. Sommeijer, MD, PhD; Vera Lustig, MD; Suzan Vrijaldenhoven, MD, PhD; Haiko J. Bloemendal, MD, PhD; Cees J. van Groeningen, MD, PhD; Annette A. van Zweeden, MD; Maurice J.D.L. van der Vorst, MD; Ron Rietbroek, MD; Cathrien S. Tromp-van Driel, MD; Machteld N.W. Wymenga, MD, PhD; Peter W. van der Linden, MD, PhD; Aart Beeker, MD; Marco B. Polee, MD, PhD; Erdogan Batman, MD; Maartje Los, MD, PhD; Aart van Bochove, MD; Jan A.C. Brakenhoff, MD; Inge R.H.M. Konings, MD, PhD; Henk M.W. Verheul, MD, PhD; and Joost Dekker, PhD

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eTable 1. Characteristics and Outcomes of Included Randomized Controlled Trials

Reference	Primary Outcome	Secondary Outcomes	Study Design	Sample	Measures	Results	Conclusions	Comments
Braeken et al,[1] 2013	Distress	QoL	Cluster randomized trial at the level of radiotherapists, with 2 intervention and 2 control groups Intervention groups were screened twice: before the first consultation and at the end of radiotherapy Potential referral for psychosocial support was based on the SIPP scores and judgment concerning patient's needs All patients had distress and QoL assessment at 3 and 12 mo	N=568: control, n=300; intervention, n=268 Patients with different types of cancer, no distant disease starting radiotherapy Baseline distress on GHQ-12: 2.89 vs 3.16 in control vs intervention groups, respectively (*P*=.53)	HADS, GHQ-12, EORTC QLQ-C30 Screening tool: SIPP	No significant difference in distress between control and intervention groups at 3 and 12 mo (*P*=.19 and *P*=.12, respectively) Distress on GHQ-12 in control vs intervention groups, respectively: 2.85 vs 2.74 at 3 mo, and 2.14 vs 1.96 at 12 mo	No effect on psychosocial well-being	An additional baseline assessment was conducted in 1 experimental group and 1 control group to check for potential premeasurement effect on the intervention outcomes
Geerse et al,[2] 2017	QoL	Distress, patient satisfaction	Intervention group: 5 screening moments, followed by face-to-face discussion with nurse, and referral for patients with high scores or expressed need All patients had QoL, distress, and satisfaction assessment at 1, 7, 13, and 25 wk after randomization	N=223: control, n=113; intervention, n=110 Patients with newly diagnosed stage Ib–IV or recurrent lung cancer Baseline global QoL score: 57.7 vs 59.2 in control vs intervention group	EORTC QLQ-C30, EQ-5D, HADS, PSQ-III Screening tool: DT/PL	No significant difference was found in the mean change global QoL score (−2.4; 95% CI, 12.1–7.2; *P*=.61) or in the other patient-reported outcomes	No effect on psychosocial well-being	Substantially higher dropout rate than originally anticipated led to an interim analysis Based on interim analysis results, study inclusion was stopped early at 223 patients because not even a trend toward a significant effect in primary outcome was found
Hollingworth et al,[3] 2013	Mood state	QoL, satisfaction with care, costs	Intervention group: patients completed assessment in a face-to-face meeting with radiographer/nurse, during which potential solutions were discussed, including referrals during second week of treatment Outcomes for all patients were collected at baseline and 1, 6, and 12 mo	N=220: control, n=112; intervention, n=108 Patients with primary solid tumor diagnosis undergoing outpatient chemotherapy or radiotherapy Mean total POMS score at baseline was 35 in both groups	POMS, EORTC QLQ-C30, EQ-5D, TPVCSQ Screening tool: DT/PL	No evidence of an intervention effect on the total POMS score at 12 mo or over the 12-mo follow-up Comparison of total POMS scores at 12 mo (estimate, −5.16; 95% CI, −10.36 to 0.04; *P*=.052) provided weak evidence of higher (worse) POMS scores in the DT/PL group	No effect on psychosocial well-being	No formal triage criteria were implemented; the DT/PL was used as a needs assessment rather than as a triage tool

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Abbreviations: CES-D, Center for Epidemiologic Studies–Depression Scale; DIS, Diagnostic Interview Schedule; DT/PL, Distress Thermometer/Problem List; EQ-5D, EuroQol 5 Dimensions questionnaire; GAS, Generalized Anxiety Screener; GHQ-12, 12-item General Health Questionnaire; GHS, German Health Survey; QLQ-C30, QoL of Cancer Patients questionnaire; HADS, Hospital Anxiety and Depression Scale; H&N35, Head and Neck module; LES, Life Experiences Survey; LWMAT, Locke-Wallace Marital Adjustment Test; PHQ-9, Patient Health Questionnaire 9; POMS, Profile of Mood States; PSI, Psychiatric Symptom Index; PSQ-III, Patient Satisfaction Questionnaire III; QoL, quality of life; SIPP, Screening Inventory of Psychosocial Problems; SSQ, Social Support Questionnaire; TPVCSQ, Trent Patient Views of Cancer Services Questionnaire.

eTable 1. Characteristics and Outcomes of Included Randomized Controlled Trials (cont.)

Reference	Primary Outcome	Secondary Outcomes	Study Design	Sample	Measures	Results	Conclusions	Comments
Maunsell et al,[4] 1996	Distress	QoL, including depression, anxiety, physical health, return to usual activities, employment, marital satisfaction	Intervention group: 12 monthly telephone screenings; patients with high distress were contacted by social worker within 2 wk All patients had telephone follow-up at baseline and 3 and 12 mo	N=250: control, n=127; intervention, n=123 Women newly diagnosed with first primary breast cancer, no distant disease; baseline distress, mean PSI of 20.5	PSI, GHQ, LES, LWMAT, DIS, SSQ, employment Screening tool: GHQ	No significant difference in distress between intervention and control groups (P=.65) Distress changes: mean PSI, 20.4 to 13.5 in intervention group and 20.7 to 14.6 in control group Distress level in both groups decreased over time ($P \leq 001$)	No effect on psychosocial well-being	All patients received brief psychosocial intervention from social worker at initial treatment; this may have obscured an effect of the intervention
Singer et al,[5] 2017	Referral to psychosocial services and distress	Uptake of outpatient care	Cluster randomized trial at the level of wards: 7 in the control arm and 6 in the intervention arm Intervention comprised screening for distress, consultation between doctor and patient regarding the patient's need for services, and provision of services All patients had assessment of well-being at the beginning and end of their hospital stay and at 3 and 6 mo after baseline	N=1,012: control, n=570 (7 wards); intervention, n=442 (6 wards) Patients treated for cancer in the wards At the beginning of their hospital stay, mean HADS distress scores were 10.2 in the control group and 11.4 in the intervention group	HADS, referral to psychosocial services, GHS Screening tool: PHQ-9, GAS-7	22% of patients in the intervention group were referred to services and 3% to standard care (odds ratio, 10.0; P<.001) Well-being 6 mo after baseline was 9.5 in the intervention group (n=341) and 9.4 for the control group (n=234) ($\beta = -0.3$; P=.71)	No effect on psychosocial well-being	
van der Meulen et al,[6] 2018	Depressive symptoms	QoL, worry of cancer	Intervention consisted of screening and nurse-guided follow-up lasting ~20 min 3 or 4 times during 12 mo All patients had assessment at baseline and at 6 and 12 mo	N=110: control, n=57; intervention, n=53 Patients with head and neck cancer Baseline depressive scores were 12.4 in the control group and 11.8 in the intervention group	CES-D, EORTC QLQ-C30, EORTC QLQ-H&N35, Cancer Worry Scale Screening tool: DT/PL	Depressive symptoms, health-related QoL, and worry of cancer were not significantly different in the treatment groups	No effect on psychosocial well-being	Feasibility trial

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Abbreviations: CES-D, Center for Epidemiologic Studies–Depression Scale; DIS, Diagnostic Interview Schedule; DT/PL, Distress Thermometer/Problem List; EQ-5D, EuroQol 5 Dimensions questionnaire; GAS, Generalized Anxiety Screener; GHQ-12, 12-item General Health Questionnaire; GHS, German Health Survey; QLQ-C30, QoL of Cancer Patients questionnaire; HADS, Hospital Anxiety and Depression Scale; H&N35, Head and Neck module; LES, Life Experiences Survey; LWMAT, Locke-Wallace Marital Adjustment Test; PHQ-9, Patient Health Questionnaire 9; POMS, Profile of Mood States; PSI, Psychiatric Symptom Index; PSQ-III, Patient Satisfaction Questionnaire III; QoL, quality of life; SIPP, Screening Inventory of Psychosocial Problems; SSQ, Social Support Questionnaire; TPVCSQ, Trent Patient Views of Cancer Services Questionnaire.

eTable 1. Characteristics and Outcomes of Included Randomized Controlled Trials (cont.)

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eTable 2. Conditional Power and Required Number of Patients to Obtain Power of 0.80

Proportion Receiving Distress Treatment in TES Program (%)	Conditional Power With n=715	Number Needed (Experimental + Control Groups) for Power of 0.80
5%	0.06	251,088
8.7%[a]	0.11	33,318
10%	0.13	20,716
13.7%[b]	0.21	7,548
15%	0.24	5,746
15.4%[c]	0.25	5,318
20%	0.39	2,552
25%	0.56	1,432
33%	0.80	716
35%	0.84	640

Abbreviation: TES, targeted selection (T), enhanced care (E), and referral to well-described effective interventions using a stepped care–oriented approach (S).
[a]Observed proportion of patients treated for psychologic distress.
[b]Upper limit of the 95% CI of the observed proportion treated.
[c]Upper limit of the 99% CI of the observed proportion treated.

eTable 3. Extended Baseline Patient Characteristics

	Total Group (N=349) n (%)	TES Program (n=184) n (%)	CAU (n=165) n (%)
Mean age (SD), y	66.1 (10.2)	66.25 (9.8)	65.84 (10.6)
Sex			
Male	224 (64.2)	113 (61.4)	111 (67.3)
Female	125 (35.8)	71 (38.6)	54 (32.7)
ECOG PS			
0	82 (23.5)	48 (26.1)	34 (20.6)
1	105 (30.1)	71 (38.6)	34 (20.6)
2	11 (3.2)	6 (3.3)	5 (3.0)
Missing	151 (43.3)	59 (32.1)	92 (55.8)
Primary tumor location			
Right-sided	107 (30.7)	62 (33.7)	45 (27.3)
Left-sided	239 (68.5)	121 (65.8)	118 (71.5)
Missing	3 (0.9)	1 (0.5)	2 (1.2)
RAS status			
WT	62 (17.8)	31 (16.8)	31 (18.8)
MT	86 (24.6)	49 (26.6)	37 (22.4)
Missing	201 (57.6)	104 (56.5)	97 (58.8)
Chemotherapy regimen			
Capecitabine	72 (20.6)	36 (19.6)	36 (21.8)
CAPOX	240 (68.8)	124 (67.4)	116 (70.3)
FOLFOX	24 (6.9)	17 (9.2)	7 (4.2)
Other	10 (2.9)	6 (3.3)	4 (2.4)
Missing	3 (0.9)	1 (0.5)	2 (1.2)
Use of monoclonal antibodies			
Yes	230 (65.9)	117 (63.6)	113 (68.5)
No	116 (33.2)	66 (35.9)	50 (30.3)
Missing	3 (0.9)	1 (0.5)	2 (1.2)
Mean number of comorbidities (SD)	2.33 (1.83)	2.44 (1.86)	2.21 (1.78)
Marital status			
Married/Domestic partnership	256 (73.4)	133 (72.3)	123 (74.5)
Unmarried/Divorced/Widowed	89 (25.5)	49 (26.6)	40 (24.2)
Missing	4 (1.1)	2 (1.1)	2 (1.2)
Education			
Low	19 (5.4)	10 (5.4)	9 (5.5)
Middle	223 (63.9)	122 (66.3)	101 (61.2)
High	101 (28.9)	49 (26.6)	52 (31.5)
Missing	6 (1.7)	3 (1.6)	3 (1.8)

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Abbreviations: CAPOX, capecitabine and oxaliplatin; CAU, care as usual; FOLFOX, leucovorin/5-fluorouracil/oxaliplatin; HADS, Hospital Anxiety and Depression Scale; HIPEC, hyperthermic intraperitoneal chemotherapy; MT, mutant type; PS, performance status; QLQ-C30, QoL of Cancer Patients questionnaire; QoL, quality of life; RFA, radiofrequency ablation; TES, targeted selection (T), enhanced care (E), and referral to well-described effective interventions using a stepped care–oriented approach (S); WT, wild type.

eTable 3. Extended Baseline Patient Characteristics (cont.)

	Total Group (N=349) n (%)	TES Program (n=184) n (%)	CAU (n=165) n (%)
Currently working			
Yes	81 (23.2)	39 (21.2)	42 (25.5)
No/Retired	264 (75.6)	143 (77.7)	121 (73.3)
Missing	4 (1.1)	2 (1.1)	2 (1.2)
Nicotine use			
Yes	219 (62.8)	114 (62.0)	105 (63.6)
No	126 (36.1)	68 (37.0)	58 (35.2)
Missing	4 (1.1)	2 (1.1)	2 (1.2)
Alcohol use			
Yes	200 (57.3)	103 (56.0)	97 (58.8)
No	143 (41.0)	77 (41.8)	66 (40.0)
Missing	6 (1.7)	4 (2.2)	2 (1.2)
Time from diagnosis of primary tumor until start of study			
<1.5 mo	116 (33.2)	52 (28.3)	64 (38.8)
1.5–10.0 mo	114 (32.9)	66 (35.9)	48 (29.1)
>10.0 mo	116 (33.2)	65 (35.3)	51 (30.9)
Missing	3 (0.9)	1 (0.5)	2 (1.2)
Prior cancer-related treatment			
No	108 (30.9)	57 (31.0)	51 (30.9)
Yes, surgery	215 (61.6)	119 (64.7)	96 (58.2)
Yes, neoadjuvant systemic therapy	31 (8.9)	18 (9.8)	13 (7.9)
Yes, radiotherapy	42 (12.0)	18 (9.8)	24 (14.5)
Yes, chemoradiation	25 (7.2)	13 (7.1)	12 (7.3)
Yes, HIPEC	1 (0.3)	1 (0.5)	
Prior treatment for metastases			
No	270 (77.4)	132 (71.7)	138 (83.6)
Yes	76 (21.8)	51 (27.7)	25 (15.2)
(Neo)adjuvant systemic therapy	6 (1.7)	3 (1.6)	3 (1.8)
Radiotherapy	18 (5.2)	12 (6.5)	6 (3.6)
Surgery	57 (16.3)	36 (19.6)	21 (12.7)
Chemoradiation	2 (0.6)	2 (1.1)	—
HIPEC	13 (3.7)	12 (6.5)	1 (0.6)
RFA	12 (3.4)	10 (5.4)	2 (1.2)
Missing	3 (0.9)	1 (0.5)	2 (1.2)
Median number of organs with metastases	2	2	2
Metastases			
Liver	261 (74.8)	136 (73.9)	125 (75.8)
Lung	146 (41.8)	78 (42.4)	68 (41.2)
Lymph nodes	138 (39.5)	67 (36.4)	71 (43.0)
Peritoneal[a]	90 (25.9)	57 (31.0)	33 (20.0)

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Abbreviations: CAPOX, capecitabine and oxaliplatin; CAU, care as usual; FOLFOX, leucovorin/5-fluorouracil/oxaliplatin; HADS, Hospital Anxiety and Depression Scale; HIPEC, hyperthermic intraperitoneal chemotherapy; MT, mutant type; PS, performance status; QLQ-C30, QoL of Cancer Patients questionnaire; QoL, quality of life; RFA, radiofrequency ablation; TES, targeted selection (T), enhanced care (E), and referral to well-described effective interventions using a stepped care–oriented approach (S); WT, wild type.

eTable 3. Extended Baseline Patient Characteristics (cont.)

	Total Group (N=349) n (%)	TES Program (n=184) n (%)	CAU (n=165) n (%)
Median number of metastases	12	10	13
Distress			
Mean HADS score (SD)	9.52 (6.6)	8.8 (6.5)	10.3 (6.7)
Mean QoL (EORTC QLQ-C30) scores (SD)			
Physical functioning	74.4 (20.6)	76.0 (20.9)	72.6 (20.2)
Role functioning	64.3 (30.7)	68.3 (28.9)	59.8 (32.0)
Emotional functioning	77.1 (18.9)	78.3 (18.1)	75.9 (19.8)
Cognitive functioning	88.9 (15.4)	89.8 (14.2)	88.0 (16.5)
Social functioning	76.2 (25.8)	79.3 (23.8)	72.8 (27.5)
Global QoL	63.0 (21.8)	64.9 (22.0)	60.9 (21.3)

Abbreviations: CAPOX, capecitabine and oxaliplatin; CAU, care as usual; FOLFOX, leucovorin/5-fluorouracil/oxaliplatin; HADS, Hospital Anxiety and Depression Scale; HIPEC, hyperthermic intraperitoneal chemotherapy; MT, mutant type; PS, performance status; QLQ-C30, QoL of Cancer Patients questionnaire; QoL, quality of life; RFA, radiofrequency ablation; TES, targeted selection (T), enhanced care (E), and referral to well-described effective interventions using a stepped care–oriented approach (S); WT, wild type.

eTable 4. Mean Observed Scores for Outcomes

	TES Program Mean (SD)	CAU Mean (SD)
Primary outcome		
Distress (HADS)		
T0	8.8 (6.5)	10.3 (6.7)
T1	8.7 (6.2)	10.2 (7.0)
T2	8.4 (6.6)	10.4 (7.6)
T3	8.0 (6.9)	9.9 (7.2)
T4	7.8 (6.0)	9.8 (7.3)
Secondary outcomes		
Physical functioning (EORTC QLQ-C30)		
T0	76.0 (20.9)	72.6 (20.2)
T2	75.3 (19.8)	67.1 (22.6)
T3	73.5 (21.9)	71.9 (21.3)
T4	76.7 (18.8)	71.9 (22.0)
Role functioning (EORTC QLQ-C30)		
T0	68.3 (28.9)	59.8 (32.0)
T2	64.9 (30.5)	55.6 (30.5)
T3	68.0 (29.6)	63.7 (28.4)
T4	71.5 (27.1)	65.3 (31.5)
Emotional functioning (EORTC QLQ-C30)		
T0	78.3 (18.1)	75.9 (19.8)
T2	81.8 (17.8)	79.3 (20.2)
T3	80.6 (20.7)	77.7 (20.8)
T4	83.8 (16.8)	80.2 (21.9)
Cognitive functioning (EORTC QLQ-C30)		
T0	89.8 (14.2)	88.0 (16.5)
T2	86.3 (17.6)	81.6 (21.7)
T3	86.9 (17.3)	81.3 (20.6)
T4	87.0 (17.3)	82.8 (18.3)
Social functioning (EORTC QLQ-C30)		
T0	79.3 (23.8)	72.8 (27.5)
T2	79.4 (22.4)	71.7 (28.0)
T3	79.1 (24.7)	74.2 (25.7)
T4	83.8 (21.0)	81.2 (24.4)

(continued)

Data are presented for patients that completed the questionnaires in the TES program arm at T0 (n=182), T1 (n=173), T2 (n=155), T3 (n=140), and T4 (n=110) and in the CAU arm at T0 (n=163), T1 (n=151), T2 (n=137), T3 (n=109), and T4 (n=87). Data are not corrected for clustering and baseline differences.
Abbreviations: CAU, care as usual; CSQ-8, Client Satisfaction Questionnaire-8; HADS, Hospital Anxiety and Depression Scale; QLQ-C30, QoL of Cancer Patients questionnaire; QoL, quality of life; T0, baseline; T1, shortly after the start of treatment; T2, 10 weeks after start of treatment; T3, 24 weeks after start of treatment; T4, 48 weeks after start of treatment; TES, targeted selection (T), enhanced care (E), and referral to well-described effective interventions using a stepped care–oriented approach (S).

eTable 4. Mean Observed Scores for Outcomes (cont.)

	TES Program Mean (SD)	CAU Mean (SD)
Secondary outcomes (cont.)		
Global QoL (EORTC QLQ-C30)		
T0	64.9 (22.0)	60.9 (21.3)
T2	68.5 (21.5)	61.8 (22.6)
T3	68.1 (21.3)	66.7 (20.4)
T4	72.5 (16.8)	65.7 (22.3)
Patient satisfaction (CSQ-8)		
T2	25.5 (5.6)	25.0 (5.5)
T3	25.7 (6.0)	25.2 (5.3)
T4	26.2 (5.4)	25.0 (5.3)
Recognition of distress by clinicians, n (%)	79 (42.9%)	62 (37.6%)
Referral for distress by clinicians, n (%)	30 (16.3%)	20 (12.1%)

Data are presented for patients that completed the questionnaires in the TES program arm at T0 (n=182), T1 (n=173), T2 (n=155), T3 (n=140), and T4 (n=110) and in the CAU arm at T0 (n=163), T1 (n=151), T2 (n=137), T3 (n=109), and T4 (n=87). Data are not corrected for clustering and baseline differences.
Abbreviations: CAU, care as usual; CSQ-8, Client Satisfaction Questionnaire-8; HADS, Hospital Anxiety and Depression Scale; QLQ-C30, QoL of Cancer Patients questionnaire; QoL, quality of life; T0, baseline; T1, shortly after the start of treatment; T2, 10 weeks after start of treatment; T3, 24 weeks after start of treatment; T4, 48 weeks after start of treatment; TES, targeted selection (T),

eAppendix 1. Review: Evaluation of Distress Screening on Psychological Well-Being

Objective

The objective of this review was to evaluate how screening programs for distress in patients with cancer affect psychological well-being.

Methods

Search Strategy

A PubMed search was performed for English-language studies published from inception up to February 20, 2018 using the terms "distress," "screening," "randomized trial," and "cancer OR oncology". Manual searches were performed on relevant systematic reviews.[1–3]

Selection Criteria and Analyses of Eligible Studies

Eligible articles included English-language studies on patients with any type of cancer at any disease stage and with any treatment that reported original data. Randomized controlled trials (RCTs) were included that compared outcomes of psychosocial well-being between patients who did and did not undergo screening for distress. Studies were excluded if the control group also received screening (even in absence of subsequent discussion or treatment).

Data Collection and Analysis

We extracted data on design, setting and sample, screening and intervention, and effect on psychological well-being. Results of the trials were evaluated using the narrative synthesis approach.

Results

A total of 395 studies were retrieved. Of those, 330 studies were excluded after title review, and an additional 54 studies were excluded after abstract review; 11 studies were selected for full-text review, resulting in a total of 6 eligible randomized trials on the effect of screening for distress on psychological well-being.[4–9] Among the 5 studies that were not included, 4 were excluded because the control group also received (minimal) screening,[10–13] making it impossible to evaluate the effect of screening itself on psychological well-being, and 1 was excluded because it lacked an outcome measure of well-being.[14]

Screening and Intervention

eTable 1 provides an overview of the characteristics and outcomes of the included RCTs. Among the 6 studies, 5 screening tools for measuring distress were used: the Distress Thermometer and Problem List,[5,6,9] the General Health Questionnaire (GHQ-12),[7] the Screening Inventory of Psychosocial Problems (SIPP),[4] and the Patient Health Questionnaire (PHQ-9) combined with the Generalized Anxiety Screener (GAS).[8] A distress management plan was used in 4 of the studies[5,7–9]; in 2 studies, no standardized plan was available on how to deal with the screening results.[4,6]

Effect of Screening on Psychological Well-Being

None of the included studies showed a screening effect on primary well-being outcomes. In one study, however, screening and stepped care resulted in improved referral to psychosocial services.[8] In Hollingworth et al,[6] a subgroup analysis suggested that the Distress Thermometer/Problem List might be more effective in patients with better mood states at enrollment. In the trial by Braeken et al,[4] post hoc analyses revealed a significant association between the intervention with early referral and improved quality of life and anxiety, suggesting that earlier referral might influence short-term quality of life and experienced anxiety in patients.

Conclusions

In this review, none of the 6 randomized trials evaluating distress screening found an effect on psychological well-being. Despite lack of supporting evidence, several clinical recommendations have been made for screening for psychological distress to be part of standard cancer care.[15,16] In many of the included RCTs, researchers stated that future studies on screening programs should include distress as a patient outcome; use appropriate samples; include a detailed, theory-based distress management plan; offer staff training; and track staff and patient use of subsequent interventions.

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eAppendix 1. Review: Evaluation of Distress Screening on Psychological Well-Being (cont.)

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