

Short form study protocol of the Outreach Palliative care Trial of Integrated Model: Japan OPTIM study

NOTE:

Please also see a published protocol: Morita T, Miyashita M, Yamagishi A, et al. A region-based palliative care intervention trial using the mixed-method approach: Japan OPTIM study. *BMC Palliat Care*. 2012;11:2.

BACKGROUNDS

Palliative care is an essential part of integrated cancer treatment [1]. Palliative care should be provided throughout an entire region, and several outcome studies have explored the effects of regional palliative care programs on places of death, the use of palliative care resources, patient-reported outcomes, family-reported outcomes, and cost [2-9]. In a cluster randomized controlled trial, a regional palliative care intervention, including developing a specialized inpatient palliative care service at an academic hospital, strengthening the cooperation between specialized palliative care and community health care services, developing clinical guidelines, and educational programs for community health care providers, contributed to an increase in the number of home deaths and higher levels of family satisfaction, but the patient-reported quality of life, measured by the EORTC-C30, was not significantly different [2-4]. A pioneer work as a regional palliative care model, the Edmonton program, observed that constructing a novel regional system, including a regional palliative care office to coordinate palliative care activities at specialist and community levels throughout the region, resulted in an increased number of home deaths and use of specialized palliative care services [5, 6]. A recent palliative care quality improvement project in Ontario included developing and disseminating standard clinical tools for collaborative care planning and symptom assessment [7, 8]. The audit study from this project demonstrated an increased documentation of symptoms and decreased use of emergency visits, while the symptom intensity and family satisfaction did not significantly improve. In addition, the Catalonia WHO demonstration project demonstrated an increase in the quantity and variety of specialized palliative care services and potential cost-saving effects [9].

More recently, the U.K. implemented the Gold Standards Framework, stressing communication and coordination in the community through developing a palliative care patient registry and regular meetings [10-13]. Qualitative studies suggest the most important benefit of the Gold Standards Framework is

facilitating communication among health care professionals in the community, although the direct effects on patient and/or family outcomes were formally unmeasured. Multiple studies from Canada, the Netherlands, and Australia which investigated the process of developing community palliative care networks again revealed the perceived importance of an increase in personal and formal contacts in health care professionals [14-16].

These studies provide important insights into the potential benefits of regional palliative care programs, but the clinical implications are still limited, because: 1) the interventions included a structural/financial change in the health care system (Norway, Edmonton, Catalonia, and the U.K.), and, thus, the results would not be applicable for many regions where such changes are difficult or unfeasible; 2) patient-oriented outcomes were not measured or explored only in a small number of populations, and interpretation of the results from a patient's view is difficult; and 3) no studies adopted the mixed-method approach using both quantitative and qualitative methodologies to interpret the complex phenomenon from multidimensional perspectives [17-20].

We believe, therefore, that a new study should include: 1) an intervention program available for many regions without structural/financial changes to the health care system, 2) adequate patient-oriented outcomes, and 3) qualitative studies along with quantitative evaluation.

The aims of this mixed-methods study were to evaluate changes in a variety of outcomes during a regional palliative care program and to explore how the changes occurred. Primary end-points were home death, coverage of specialist services, and patient- and family-reported qualities of palliative care. The ultimate purpose was to obtain insights to achieve quality palliative care at a regional level.

METHODS AND DESIGN

Overview and aims

This is a regional intervention trial, consisting of a pre-post outcome study and qualitative process studies. Initially, this study was designed as a cluster randomized controlled trial, but we have decided to adopt a mixed-method design because: 1) intervention itself should be applied to all populations over the country and a clear distinction between intervention and control groups is difficult [20], 2) a concealment problem is

likely to occur [2-4], and 3) the most important mission at a national level is not to clarify if one specific intervention actually changes outcomes, but to obtain comprehensive insights into how to disseminate palliative care throughout the country [17, 18].

The primary aim of the pre-post outcome study is to evaluate the change in the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care after the regional palliative care program. The secondary aims are to explore the changes in a variety of outcomes, including the distribution of locations of death; patient- and/or family-reported quality of life, whether patients died where they actually preferred, time spent at home/hospitals, satisfaction, pain, care burden; knowledge, belief, and concerns about palliative care; and knowledge, difficulties, and self-reported practice about palliative care of physicians and nurses. Qualitative process studies are performed to obtain a deep insight into how and why the regional palliative care program does or does not work. Ethical and scientific validity was confirmed by the institutional review board of this study and all participating institutions.

Time schedule

We obtain preintervention outcomes before or in the earlier stage of the intervention periods; and obtain postintervention outcomes and perform qualitative interviews after or in the late stage of the intervention periods. Intervention is implemented from April 2008 through March 2011. Location of death of cancer patients and the number of patients who receive specialized palliative care services are obtained each year from 2007 to 2010. Patients are consecutively recruited from those who receive medical treatment in participating hospitals in March to April in 2008 (preintervention) and November to December in 2010 (postintervention). Families are sampled from bereaved families of the patients who die from April 2007 through March 2008 (preintervention) and from April 2010 through March 2011 (postintervention), and questionnaires are sent in October 2008 and October 2011, respectively. Physicians and nurses are sampled from those working in February 2008 (preintervention) and in January 2011 (postintervention). Interviews are performed from January through March 2011.

Setting

To explore the potential influence of the variations in the existing health care system, we have decided to conduct this trial in 4 regions with different palliative care systems across Japan: Tsuruoka (170,000 population, Yamagata Prefecture), Kashiwa (670,000 population, Chiba Prefecture), Hamamatsu (820,000 population, Shizuoka Prefecture), and Nagasaki (450,000 population, Nagasaki Prefecture). Kashiwa and Hamamatsu have specialized hospital palliative care teams in a cancer center and general hospitals, respectively; Nagasaki has a coordinated palliative care system for home patients in addition to hospital palliative care teams; and Tsuruoka has no formal specialized palliative care service at the beginning of the study.

Interventions

Designing interventions

Interventions were designed on the basis of literature review, preliminary survey, and discussion among the researchers and clinical practitioners from the study regions [21-33].

To construct an intervention framework, we initially reviewed the existing domestic and international literature available to identify barriers to provide quality palliative care [21-23], and performed a preliminary survey of 8,000 general public and 8,000 medical health care providers in the 4 regions before planning the interventions [24]. The task force then drafted the intervention protocol with close collaborative with representative health care providers from the 4 regions, and has finalized intervention protocol. The intervention protocol describes the minimum requirements for this study to allow it to meet the specific situations of regions [19, 20].

To deliver the intervention, each region is asked to establish a “regional palliative care center” with several local leaders, who receive a start-up 2-day workshop from the study team before intervention with continuous follow-up. Local leaders include physicians, nurses, and medical social workers who have already been working as a clinical specialist in the region. Furthermore, local leaders foster link-staffs at each regional level. To facilitate interventions, meetings among local leaders are planned to be held about 25 times during this study period; a certified community nurse visits each region and followed up by telephone and e-mail as a facilitator; and interactive conferences among link-staffs from the 4 regions are held 3 times.

The interventions include 4 areas: 1) to improve the knowledge and skills of palliative care providers, 2) to

increase the availability of specialized palliative care services for community patients, 3) to coordinate community palliative care resources , and 4) to provide appropriate information about palliative care to the general public, patients, and families. We designed all interventions not to require a fundamental change in the health care system, that is, to optimize the resources within the region.

To investigate the actual implementation, we regularly monitor the intensity of interventions by telephone and visiting the intervention area [18]. In addition, in the surveys, we investigate the levels of exposure to each intervention (e.g., whether they used or noticed materials, or they participated in workshops).

Specific interventions

To improve the knowledge and skills of palliative care providers, we have prepared a pocket-size manual of palliative care (a book and videos) and 13 assessment tools (12 educational pamphlets for patients and families for each symptom, such as pain; and 1 comprehensive assessment tool). These are provided with printed materials and a web site. The local leaders are asked to disseminate these materials and hold an interactive workshop to educate them on how to use these materials [25-28].

To increase the availability of specialized palliative care services for community patients, each region is asked to establish a community palliative care team through optimizing the existing healthcare resources, because, at the time of the study, such community palliative care teams are not available in Japan. In addition, the community palliative care team provides outreach educational visits for community intuitions [29].

To coordinate community palliative care resources, each region is asked to establish a “regional palliative care center”. The regional palliative care center is then asked to hold a multidisciplinary conference to develop collaborative relationships among health care workers in the region, and share and resolve problems [10, 14-16]. In addition, local leaders facilitate the use of patient-held-records to maintain continuity of care [30], and facilitate the introduction of a discharge planning system for all hospitals in the region [31].

To provide appropriate information about palliative care, we have prepared a hand-sized leaflet, note-sized leaflets, posters, and DVDs about palliative care, and ask local leaders to put them in public and health care

institutions [32, 33]. In addition, local leaders ask public libraries to provide a “book set” (a set of 100 books about palliative care), and provide workshops for the general public. Target themes identified as barriers include the misconception about cancer pain and opioids, palliative care, and death at home [33].

Subjects

Questionnaires are sent to patients, bereaved family members, physicians, and nurses recruited consecutively following the inclusion criteria by mail. We intend to obtain the sample as a nearly representative sample of each region as much as possible.

Patients

Due to the lack of an established method to identify all cancer patients living in a specific area in Japan, we identify all hospitals in the study areas with reference to hospital lists from the Japan Hospital Association, the largest authorized organization of hospitals in Japan, and the local resource information. In the pre-intervention survey, we obtained the participation of a total of 23 of 34 hospitals treating cancer patients (8,964 beds of 11,033 beds, 81%).

Inclusion criteria are: 1) adults with a metastatic or recurrent cancer of the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, 2) outpatient visits to the oncology department or each specialty division, such as respiratory medicine for lung cancer patients (not palliative care division only), and 3) the patient had been informed of the malignancy. We have determined to exclude malignancy of the brain, blood, central nervous system, neck, soft tissue, and other uncommon primary sites, due to the infrequent prevalence and increased technical difficulties in patient recruitment. We have decided to examine only patients who were informed of malignancy, because we use the term “cancer” in the questionnaire. Exclusion criteria include: 1) inability of the patient to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the patient as determined by the principal treating physicians, and 3) poor physical condition unable to complete the questionnaire.

Bereaved family

Due to the legal limitation of a mortality-follow back survey, we identify all hospitals in the study areas in the same way as the patient survey, and general practice clinics with experience of caring for terminally ill cancer patients with reference to the local resource information.

Inclusion criteria for this bereaved family survey are: 1) bereaved adult family members of an adult cancer patient who died in the institution or at home (one family member was selected for each patient), 2) a primary tumor site of either the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, 3) received medical treatments on at least 3 or more days by the institution, and 4) informed of malignancy. Exclusion criteria include: 1) incapacity to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the family as determined by the principal treating physicians, 3) treatment-associated death or death from commodity, 4) death in intensive care units, and 5) family member unavailable.

Physicians and nurses

We identify hospitals treating cancer patients in the same way as the patient survey, all general practice clinics, and district nurse services.

Inclusion criteria for the physician and nurse survey are: 1) hospital physicians and nurses working at cancer-related branches for at least 3 years (internal medicine, surgery, respiratory medicine, gastro-enterology, urology, breast cancer, gynecology, hematology, radiation oncology, clinical and medical oncology, otolaryngology, and palliative medicine), 2) representative physicians of general practice clinics, and 3) all district nurses. The rationale for choosing physicians with 3 or more year clinical experience is that they have completed the residency training. To obtain representative physicians of clinics, we ask them to complete the questionnaire in the cover letter. Subjects are excluded if they have treated no cancer patients during the most recent year.

Outcome Measures (Table 1)

We have determined that this study adopt 4 primary end-points due to the complex nature of the intervention: 1) number of home deaths, 2) number of patients who received specialized palliative care services, 3) patient-reported quality of palliative care, and 4) bereaved family-reported quality of palliative care [20]. In addition, we adopt multiple end-points to interpret the results from multiple perspectives.

Location of death

We record the number of cancer patients who died at home, hospitals, and nursing homes from the national government registry every year, and, further, the number of patients who died in palliative care units from each palliative care unit. As the reference data, we obtain the average rate of home death in Japan during this study period. The rationale of setting the number of home deaths as one of the primary end-points is that,

while many patients want to die at home, home deaths actually occur at a rate of only 6.0% in Japan [24].

Use of specialized palliative care services

The rationale of setting the number of patients who received specialized palliative care services as one of the primary end-points is that multiple studies revealed the beneficial effects of specialized palliative care services on patient outcomes [34, 35], and, thus, we believe it is reasonable to assume that higher involvement in specialized palliative care services would result in the improvement in patient outcomes [36]. To calculate the number of patients who received specialized palliative care services, we initially identify all specialized palliative care services, and ask each service to provide a complete patient list every year. The specialized palliative care service is defined as “specialized palliative care provided by palliative care specialists”, including: 1) palliative care unit, 2) hospital palliative care team, 3) community palliative care team, 4) outpatient palliative care clinic, and 4) home palliative care team.

The number of patients who received specialized palliative care services is defined as the total of number of patients listed in each specialized palliative care service, and, thus, if one patient received two types of specialized palliative care service, the number of uses of specialized palliative care services is two. Although we have acknowledged the non-duplicated counting is ideal, we gave up on this calculation because not all participating institutions allow providing patient data beyond the institutions due to privacy issues. The ratio of the number of patients who received specialized palliative care services to all cancer death was calculated.

Quality of palliative care

The quality of palliative care is measured by both patients and bereaved families using the Care Evaluation Scale, a well-validated and the most commonly used measurement tool to quantify the user-perceived quality of palliative care in Japan [35]. The psychometric properties are established in both patients and bereaved family members [37, 38]. The full version of the Care Evaluation Scale consists of 8 subscales for patients and 10 subscales for families with a 6-point Likert-type scale from “1: improvement is not necessary at all” to “6: highly necessary”. One item example is “doctors dealt promptly with discomforting symptoms of the patient”. For this study, we have excluded 3 subscales, environment, cost, and availability, because the intervention does not intend to change these outcomes. For the primary end-points, we use 3 subscales

(physical care provided by physicians, physical care provided by nurses, and psycho-existential care) as a single scale, because this directly measures the degree to which patients/family members evaluate medical professionals respond to patients' physical and psychological distress. All subscales of the Care Evaluation Scale are used for the secondary end-points.

Quality of life

Quality of life is measured by both patients and bereaved families using the Good Death Inventory, a specific measure of the quality of life of Japanese patients with advanced cancer [39, 40]. We have decided to use the Good Death Inventory, not common tools such as EORTC or FACT, because: 1) we intend to investigate broader areas of quality of life Japanese palliative care populations regard as important, especially psycho-existential components [41, 42], and 2) existing quality of life measures largely depend on patient functional levels and previous studies failed to detect potentially beneficial effects of intervention [4]. The full version of this scale consists of 10 domains with a 7-point Likert-type scale from "1: strongly disagree" to "7: strongly agree". One item example is "I am free from physical distress". The subscale "living in a favorite place" includes "(the patient) is able to stay at his/her favorite place", and, thus, we can analyze not only the death location but also whether the death location was a preferred place of death of the patients [2].

Satisfaction

Satisfaction of the patient and family with medical care is measured using a single item scale: "Are you satisfied with the medical care you currently receive?" with a 6-point Likert-type scale varying from "1: very dissatisfied" to "6: very satisfied".

Pain intensity

Pain intensity of the patients is measured using the Japanese version of the Brief Pain Inventory, with a score given for the pain at its worst (0-10), at its best (0-10) and a score for the average pain felt (0-10) over the previous 24 hours. The reliability and validity in Japanese populations has been established [43].

Knowledge, perceptions, and concerns about palliative care

Knowledge, perceptions, and concerns about palliative care of the patients and families is measured using 10 items, similar to previous surveys [33], on a 5-point Likert-type scale from 1:strongly disagree to 5:strongly agree. Knowledge of opioids is examined using 2 items: "opioids can relieve most pain caused by cancer" and "opioids are addictive and/or shorten life". Beliefs about palliative care are examined using 3 items: "palliative care relieves pain and distress", "palliative care is provided along with chemotherapy and/or radiation therapy", and "palliative care is only for terminally ill patients". Concerns about homecare

are examined based on 5 items: “pain can be alleviated as effectively through home-visit services as it can at the hospital”, “home-visit services cannot respond to sudden changes in a patient’s condition”, “it is hard to find home-visiting physicians”, and “being taken care of at home puts a burden on the family”.

Feelings of support and security regarding cancer care in the region

Feelings of support and security regarding cancer care in the region are measured by patients and families using the newly developed Sense of Security Scale [44]. This is 5-item scale to assess feelings of support and security concerning cancer care in a region. One item example is “I would feel secure as a variety of medical care services are available in the region”.

Care burden

Care burden is measured using the Caregiving Consequences Inventory [45]. The Caregiving Consequences Inventory is developed to quantify caregiving consequences from a bereaved family member's perspective, and it consists of 4 positive domains and 1 burden domain. For this study, the burden domain is used.

Time spent at home/hospitals

Due to a lack of administrative data available to calculate time spent at home and hospitals, we ask bereaved family members the time spent at home during the last 1 and 3 months.

Knowledge, difficulty, and self-perceived practice of palliative care of physicians and nurses

Physician- and nurse-reported knowledge is measured using Palliative Care Knowledge Test [46]. This scale consists of 5 subscales, with correct, incorrect, and do not know responses.

Physician- and nurse-reported difficulty of palliative care is measured with the Palliative Care Difficulty Scale, a validated tool to quantify the levels of difficulty when health professionals provide palliative care [47]. This scale consists of 5 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is “it is difficult to get support from experts on alleviating symptoms”.

Physician- and nurse-reported self-perceived practice is measured employing the Palliative Care Self-reported Practice Scale, a validated tool to quantify the levels of adherence to recommended practices in palliative care fields ⁴⁷. This scale consists of 6 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is “I routinely inquire about the family’s concerns in the dying phase”.

Quality indicators

As quality indicators as region-level palliative care, we collect 20 quality indicators from nation-level

administrative database, such as opioids consumption, the number of home care service, the number of palliative care specialists, and the number of palliative care units.

Qualitative studies

Qualitative studies consisting of 3 studies.

Descriptive study

A descriptive study is performed to describe the process in developing regional palliative care in each local context. The study methodology is descriptive case studies, and this includes a variety of materials each region has made or arranged for local interventions.

Interview study

This study is performed to understand the process of how and why the regional palliative care program makes changes in the region. The ultimate purpose of this study is to propose a model for shaping regional palliative care. The research methodology is a grounded theory approach, and the data source is in-depth interviews with health care professionals.

Systematic collection of barriers and potential resolutions

This study is performed to systemically identify the barriers of palliative care at a regional level and potential resolutions. The research methodology is content analyses, and the data source is multiple focus-groups repeatedly conducted during the entire study period, field notes, and documents obtained.

Sample size calculations

As this study have 4 primary-end-points, i.e., the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care, we have set alpha error of 0.0125 (two-sided) by the Bonferroni correction for multiple comparisons.

Patient-reported quality of palliative care and family-reported quality of palliative care

To detect 0.2 effect size (one-fifth difference of standard deviation) for quality of palliative care (the Care Evaluation Scale) under statistical power of 0.8, 558 responses for each pre-intervention and post-intervention period is required for the analyses³⁵. We have thus determined that 1500 patients and bereaved family members should be surveyed at each time in consideration of the estimated response rate (40-60%) and missing values (10%) [35].

The number of home deaths and use of specialized palliative care services

We first assumed 6% and 8% as each pre-intervention value from the national data, respectively, and we expected to achieve 12% and 20% as meaningful increases after the intervention, respectively; and this led to the calculated sample size of 506 and 186 at each point, respectively. In practice, as we survey all cancer deaths in 4 regions (5000), the sample size is sufficient.

Statistical analyses

To compare the changes in outcomes before and after the interventions, the home death rate and the ratios of patients who receive specialized palliative care services are compared by means of logistic regression analyses. The significance of intervention is evaluated by time interaction term (i.e., time trend). In addition, for comparison with the national reference data of home death rates, repeated measures analysis with robust variances (i.e., Generalized Estimating Equation approach) is used to account for the longitudinal nature of the data. The Care Evaluation Scale, care burden score, Palliative Care Difficulty Scale, and Palliative Care Knowledge Test are compared by means of Student's *t*-test. The length of hospital admission was compared by means of the chi-square trend test.

Adjustments are performed with patient data (patient age, sex, primary tumor site, and region), bereaved family data (patient age, sex, primary tumor site, family age, sex, relationship [husband/wife vs. others], and region), physician data (age, sex, working site, number of terminally ill patients with cancer seen per year, and region), and nurse data (age, sex, education, working site, total number of terminally ill cancer patients cared for, experience of working in palliative care units, and region). To adjust for difference in the proportions of place of death of the subjects sampled, the weighted averages of death location according to census data of 4 regions are used for bereaved family outcomes.

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Table 1 Outcome measures

	Primary end-points	Secondary end-points
Location of death	Home death	Distribution of location of death (home, hospital, palliative care units, nursing home)
Use of specialized palliative care services	Number of patients who received specialized palliative care services	Backgrounds of patients referred to specialized palliative care services
Patients		
Quality of palliative care	Total score of 3 subscales of “physical care provided by physicians”, “physical care provided by nurses”, “psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale -physical care provided by physicians -physical care provided by nurses -psycho-existential care -help with decision-making -coordination/consistency of care
Quality of life		Good Death Inventory -physical and psychological comfort -living in a favorite place -maintaining hope and pleasure

		-having independence
		-having environmental comfort
		-being respected as an individual
		-a feeling of fulfillment at life's completion
Pain		Brief Pain Inventory
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		-Knowledge of opioids
		-Beliefs about palliative care
		-Concerns about home care
Feelings of support and security about cancer care in the region		Sense of Security Scale
Bereaved family members		
Quality of palliative care	Total score of 3 subscales of "physical care provided by physicians", "physical care provided by nurses", "psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale
		-same as patient, and,
		-help with decision making for family
		-family care
Quality of life of the patient (proxy)		Good Death Inventory (same as patient)
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		-Knowledge of opioids
		-Beliefs about palliative care

Feelings of support and security
about cancer care in the region

Care burden

Time spent at home

Physicians and nurses

-Concerns about homecare

Sense of Security Scale

Caregiving Consequence Inventory

-Burden

Time spent at home

-Knowledge

Philosophy, pain, dyspnea, delirium, and gastro-intestinal
symptoms

-Difficulties

Expert support, alleviating symptoms, community
coordination, communication in multidisciplinary teams, and
communication with patients and families

-Self-reported practice
