



Graduate Diploma in Health
Research PROGRAM – 2018
SUPERVISOR & PROJECT
INFORMATION FORM

Please complete and return via email only (gdip.hres@utoronto.ca) by **September 4, 2018**
(forms received after this date will not be posted).

Supervisor Information

Name: Dr. Camilla Zimmermann

Email:

Camilla.Zimmermann@uhn.ca

Degree(s): MD, PhD, FRCPC

SGS Department:

Institute of Medical Sciences

Academic Rank: Senior Scientist, Professor of Medicine

Field of Research: Palliative care in oncology

Research Institution Affiliation (if applicable): Princess

Margaret Research Institute

Allocation of student contact time: 1 hour / week
(number of hours per week YOU are available to the student for any concerns or to review progress)

Project Information (for posting on GDipHR website)

Title: Symptom screening with Targeted Early Palliative care (STEP) versus Early Palliative Care (EPC) versus standard care for patients with advanced cancer: A randomised pilot trial

Description (max 500 words):

Background: It has been shown in several studies that early involvement of a specialized palliative care team results in improved quality of life for patients with advanced cancer. However, resources are limited for all patients with advanced disease to be assessed and followed routinely by these teams. Although it is known that the patients with the greatest palliative care needs are those with the highest symptom severity, these patients are often not referred to palliative care in a timely fashion, with most still being referred in the last weeks of life. This study builds on a model of symptom screening, which is recommended in guidelines and mandated by Cancer Care Ontario.

Objectives/Aims: We are conducting a pilot randomised controlled trial (RCT) in which ambulatory patients with advanced cancer and a prognosis of 6-24 months will be allocated to one of three groups: symptom screening alone (usual care); Symptom screening with Targeted Early Palliative care involvement (STEP); and routine Early Palliative Care (EPC). The purpose of this pilot study is to assess the feasibility of conducting a larger three arm individually randomised trial and to establish specific parameters for it's planning. We will assess the patients' quality of life (QOL), depression, satisfaction with care, and symptom burden at baseline, 2, 4, and 6 months using validated patient-reported outcome measures.

The specific objectives are to determine: (i) the feasibility of a three-arm individually randomized controlled trial of early palliative care; (ii) parameters needed to calculate the sample size of the full RCT (effect size, accrual, adherence); and (iii) timing of the primary endpoint (4 vs. 6 months).

Methods: The pilot study will take place at the Princess Margaret Cancer Centre. Patients are systematically pre-screened for eligibility and recruited from five medical oncology clinics (Lung, Gastrointestinal, Genitourinary, Breast and Gynaecology). Patients routinely complete the Edmonton Symptom Assessment System using the Distress Assessment and Response Tool before appointments in clinic waiting areas and rate 9 common symptoms on a scale of 0-10 for severity. Patients providing informed consent will complete baseline measures and then will be randomised to receive either the STEP intervention (patients who report a score within a pre-set algorithm of symptom severity will receive a nurse-led triage and targeted referral to an outpatient specialized palliative care clinic), EPC intervention (patients notified via telephone by research staff and an outpatient palliative care referral form is sent for patients who agree), or to only continue their standard oncology care (control arm). The planned sample size for this pilot study is 60 patients (approximately 20/arm).

Significance: Our trial of early palliative care vs. standard oncology care is one of 3 high-impact trials demonstrating that early involvement of a palliative care team improves QOL in advanced cancer patients. The study addresses an important question: what is the most practicable delivery of early palliative care to those in greatest need of these services? The future three-arm RCT will help inform the development of the best early palliative care delivery model that is directly translatable into practice.

If human subjects are involved, have the appropriate Research Ethics Board approvals been obtained?

YES NO Application Submitted N/A

Yes, REB approvals have been obtained.

Do you expect this work will be published within the 20 months?

YES NO Uncertain

Yes, we expect this work will be published within the 20 months.

Student's roles and responsibilities (please be as specific as possible):

Our student will be trained by our study coordinators to independently: screen for potentially eligible study patients using electronic patient records and assess study-specific inclusion and exclusion criteria; recruit eligible study patients from specified solid tumour medical oncology clinics; obtain informed consent from interested patients; administer study questionnaires to consenting participants; obtain randomisation information from Princess Margaret biostatistician and complete the randomisation process; and perform data-related tasks such as data collection from electronic patient records, data entry, cleaning and database maintenance. Our student will also be involved with the preparation of study documents (printing, photocopying) as well as preparing study questionnaire mail-out packages, and conducting reminder calls for participants to complete and return their follow-up questionnaires. In addition, our student will be given the opportunity to perform simple statistics for interim analysis regarding participant recruitment rate, retention rates as well as questionnaire completion rates at each study time point (baseline, 2, 4 and 6 months). Our student may be asked to help assist with other related research projects if time permits.

Please indicate who will serve as the student's direct report for daily oversight (PI, PhD student, technician, etc...).

The clinical research coordinators will serve as the student's direct report for daily oversight.