



PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

PCRC De-identified Data Repository (DiDR) Study Summary

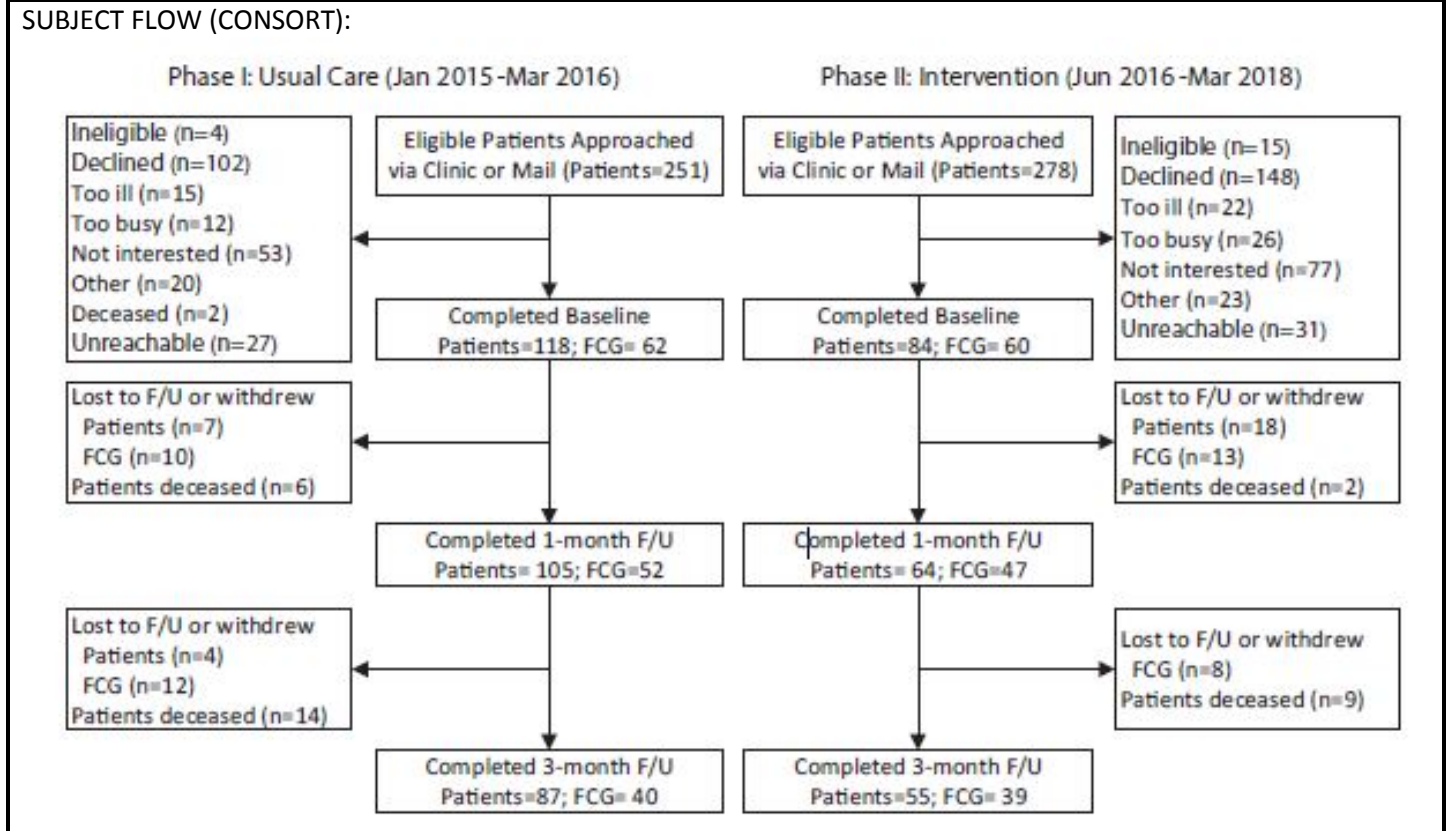
TITLE: Translation of a lung cancer palliative care intervention for clinical practice			
PRINCIPLE INVESTIGATOR(S): Betty Ferrell, PhD, RN, MA, FAAN, FPCN, CHPN	SITE(S) (if applicable): 3 Kaiser Permanente Southern California Sites		
COORDINATING SITE: City of Hope Medical Center			
STUDY PERIOD			
START: Jan 2015			
LAST SUBJECT CONTACT: March 2018			
OBJECTIVES: The objective of this study was to determine the effects of a nurse-led PC intervention for patients with non-small-cell lung cancer and their family caregivers (FCGs) in a community-based setting.			
PARTICIPANTS			
	ENROLLMENT	ELIGIBILITY CRITERIA	
Patients:	202	English speaking, >= 18 years old, Stage 2-4 non-small-cell lung cancer (NSCLC)	
Informal Caregivers:	122	Family care givers of patients >= 18, designated by patient as “a person closely involved in their care”	
Health Care Providers:	n/a	n/a	
METHODOLOGY: Two-group, prospective sequential, quasi-experimental, tandem enrollment design with Phase 1 (usual care) followed by Phase 2 (intervention).			
INTERVENTION (if applicable): Translation of a Lung Cancer Palliative Intervention (TLC-PCI) described here: <u>Nguyen HQ, Cuyegkeng T, Phung TO, Jahn K, Borneman T, Macias M, Ruel N, Ferrell BR. Integration of a Palliative Care Intervention into Community Practice for Lung Cancer: A Study Protocol and Lessons Learned with Implementation. J Palliat Med. 2017 Dec;20(12):1327-1337.</u>			
MEASURES: <ul style="list-style-type: none"> • Quality of life (QOL) by Functional Assessment of Cancer Therapy-Lung (FACT-L) – Source: Patient reported • Spiritual well-being: Functional Assessment of Chronic Illness Therapy Spirituality Subscale (FACIT) – Source: Patient reported • Distress by Distress Thermometer – Source: Patient reported • Health care utilization (acute care encounters, use of supportive services, advance care planning and proxy decision maker documentation, chemotherapy in last two weeks of life, home based palliative care, hospice referral and enrollment, place of death) – Source: electronic medical record • Family caregiver outcomes by City of Hope-QOL-Family instrument, Preparedness Scale, Caregiver Burden Scale, and Distress thermometer – Source: caregiver reported 			



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SUBJECT FLOW (CONSORT):





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STUDY CALENDAR:

Source of Data	Study Variables	Measurement	Baseline	1 month	3 month
Nurse Completed Forms	Chart Audit- Demographic, Disease, Treatment, and System Use	Chart Audit Data Form			X
Patient Completed	Demographic Data		X		
	Quality of Life	FACT – Lung & FACIT-Sp-12	X	X	X
	Symptoms	MSAS	X	X	X
	Psychological Distress	Distress Thermometer	X	X	X
	Satisfaction Form				X
Family Caregiver Completed	Demographics	Demographics			
	Distress	Distress Thermometer	X	X	X
	QOL	COH-QOL	X	X	X
	FCG Burden	Burden Scale	X	X	X
	Preparedness	Preparedness	X	X	X
	Satisfaction	Satisfaction Form			X



BASELINE CHARACTERISTICS (TABLE 1)

Table 1
Sociodemographic Characteristics of Patients and Family Caregivers

Variable	Patients		Caregivers	
	Phase I: Usual Care (n = 118)	Phase II: PCI (n = 84)	Phase I: Usual Care (n = 62)	Phase II: PCI (n = 60)
Age (yrs)	67.5 ± 10.3	67.6 ± 11.3	63.8 ± 11.5	63.0 ± 12.4
Female	71 (60.2%)	47 (56.0%)	38 (61.3%)	35 (58.3%)
BMI	26.5 ± 5.1	25.6 ± 5.2	—	—
Hispanic or Latino				
Yes	15 (12.7%)	10 (11.9%)	5 (8.2%)	9 (15.5%)
No	103 (87.3%)	73 (86.9%)	56 (91.8%)	49 (84.5%)
Missing	0 (0.0%)	1 (1.2%)	1 (1.6%)	2 (3.3%)
Race				
African American	6 (5.1%)	8 (9.5%)	5 (8.1%)	3 (5.4%)
Asian	9 (7.6%)	6 (7.1%)	3 (4.8%)	1 (1.8%)
Caucasian	102 (86.4%)	64 (76.2%)	53 (85.5%)	47 (83.9%)
Native American	0 (0.0%)	1 (1.2%)	1 (1.6%)	1 (1.8%)
Other	1 (0.8%)	4 (4.8%)	0 (0.0%)	4 (6.7%)
Missing	0 (0.0%)	1 (1.2%)	0 (0.0%)	4 (6.7%)
Religion				
None	16 (13.6%)	11 (13.1%)	11 (17.7%)	8 (13.3%)
Catholic	43 (36.4%)	21 (25.0%)	18 (29.0%)	15 (25.0%)
Protestant	44 (37.3%)	35 (41.7%)	22 (35.5%)	24 (40.0%)
Other	15 (12.7%)	16 (19.0%)	11 (17.7%)	12 (20.0%)
Missing	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (1.7%)
Education				
High school	45 (38.1%)	40 (47.6%)	20 (32.3%)	20 (33.3%)
College	73 (61.9%)	44 (52.4%)	42 (67.7%)	39 (65.0%)
Missing	—	—	0 (0.0%)	1 (1.7%)
Marital status				
Single	9 (7.6%)	6 (7.1%)	4 (6.4%)	2 (3.3%)
Separated or divorced	10 (8.5%)	14 (16.7%)	54 (87.1%)	51 (85.0%)
Widowed	19 (16.1%)	9 (10.7%)	1 (1.6%)	6 (10.0%)
Married or partnered	80 (67.8%)	55 (65.5%)	3 (4.8%)	1 (1.7%)
Living situation				
Alone	18 (15.2%)	10 (11.9%)	—	—
Spouse	51 (43.2%)	46 (54.8%)	—	—
Spouse and others	25 (21.2%)	14 (16.7%)	—	—
Adult children	9 (7.6%)	6 (7.1%)	—	—
Other	15 (12.7%)	8 (9.5%)	—	—
Relationship to patient				
Spouse/partner	—	—	42 (67.7%)	45 (75.0%)
Parent	—	—	0 (0.0%)	1 (1.7%)
Daughter	—	—	9 (14.5%)	8 (13.3%)
Son	—	—	2 (3.2%)	0 (0.0%)
Other	—	—	9 (14.5%)	4 (6.7%)
Missing	—	—	0 (0.0%)	2 (3.3%)
Employment status ^a				
Self-employed	3 (2.5%)	5 (6.0%)	—	—
Employed <32 hours/week	3 (2.5%)	1 (1.2%)	—	—
Employed ≥32 hours/week	15 (12.7%)	3 (3.6%)	—	—
Unemployed	97 (82.2%)	72 (85.7%)	—	—
Missing	0 (0.0%)	3 (3.6%)	—	—
Household income ^c				
\$10,000 or less	2 (1.7%)	2 (2.4%)	1 (1.6%)	1 (1.7%)
\$10,001 to \$20,000	10 (8.5%)	6 (7.1%)	5 (8.1%)	4 (6.7%)
\$20,001 to \$30,000	16 (13.6%)	3 (3.6%)	4 (6.5%)	3 (5.0%)
\$30,001 to \$40,000	11 (9.3%)	9 (10.7%)	4 (6.5%)	6 (10.0%)
\$40,001 to \$50,000	15 (12.7%)	10 (11.9%)	13 (21.0%)	7 (11.7%)
Greater than \$50,000	61 (51.7%)	39 (46.4%)	32 (51.6%)	28 (46.7%)
Prefer not to answer	3 (2.5%)	15 (17.9%)	3 (4.8%)	11 (17.4%)
Lung cancer stage				
II	10 (8.5%)	2 (2.4%)	—	—
III	32 (27.1%)	20 (24.1%)	—	—
IV	76 (64.4%)	61 (73.5%)	—	—
Years since lung cancer diagnosis	0.9 ± 1.7	1.0 ± 3.0	—	—
Treatment (from dx to 3 mo f/u)				
Chemotherapy	71 (60.2%)	50 (59.5%)	—	—
Radiation therapy	22 (18.6%)	14 (16.7%)	—	—



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Table 1
Continued

Variable	Patients		Caregivers	
	Phase I: Usual Care (n = 118)	Phase II: PCI (n = 84)	Phase I: Usual Care (n = 62)	Phase II: PCI (n = 60)
Lung cancer–related surgery	0 (0.0%)	1 (1.2%)	—	—
Other cancer diagnosis	29 (24.6%)	25 (29.8%)	—	—
Charlson Comorbidity Index	8.6 ± 3.14	9.7 ± 2.78	—	—
Study site				
1	55 (46.6%)	31 (36.9%)	27 (43.6%)	19 (31.7%)
2	32 (27.1%)	36 (42.9%)	23 (37.1%)	29 (48.3%)
3	31 (26.3%)	17 (20.2%)	12 (19.4%)	12 (20.0%)

Data are presented as n (%) or mean ± SD.
*P < 0.05, patients only.



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PCRC STANDARDIZED DATA ELEMENTS

Please see the separate information sheet [“DISC Standardized Data Elements”](#) for the exact wording and format of the data elements.

DATA ELEMENT	Collected?	Var Name(s)	Data source (e.g. self-report, EHR) or reason not applicable
1. Site ID (if multi-site)	<input checked="" type="checkbox"/>	sitenum	
2. Who is the research participant? (e.g., patient, caregiver, etc.)	<input checked="" type="checkbox"/>	participant_type	
3. Sex	<input checked="" type="checkbox"/>	gendergrp	Self-reported
4. Ethnicity	<input checked="" type="checkbox"/>	hispaniclatinogrp	Self-reported
5. Race	<input checked="" type="checkbox"/>	racegrp	Self-reported
6. Age in years	<input checked="" type="checkbox"/>	age	Self-reported
7. Current Marital Status	<input checked="" type="checkbox"/>	maritalstatusgrp	Self-reported
8. Primary life-limiting diagnosis/illness	<input checked="" type="checkbox"/>		All eligible participants had NSCLC
9. Performance status (AKPS)	<input type="checkbox"/>		
10. Enrolled in Hospice	<input checked="" type="checkbox"/>	hospiceenrollynggrp	EHR
a. If yes to hospice, where is hospice care provided?	<input type="checkbox"/>		
11. Receiving Palliative Care (PC)?	<input checked="" type="checkbox"/>	palliativeyn	EHR
a. If yes to receiving PC, where is PC provided?	<input type="checkbox"/>		
12. Source of Death information	<input type="checkbox"/>		
13. Location of Death	<input checked="" type="checkbox"/>	placeofdeathgrp	EHR
14. Enrolled in Hospice at time of death?	<input type="checkbox"/>		
15. Receiving PC at time of death?	<input type="checkbox"/>		

Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.

PCRC OUTCOME INSTRUMENTS

CONTENT (e.g., PS)	ABBREV (e.g., AKPS)	INSTRUMENT NAME (e.g., Australian Modified Karnofsky Performance Status)
Distress	DT	Distress Thermometer (for patient and FCG)
Spiritual Well-being	FACIT-SP-12	Functional Assessment of Chronic Illness Therapy Spirituality Subscale (Pt)
QOL	FACT-L	Functional Assessment of Cancer Therapy-Lung (FACT-L) (Pt)
Symptoms	MSAS	Memorial Symptom Assessment Scale
FCG QOL	COH-QOL	City of Hope-QOL-Family instrument
FCG Burden	Burden Assessment	Caregiver Burden Assessment (FCG)
Preparedness	Preparedness	Preparation for Caregiving (FCG)