

# Outcomes of Family Care in Advanced Cancer

Funded by the National Cancer Institute, Office of Cancer Survivorship

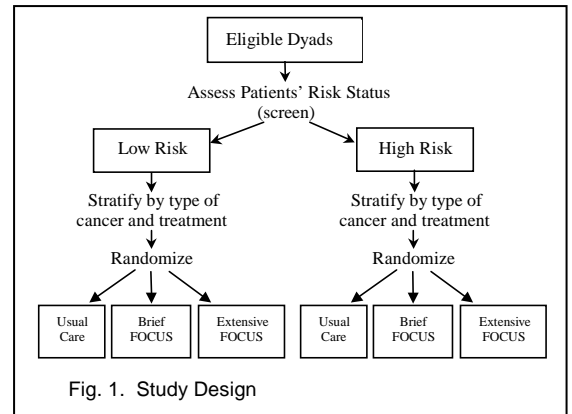
Multi-site study. This study is being conducted in collaboration with researchers, physicians, nurses and referral staff in oncology clinics at: the University of Michigan Comprehensive Cancer Center, St. Joseph Mercy Cancer Center, Providence Hospital, and Karmanos Cancer Center (Laurel Northouse PhD, RN Coordinating site PI, phone:743 615 4016; email lnortho@umich.edu).

## Study Objectives:

1. To determine if family dyads randomly assigned to either a brief or extensive family-based program of care (FOCUS Program) have better patient and caregiver outcomes than dyads randomly assigned to usual care.
2. To determine if the brief or extensive programs of care have a differential effect on patient and caregiver outcomes depending on the patient's baseline level of risk for distress.

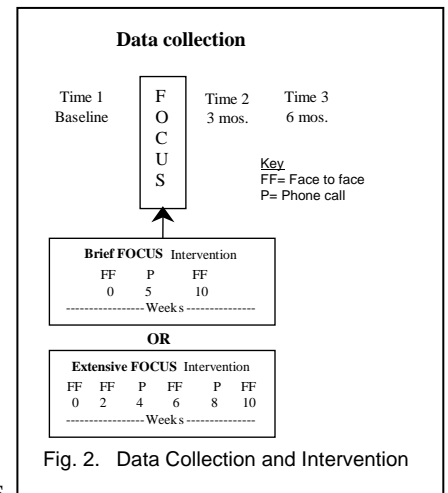
## Study Design:

In this randomized clinical trial, patients with advanced breast, colorectal, lung, or prostate cancer are screened for risk for distress at baseline and designated as either low risk or high risk (see Fig 1). Patients and caregivers (in dyads) are stratified by the patient's type of cancer and treatment then randomized to either: 1) Usual care, 2) Brief FOCUS program, or 3) Extensive FOCUS program. Data are collected prior to intervention, at three months, and six months follow-up. The brief and extensive programs are administered between Time 1 and Time 2 (see Fig. 2). The brief program consists of three nurse-contacts and the extensive program consists of six nurse-contacts.



## Sample:

Accrual needs: A target sample of 324 dyads, that complete all aspects of the study, is needed in order to have sufficient power to meet study aims. We plan to enroll 470 dyads over 3 ½ years to meet accrual goals with an estimated retention rate of 69.



Eligibility: For this study, “advanced cancer” refers to patients with continuing disease (Stage III or IV) who are expected to live at least six months. “Family caregiver” is the family member or significant other identified by the patient as his or her primary source of emotional or physical support during the advanced phase of cancer. Cancer-specific criteria are listed in the study protocol.

## Intervention:

The FOCUS Program is a supportive-educative program offered to cancer patients and their family caregivers. The program is delivered with a combination of face-to-face home visits and telephone calls (see Fig. 2). Program content addresses ways for patients and caregivers to support one another, maintain hope, use active coping strategies, obtain information, and manage symptom distress.