Pilot randomized control trial of a Patient-Controlled Cognitive-Behavioral Intervention for the Pain, Fatigue, and Sleep Disturbance Symptom Cluster in Cancer

Reference: Kristine L. Kwekkeboom, PhD, RN, Kristen Abbott-Anderson, MS, RN, Catherine Cherwin, MS, RN, Rachel Roiland, MS, RN, Ronald C. Serlin, PhD, and Sandra E. Ward, PhD, RN
University of Wisconsin-Madison, Madison, Wisconsin, USA
Presented by: Antonio Noguera on December 18, 2012. Grey Nuns TPCU.

Abstract

Context. Pain, fatigue, and sleep disturbance commonly co-occur in patients receiving treatment for advanced cancer.

Objectives. A pilot randomized controlled trial was conducted to assess initial efficacy of a patient-controlled cognitive-behavioral (CB) intervention for the pain, fatigue, and sleep disturbance symptom cluster.

Methods. Eighty-six patients with advanced lung, prostate, colorectal, or gynecologic cancers receiving treatment at a comprehensive cancer center were stratified by recruitment clinics (chemotherapy and radiation therapy) and randomized to intervention or control groups. Forty-three patients were assigned to receive training in and use of up to 12 relaxation, imagery, or distraction exercises delivered via an MP3 player for two weeks during cancer treatment. Forty-three patients were assigned to a waitlist control condition for the same two week period. Outcomes included symptom cluster severity and overall symptom interference with daily life measured at baseline (Time 1) and two weeks later (Time 2).

Results. Eight participants dropped out; 78 completed the study and were analyzed (36 intervention and 42 control subjects). Participants used the CB strategies an average of 13.65 times (SD = 6.98). Controlling for baseline symptom cluster severity and other relevant covariates, it was found that the symptom cluster severity at Time 2 was lower in the intervention group (MAdj = 2.99, SE ¼ 0.29) than in the waitlist group (MAdj = 3.87, SE ¼=0.36), F(1, 65) = 3.57, P = 0.032. Symptom interference with daily life did not differ between groups. No significant adverse events were noted with the CB intervention.

Conclusion. Findings suggest that the CB intervention may be an efficacious approach to treating the pain, fatigue, and sleep disturbance symptom cluster. Future research is planned to confirm efficacy and test mediators and moderators of intervention effects.
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Strengths

Not time consuming and easy intervention for the patient
Prospective study with control group
Exhaustive assessment

Weakness

Too many variables that can confound the results
Statistically significant but not clinically significant decrease of long term scores
No account of secondary effects or response to chemotherapy and radiotherapy
Placebo in control group (follow up and hope) and nocibo in intervention group (no effectiveness)

Relevance for palliative care

Patient controlled cognitive-behavioral interventions could be useful for pain, sleep disturbances, and fatigue crisis.

Table 1

Demographic and Clinical Characteristics by Treatment Group ($N = 86$)

Characteristics	Intervention ($n = 43$), n (%)	Waitlist ($n = 43$), n (%)	Total ($N = 86$), n (%)
Age, mean (SD)	60.44 (10.76)	60.14 (11.54)	60.29 (11.09)
Gender			
Male	14 (33)	21 (49)	35 (41)
Female	29 (67)	22 (51)	51 (59)
Ethnicity			
Non-Hispanic/Latino	43 (100)	43 (100)	86 (100)
Race			
White	41 (96)	39 (91)	80 (93)
Black	1 (2)	3 (7)	4 (5)
Asian	0 (0)	1 (2)	1 (1)
Native American /Alaskan native	1 (2)	0 (0)	1 (1)
Education			
<HS diploma	1 (2)	2 (5)	3 (4)
HS diploma/GED	8 (19)	11 (26)	19 (22)
Undergrad college	26 (60)	23 (53)	49 (57)
Graduate school	8 (19)	7 (16)	15 (17)
Cancer diagnosis			
Lung	10 (23)	15 (35)	25 (29)
Prostate	6 (14)	9 (21)	15 (17)
Colorectal	6 (14)	4 (9)	10 (12)
Gynecologic	21 (49)	15 (35)	36 (42)
Current treatment			
Chemotherapy	30 (70)	32 (75)	62 (72)
Radiation therapy	9 (21)	10 (23)	19 (22)
Chemo + radiation	4 (9)	1 (2)	5 (6)
Concurrent symptoms			
Nausea	20 (47)	26 (60)	46 (53)
Distress	34 (79)	37 (86)	71 (83)
Shortness of breath	24 (56)	28 (65)	52 (60)
Trouble remembering	33 (77)	30 (70)	63 (73)
Lack of appetite	28 (65)	29 (67)	57 (66)
Drowsiness	42 (98)	40 (93)	82 (95)
Dry mouth	31 (72)	33 (77)	64 (74)
Sadness	27 (63)	33 (77)	60 (70)
Vomiting	4 (9)	5 (12)	9 (10)
Numbness	23 (53)	25 (58)	48 (56)
Supportive meds ordered			
Opioids	25 (58)	26 (61)	51 (59)
Steroids	32 (74)	29 (67)	61 (71)
Psychostimulants	3 (7)	2 (5)	5 (6)
Hypnotics/sedatives	17 (40)	15 (35)	32 (37)
Antidepressants	9 (21)	5 (12)	14 (16)
Antiemetics	37 (86)	37 (86)	74 (86)
Colony-stimulating factors	1 (2)	3 (7)	4 (5)
Other	24 (56)	19 (44)	43 (50)

HS = high school; GED = General Educational Development.

Table 2

Mean (SD) of Time 1 Variables by Completion Status ($N = 86$)

Variables	Those Without Time 2 Data ($n = 8$), Mean (SD)	Those With Time 2 Data ($n = 78$), Mean (SD)	t	*P*
Symptom cluster severity	3.63 (1.89)	3.77 (1.62)	−0.195	0.85
Pain severity	2.63 (2.05)	2.19 (1.76)	0.579	0.58
Fatigue severity	3.78 (1.62)	3.91 (2.05)	−0.214	0.84
Sleep disturbance severity	4.50 (2.54)	5.21 (2.54)	−0.753	0.47
Symptom interference	4.81 (2.12)	4.04 (2.58)	0.959	0.36
Number of concurrent symptoms	5.88 (1.96)	6.47 (2.16)	−0.753	0.45
Number of supportive meds	3.88 (1.73)	3.24 (1.35)	1.003	0.35
Anxiety	8.13 (5.19)	9.27 (5.42)	−0.591	0.57
Depression	9.88 (7.32)	7.86 (7.20)	0.743	0.48

Table 3

Mean (SD) of Outcome Variables at Time 1 and Time 2 by Group (Unadjusted)

	Time 1		Time 2	
Variables	Intervention ($n = 43$)	Control ($n = 43$)	Intervention ($n = 36$)	Control ($n = 42$)
Symptom cluster severity[a]	3.59 (1.46)	3.92 (1.79)	2.89 (1.48)	3.53 (1.82)
Pain severity[b]	1.97 (1.64)	2.49 (1.88)	1.65 (1.61)	2.23 (1.96)
Fatigue severity[a]	3.77 (1.76)	4.03 (2.23)	3.32 (1.74)	3.96 (1.82)
Sleep disturbance severity	5.04 (2.49)	5.25 (2.59)	3.71 (2.15)	4.39 (2.70)
Symptom interference	3.82 (2.55)	4.40 (2.53)	3.34 (2.58)	3.98 (2.35)

Sleep disturbance severity scores were computed as *z*-scores transformed to a 0−10 scale. Significant differences were observed in covariate adjusted means.

[a] $P < 0.05$.

[b] $P < 0.01$.

Table 4

Mean (SD) of Pre- and Post-CB Strategy Symptom Severity and Distress Ratings (Intervention Group)

Symptom	Pre-CB Strategy, Mean (SD)	Post-CB Strategy, Mean (SD)	$t_{(df)}$	*P*
Pain severity	3.27 (1.67)	2.26 (1.47)	$t_{(31)} = 9.18$	0.000
Fatigue severity	4.31 (1.52)	3.03 (1.64)	$t_{(32)} = 8.89$	0.000
Sleep disturbance severity	4.23 (2.09)	2.73 (1.99)	$t_{(29)} = 6.85$	0.000
Pain distress	3.32 (1.57)	1.94 (1.29)	$t_{(28)} = 7.11$	0.000
Fatigue distress	3.71 (1.57)	2.33 (1.59)	$t_{(32)} = 9.47$	0.000
Sleep disturbance distress	3.83 (2.19)	2.21 (1.94)	$t_{(29)} = 6.99$	0.000

CB = cognitive-behavioral.