PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

PCRC De-identified Data Repository (DiDR) Study Summary

TITLE: **Reducing End-of-Life Symptoms with Touch (REST)**		
PRINCIPLE INVESTIGATOR(S):	**Jean Kutner, MD, MSPH** **Marlaine Smith, RN, PhD, AHN-BC, FAAN**	SITE(S) (if applicable): **15 U.S. hospices that were members of the Population-based Palliative Care Research Network (PoPCRN)**
COORDINATING SITE:	**University of Colorado Cancer Center**	
STUDY PERIOD		
START:	**Nov 2003**	
LAST SUBJECT CONTACT:	**Mar 2007**	

OBJECTIVES:
The purpose of this study is to determine whether massage therapy is effective in reducing pain and distress and improving quality of life among cancer patients at life's end.

PARTICIPANTS		
	ENROLLMENT	ELIGIBILITY CRITERIA
Patients:	**380**	**Inclusion:** • **18 years and older** • **Advanced cancer (stage III or IV), with at least moderate pain 1 week prior to study entry** • **Life expectancy of at least 3 weeks** • **Able to speak English** **Exclusion:** • **Massage therapy within 1 month prior to study entry** • **Current use of anticoagulants** • **Platelet count less than 10,000** • **Unstable spine that would interfere with touch therapy**
Informal Caregivers:	**n/a**	**n/a**
Health Care Providers:	**n/a**	**n/a**

METHODOLOGY:
Multisite, randomized control trial

INTERVENTION (if applicable):
Six 30-minute massage or simple-touch sessions over 2 weeks

MEASURES:
Primary outcomes were immediate (Memorial Pain Assessment Card, 0- to 10-point scale) and sustained (Brief Pain Inventory [BPI], 0- to 10-point scale) change in pain. Secondary outcomes were immediate change in mood (Memorial Pain Assessment Card) and 60-second heart and respiratory rates and sustained change in quality of life (McGill Quality of Life Questionnaire, 0- to 10-point scale), symptom distress (Memorial Symptom Assessment Scale, 0- to 4-point scale), and analgesic medication use (parenteral morphine equivalents [mg/d]). Immediate outcomes were obtained just before and after each treatment session. Sustained outcomes were obtained at baseline and weekly for 3 weeks.

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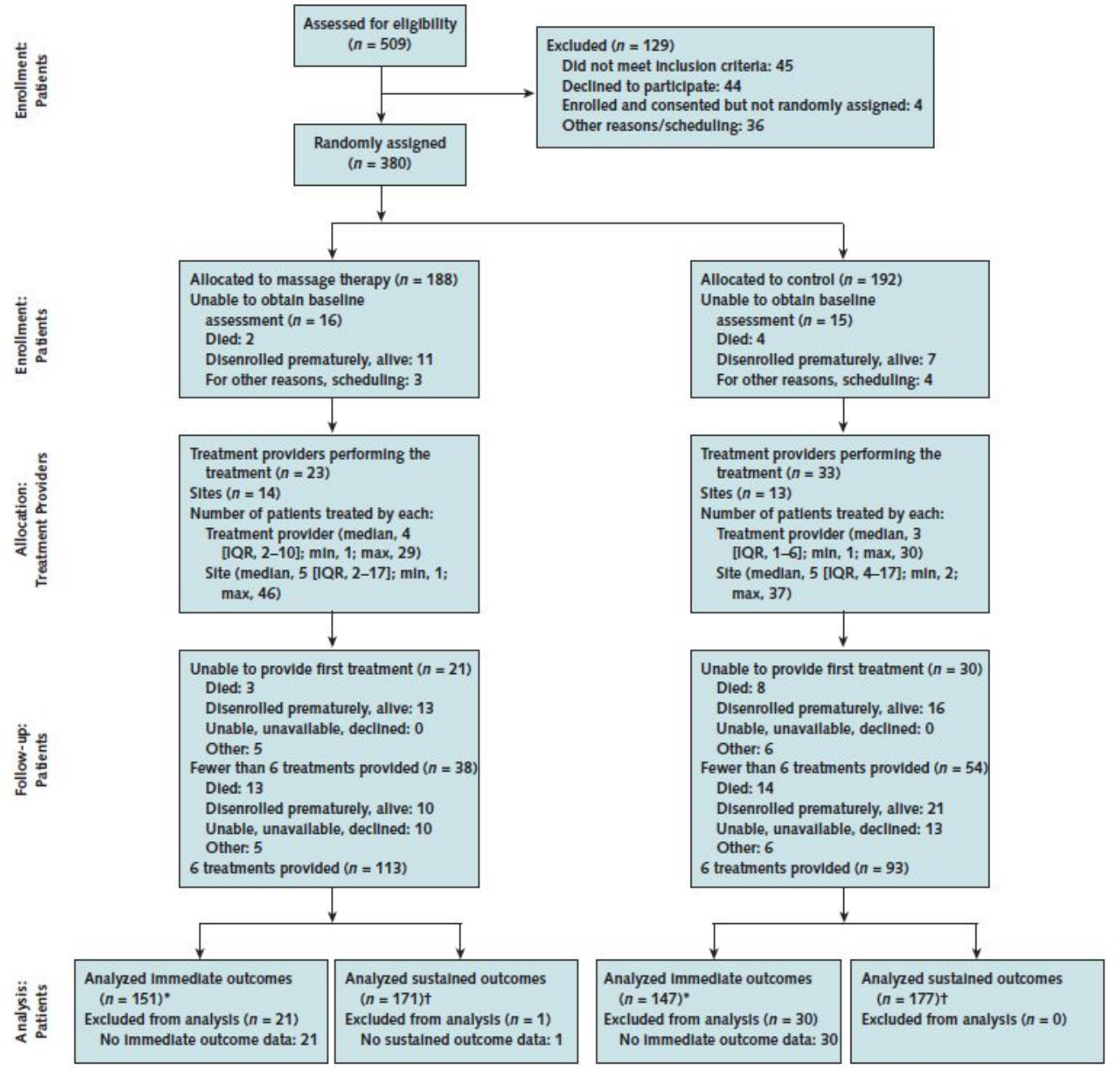
SUBJECT FLOW (CONSORT):



Assessments refer to the weekly or sustained outcomes. Immediate outcome data collection occurred in conjunction with every treatment session. IQR = interquartile range; max = maximum; min = minimum.
* Number who had any treatment: 113 + 38 for massage therapy and 93 + 54 for control.
† Number with baseline or any sustained outcome assessments: 188 − 17 for massage therapy and 192 − 15 for control.

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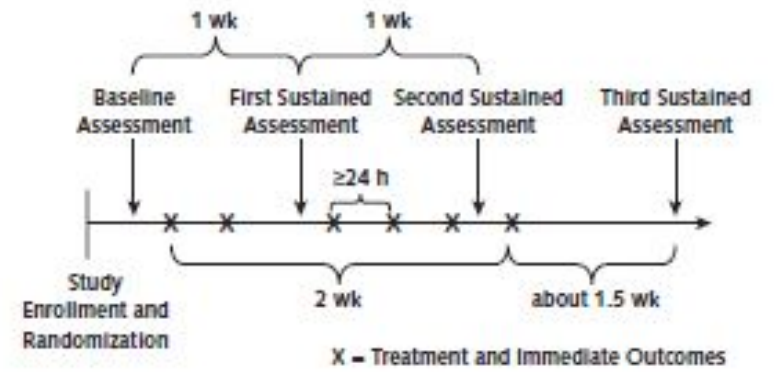
STUDY CALENDAR:

Figure 1. Study overview: timing of study procedures.



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BASELINE CHARACTERISTICS (TABLE 1)

Table 1. **Participant Characteristics***

Characteristic	Massage Therapy Group (*n* = 188)	Control Group (*n* = 192)
Women, *n (%)*	120 (64)	112 (58)
Mean age (SD), *y*	65.2 (14.4)	64.2 (14.4)
Non-Hispanic white race, *n (%)*	161 (86)	164 (85)
Married or in a committed relationship, *n (%)*	93 (49)	77 (40)
Medicare as primary payer/insurance, *n (%)*	114 (61)	109 (57)
College-level or higher education, *n (%)*	72 (39)	79 (42)
Receiving care at home, *n (%)*	145 (77)	155 (81)
Mean time after initial cancer diagnosis (SD), *y*	2.5 (3.9)	2.9 (5.1)
Cancer type, *n (%)*		
Lung	48 (26)	48 (25)
Breast	34 (18)	29 (15)
Pancreatic	13 (7)	22 (12)
Colorectal	12 (6)	17 (9)
Prostate	10 (5)	11 (6)
Presence of metastasis, *n (%)*	188 (100)	192 (100)
Presence of bone metastasis, *n (%)*	55 (29)	46 (24)
Mean number of comorbid conditions (SD)	2.2 (2.2)	2.3 (2.2)
Concomitant medical conditions, *n (%)*†		
Medical diagnoses	104 (55)	110 (57)
Neurologic diagnoses	13 (7)	18 (9)
Vascular diagnoses	18 (10)	13 (7)
Received previous professional massage therapy, *n (%)*	76 (40)	74 (39)
Mean perception of helpfulness of massage therapy (SD)‡	4.0 (1.0)	3.9 (1.1)
Mean score of worst pain in past 24 hours (SD) (scale, 0–10 points)	6.7 (2.4)	6.4 (2.5)
Mean score of worst pain in past week (SD) (scale, 0–10 points)	8.0 (1.9)	7.6 (2.2)
Mean goal pain level (SD) (scale, 0–10 points)	0.2 (0.8)	0.3 (0.8)
Constant pain present, *n (%)*	97 (52)	103 (55)
Intermittent pain present, *n (%)*	133 (71)	135 (70)
Brief pain present, *n (%)*	56 (30)	46 (24)
Neuropathic pain present, *n (%)*§	38 (23)	51 (29)
Mean number of body sections with pain (SD)	6.9 (6.5)	7.4 (6.5)
Median frequency of routine care (IQR), *h/wk*		
Chaplain	0 (0–15)	0 (0–15)
Home health aid	0 (0–45)	0 (0–51.3)
Nurse	45 (22.5–90)	48.8 (22.5–103.8)
Physician	0 (0–8.75)	0 (0–3.8)
Social worker	15 (0–26.3)	15 (0–31.3)
Volunteer	0 (0–7.5)	0 (0–7.5)

IQR = interquartile range.
* Of 380 participants.
† "Medical diagnoses" are heart disease, diabetes, HIV/AIDS, hypertension, infection, kidney or renal disease, liver disease, lung disease, or pulmonary embolus. "Neurologic diagnoses" are delirium, dementia, neurologic disease (for example, Parkinson disease, amyotrophic lateral sclerosis, or multiple sclerosis) or stroke. "Vascular diagnoses" are deep venous thrombosis, peripheral vascular disease, and pressure ulcers.
‡ Perceived helpfulness of massage therapy for pain was measured on a 1- to 5-point scale, in which 1 means "not at all helpful" and 5 means "very helpful."
§ Presence of neuropathic pain was defined as score ≥3 on the composite Neuropathic Pain Scale.

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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)	☒	site	
2. Who is the research participant? (e.g., patient, caregiver, etc.)	☐		n/a, only patients enrolled
3. Sex	☒	gender	self-report or EHR
4. Ethnicity	☒	yesLatinx	self-report or EHR
5. Race	☒	raceSum	self-report or EHR
6. Age in years	☒	age	self-report or EHR
7. Current Marital Status	☒	marital	self-report or EHR
8. Primary life-limiting diagnosis/illness	☒	priCa	EHR
9. Performance status (AKPS)	☒	kps	Karnofsky Performance Scale used; On-Site Data Collector
10. Enrolled in Hospice	☒	site	most participants were from hospice sites
a. If yes to hospice, where is hospice care provided?	☒	site, ploc	
11. Receiving Palliative Care (PC)?	☐		
a. If yes to receiving PC, where is PC provided?	☐		
12. Source of Death information	☐		
13. Location of Death	☐		
14. Enrolled in Hospice at time of death?	☐		
15. Receiving PC at time of death?	☐		

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

PATIENT REPORTED OUTCOME INSTRUMENTS

CONTENT *(e.g., PS)*	ABBREV *(e.g., AKPS)*	INSTRUMENT NAME *(e.g., Australian Modified Karnofsky Performance Status)*
Immediate Pain/Mood	MPAC	Memorial Pain Assessment Card
Sustained Pain	BPI	Brief Pain Inventory
QOL	MQOLQ	McGill Quality of Life Questionnaire
Symptom Distress	MSAS	Memorial Symptom Assessment Scale
Neuropathic Pain	NPS	Neuropathy Pain Scale