The FOCUS Program:
Intervention Program for Prostate Cancer Patients and Their Spouses/Partners

Intervention Training Manual

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FOCUS-Prostate Intervention Training Program

Training Schedule

Week	Time	Topic	Content
1	4 hours	Project Kick-Off	Videotape: "Not by Myself: Talking about Prostate Cancer" Overview of study (see Appendix A) Review of staff roles (see Appendices B and C) Administrative policies (e.g. payroll)
2	4 hours minimum	Independent Home Study	Self-study of materials (e.g. research proposal, FOCUS intervention protocol, patient/family education materials)
3	4 hours	General Orientation to FOCUS Protocol	Review protocol, symptom management cards; distribute portable file boxes for home visits
4	3.5 hours	Living with Prostate Cancer	Presentation by. prostate cancer survivor and wife on their experiences
		Treatment of Newly Diagnosed Prostate Cancer	Presentation by Howard Sandler, MD, radiation oncologist, U of Michigan
5	6.5 hours	Sexuality Issues for Prostate Cancer Couples: Assessment and Intervention Strategies	Presentation by sexuality consultant, Leslie Schover, PhD, MD Anderson Cancer Center
6	2.5 hours	Participant Recruitment and Retention in Urban Areas	Presentation by Diane Brown, PhD, Wayne State University, Detroit
	3 hours	Survivorship Issues	Presentation by African American physician who is a prostate cancer survivor and wife
7	1 hour	Treatment of Advanced Prostate Cancer	Presentation by Karin Olson, Physician Assistant, medical oncology, U of Mich
	4 hours.	Final Orientation to Intervention Protocol	Review 5 components (F-O-C-U-S). Discuss recordkeeping, nurse's notes, need for intervention rating
	1 hour	Videotape of Actual FOCUS Session	New nurses view a videotape of a cancer patient and spouse who received a session of the FOCUS intervention in a prior research study
8-10	4 hours per observation session (8 hours total)	Home Visit Observations	Each new nurse accompanies an experienced FOCUS nurse on a home visit to observe an intervention session. Nurses observe two different dyads before starting their own caseloads.

Total: 41.5 hours (minimum)

Detailed Outline of Training Sessions

OVERVIEW

Intervention Trainees:

The FOCUS Program is designed to be delivered by health professionals. In the FOCUS-Prostate study, all interveners were Master's-prepared, Advanced Practice nurses. Since the intervention nurses were experienced professional nurses, many skills necessary for delivering the intervention were not covered such as patient confidentiality, psychosocial assessment, and basic nursing skills (e.g. general physiology, nutrition, infection control, pain management, and medications). *The FOCUS Program was tested only with professional nurse interveners.*

Intervention Recipients:

The FOCUS Program was delivered in home visits and phone calls to prostate cancer patients and their wives/partners over a 3 month period. Patients were diagnosed with prostate cancer and were in one of three phases of the illness: a) newly diagnosed, following initial treatment (post-prostatectomy or post-radiation treatment); b) biochemical recurrence with rising PSA following initial treatment; or 3) advanced disease with metastasis.

Goals of Training:

1. To prepare intervention nurses to carry out the FOCUS Program protocol with intervention fidelity.
2. To increase awareness of multiple aspects of medical and psychosocial issues related to prostate cancer and its treatment.
3. To promote understanding of the effects of illness on spouse/partners.

WEEK 1: PROJECT KICK-OFF

Learning Objectives:

1. To gain awareness of effects of prostate cancer on patients and spouses.
2. To understand the research study purpose and design.
3. To learn about the various roles of research team members.
4. To become knowledgeable of administrative policies.

Agenda:

I. Introductions and orientation to training schedule

II. Videotape: "Not by Myself: Talking about Prostate Cancer." An educational video with Billy Davis Jr. and Marilyn MaCoo, a couple who have successfully faced prostate cancer. The video was part of the "Two against One: Couples Battling Prostate Cancer" program of the Us Too, International advocacy group (sponsored by Amgen and Praecis Pharmaceuticals, 1-877-550-9624, www.2against1.com).

III. Overview of study (see Appendix A))

- A. Study purpose and design
- B. Eligibility criteria for participants
- C. Data collection timeline
- D. Accrual/incentives for study participants

IV. Review of staff roles (see Appendices B and C)

- A. Job descriptions
- B. Chain of communication among research team

V. Administrative policies

- A. Mandatory monthly staff meetings
- B. Payroll
- C. IRB human subjects certification

Materials:

Notebook for each staff member to store training materials
Nametags to wear to home visits, business cards
Research staff contact list
One page summary of study, Appendix A
Chain of communication flowchart, Appendix B
Intervention nurse job description, Appendix C

WEEK 2: INDEPENDENT HOME STUDY (NO MEETING THIS WEEK)

Learning Objectives:

1. To develop an understanding about the study protocol and intervention materials.
2. To engage in self-study and increase knowledge about ways to help patients and spouses cope with prostate cancer and its treatments.

Procedure

A. Instruct staff to read/review all materials starting with the study protocol, the FOCUS Program protocol and the Prostate Cancer Treatment Guidelines.

B. Encourage staff to bring any questions about study materials to next training session for clarification.

Homework Assignment: To be read within the next 4 weeks

1. Study protocol (21-page research proposal)

2. FOCUS Program intervention protocol (21-page manual/checklist)

3. Symptom management cards (e.g. fatigue, nausea and vomiting, urinary incontinence)

4. Chemotherapy and hormone therapy drug handouts (obtained from the book titled, Patient Education: Guide to Oncolopy Drugs, ACS, 2000)

5. Patient/family education materials: Fostering an Optimistic Outlook (developed by research team), Helping Your Children Cope with Your Cancer (developed by research team), Ten Commandments of Good Listening (author unknown), Rhythmic Walking (Maryl Winningham, PhD, RN, Cancer Nursing, Oct. 1991)

6. Published booklets:
   NCI: Taking Time, Facing Forward, When Cancer Recurs, Chemotherapy and You, Eating Hints for Cancer Patients, Managing Cancer Pain
   ACS/NCCN: Prostate Cancer Treatment Guidelines, Sexuality and Cancer
   State of Michigan: Planning for Your Peace of Mind

7. Relaxation tape: Letting Go of Stress (Emmett E. Miller, MD, http://www.drmiller.com)

WEEK 3: GENERAL ORIENTATION TO FOCUS PROTOCOL

Learning Objectives:

1. To obtain an indepth understanding of the various aspects of the intervention protocol.
2. To increase knowledge about symptom management and patient/family educational materials.

Agenda:

I. Overview of intervention protocol
   - A. Intake form (Patient Information Form, PIF) for new dyad entering study
   - B. Timing of home visit and phone sessions
   - C. General format of visits
   - D. Discuss specific intervention strategies according to session
   - E. Tailoring intervention depending on the patient's phase of illness

II. Review symptom management cards and other patient/family handouts

III. Distribute portable file boxes to carry materials to home visits (sample file box was demonstrated)

IV. Homework assignment: continue reading all intervention materials

Materials:

Patient Information Form
Handouts: Overview of FOCUS Program (table)
Portable file boxes, hanging files, file folders

WEEK 4: LIVING WITH PROSTATE CANCER AND TREATMENTS FOR NEWLY DIAGNOSED PROSTATE CANCER

Learning Objectives:

1. To increase awareness of the issues faced by prostate cancer survivors and their spouse/partners
2. To obtain information about treatment options and morbidity for newly diagnosed prostate cancer patients.

Agenda:

I. Presentation: "Living with Prostate Cancer: Survivors' and Partners' Perspectives" by prostate cancer patient and wife

A. 10-year prostate cancer survivor and wife describe their experiences with diagnosis and treatment (radiation and hormone therapy)

B. Question and answer session with nurses and couple

II. Presentation: "Treatment of the Newly Diagnosed Localized Prostate Cancer Patient," by Howard Sandler MD, radiation oncologist, University of Michigan

A. Diagnostic testing for prostate cancer: PSA screening, Gleason scores

B. Treatment options:
   1. Watchful waiting
   2. Radiotherapy
   3. Prostatectomy
   4. Hormone therapy: Androgen ablation

C. Morbidity associated with treatments
   1. Surgery: urinary and sexual problems
   2. Radiotherapy: gastrointestinal and sexual problems
   3. Androgen ablation: sexual problems, hot flashes, weight gain

Materials: No additional materials distributed

WEEK 5: SEXUALITY ISSUES FOR PROSTATE CANCER COUPLES: ASSESSMENT AND INTERVENTION STRATEGIES

Learning Objectives:

1. To develop assessment skills pertaining to sexuality concerns of prostate cancer patients and their spouse/partners
2. To learn new strategies for helping patients and spouses with sexual problems.

Agenda:

I. Presentation: "Assessing Sexuality in Cancer Patients" by Leslie Schover, PhD, sexuality expert from MD Anderson Cancer Center.
   - A. Screening for problems
   - B. Sexual communication between partners
   - C. Assessing sexual function
   - D. Question and answer period

II. Presentation: "Sexual Rehabilitation After Prostate Cancer" by Leslie Schover, PhD
   - A. Sexual problems after various prostate cancer treatments
   - B. Findings from a research study on prostate cancer survivors who seek help for sexuality problems
   - C. Role of sex therapy
   - D. Question and answer period

III. Presentation: "Sexuality Interventions after Prostate Cancer" by Leslie Schover, PhD
   - A. Elements of an intervention
   - B. Importance of the partner
   - C. Coping with symptoms (e.g. urinary incontinence during sexual activity)
   - D. Question and answer period

Materials: No additional materials distributed

WEEK 6: PARTICIPANT RECRUITMENT/RETENTION IN URBAN AREAS AND SURVIVORSHIP ISSUES

Learning Objectives:

1. To learn about barriers to recruiting and retaining research participants.
2. To increase sensitivity to cultural and literacy issues.
3. To gain understanding of the survivorship issues faced by African American prostate cancer survivors and their spouse/partners.

Agenda:

I. Presentation: "Participant Recruitment and Retention in Urban Areas" by Diane Brown, PhD, Director of the Urban Center at Wayne State University
   - A. Barriers to recruitment in urban areas
   - B. Predictors of participation of African Americans
   - C. Benefits of diversity in research studies
   - D. Sensitivity to cultural and literacy issues

II. Presentation: "Survivorship issues in African American Prostate Cancer Patients and Their Partners" by African American physician in Detroit who is a prostate cancer survivor and his wife
   - A. Problems dealing with urinary incontinence following treatment
   - B. Emotional side of prostate cancer for survivors and partners
   - C. Masculine identity and sexual concerns post-treatment
   - D. Intimacy and relationship issues
   - E. Strategies that helped couple to cope with treatment and symptom management.

Materials: No additional materials distributed

WEEK 7: TREATMENT OF ADVANCED PROSTATE CANCER AND FINAL ORIENTATION TO FOCUS INTERVENTION

Learning Objectives:

1. To obtain information about treatment options, symptom management and supportive care for advanced prostate cancer patients.
2. To complete final orientation to FOCUS Program in order to successfully deliver the program and maintain intervention fidelity.
3. To increase understanding of intervention delivery by watching actual FOCUS session on videotape.
4. To gain knowledge of techniques for communicating effectively with patients and spouse/partners.

Agenda:

I. Presentation: "Treatment of Advanced Prostate Cancer" by Karin Olson, oncology physician assistant, University of Michigan

- A. Pretreatment risk assessment (low-intermediate-high)
- B. Hormonal therapy: first and second line
- C. Chemotherapy options
- D. Use of bisphosphonates
- E. Supportive and palliative care
- F. Symptom management (e.g. pain management)

II. Final orientation to FOCUS intervention protocol

- A. Review five components: F-O-C-U-S
- B. Discuss strategies to promote intervention fidelity
    1. All five components to be addressed in each face-to-face session.
    2. Be sure to identify family strengths as part of "F" component, note specific strengths.
    3. Ask about usual ways of maintaining optimism and encourage' additional strategies as needed under the "O" component.
    4. Discuss healthy lifestyle and health maintenance behaviors as a part of "C' component.
    5. Reinforce that uncertainty is normal during cancer experience in "U' component.
    6. Give dyad only those symptom management cards that pertain to them in "S" component. Assess physical and emotional symptoms of both patient and spouse/partner. Provide appropriate self-care strategies to each member of the dyad.
    7. Maximize effect of patient education materials by highlighting strategies appropriate to the dyad.
    8. Summarize key points discussed at the end of each session.
- C. Recordkeeping and maintaining nurses notes

D. Discuss criteria for rating dyad's need for intervention by nurse

E. Discuss case report form for new dyads that is used for supervision and feedback at monthly staff meetings

F. Review process for audiotaping randomly-selected sessions for evaluation by Principal Investigator.

III. View videotape of cancer patient and spouse who received FOCUS intervention in prior study

A. Identify facilitative communication used by nurse

B. Identify key elements of F-O-C-U-S discussed in videotape

Materials:

Review of FOCUS intervention protocol previously distributed
Videotape of actual FOCUS session with patient 'and spouse from prior study

WEEKS 8-10: HOME VISIT OBSERVATIONS (NO MEETING)

Learning Objectives:

1. To experience an actual intervention session by observing a FOCUS nurse conducting a home visit.
2. To increase knowledge about recordkeeping associated with maintaining a caseload.

Procedure

A. Each new nurse accompanies a nurse who is experienced with delivering the FOCUS intervention on a home visit.

B. Nurses observe two different dyads (with two different experienced nurses) before starting their own caseload.

C. After the observation session, the new nurse and the experienced nurse meet to debrief about the home visit.

D. New nurses also discuss recordkeeping (e.g. nurse's notes) with the experienced nurse following the home visit.

Appendix A

FOCUS: Prostate Cancer Family Study
Funded by the National Cancer Institute

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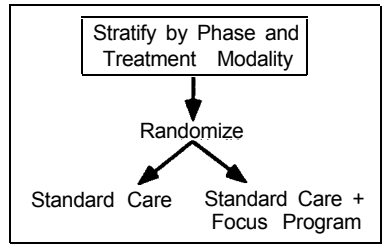
Purpose of the study:
To determine if a family intervention (The FOCUS Program) can improve the quality of life of men with prostate cancer and their spouses/partners.

Study Design:
This study is a randomized clinical trial. Couples will be randomly assigned to receive standard care alone (control **group)** or standard care plus the FOCUS Program (experimental group). The FOCUS program is a supportive-educative, family-centered intervention that consists of 5 contacts (home visits and followup phone calls) with a masters-prepared nurse.



Sample:
Accrual needs: We plan to enter 150 couples from UM over three year period of time or 50 couples per year. We need names of 10 eligible couples per month. We assume that half of these couples (50% response rate) will agree to enroll in the study. Data collection will start August 1, 2001. A breakdown of the 10 couples that we need per month, per phase of illness is as follows:

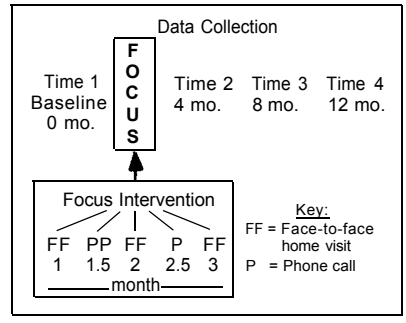
Newly diagnosed	Post tx rising PSA	Advanced/Recurrent
5 couples:	2 couples:	3 couples:
2.5 post prostatectomy	*1 receiving tx*	*1.5 hormone sensitive*
2.5 post external beam	*1 observation*	*1.5 hormone refract.*
(no brachytherapy)		

Eligibility:
Newly diagnosed localized disease: Men can enter 2-4 months following prostatectomy or completion of radiation therapy. Men must have spouse/partner willing to participate.

Post-treatment rising PSA: No time specification for length of time post-treatment. Men will enter the study 1-3 months following confirmation (two values) of rising PSA.

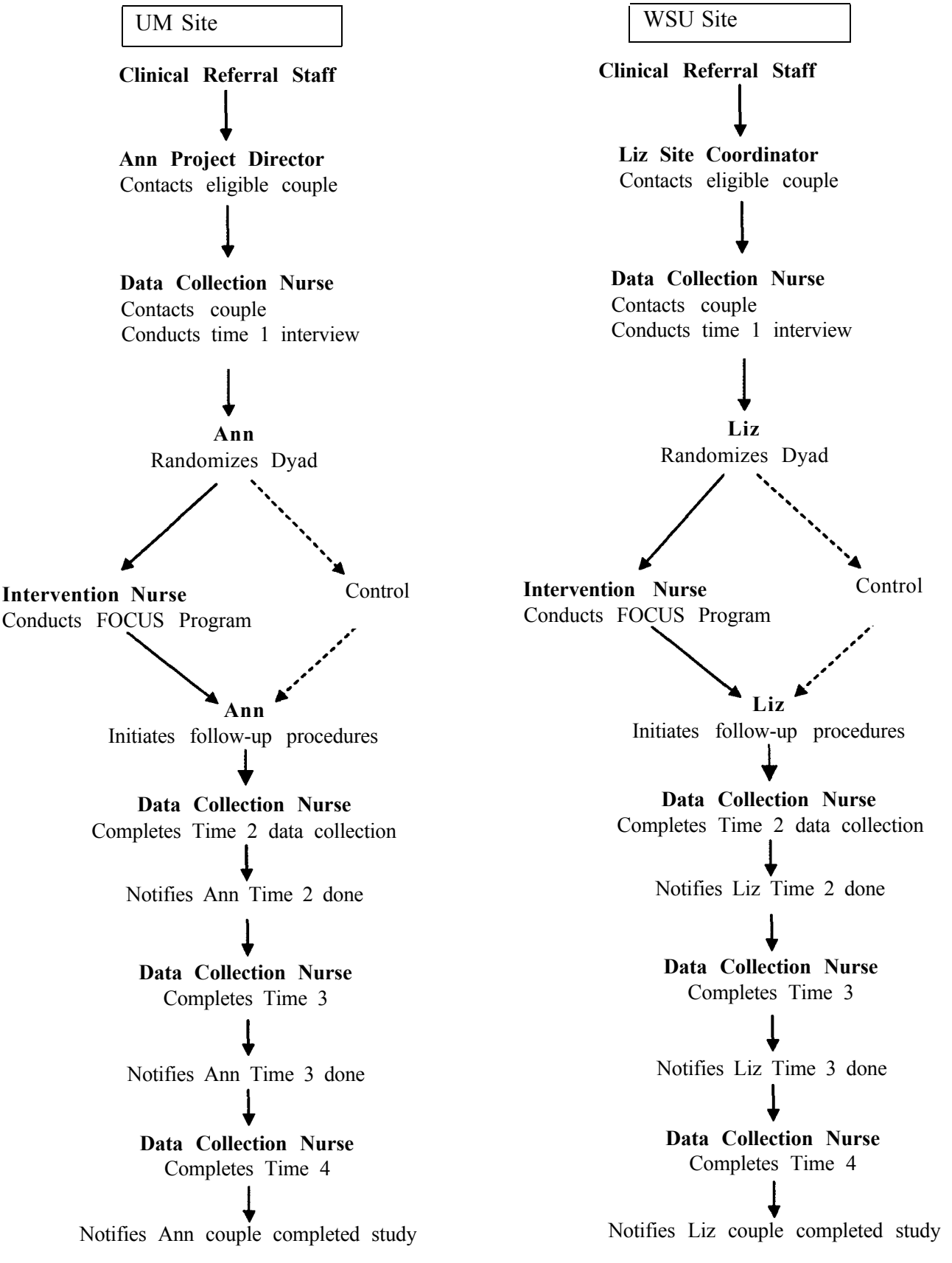
Advanced/recurrent disease: Men who have metastatic disease at diagnosis or who have progression of disease will be eligible 1-3 months after disease progression or after metastasis is confirmed and treatment has been initiated.

Data collection timeline: (all data collection occurs in patients' homes) Referral staff will identify patients who meet eligibility criteria and ask patients if they are willing to be called by a member of the research staff who will explain the study. in more detail. Referral staff will complete referral and refusal forms and email them to Ann Schafenacker RN, MSN, Project Director.



Appendix B

FOCUS: Chain of Communication



Appendix C

UNIVERSITY OF MICHIGAN
JOB POSTING

Job Title: Research Associate I Health Science
Two part-time positions

Grade: 06

Department: School of Nursing

Hours: 8 (20%)

DUTIES:
Participate in the execution of an NCI funded research project. Deliver treatment (family-focused nursing intervention) to subjects in the experimental group. Assess family and provide appropriate tailored interventions per protocol manual. Keep detailed nursing notes on intervention sessions.
Assist in the preparation of research papers and manuscripts for publication and presentations and in the writing of reports, articles and other documents.
Attend monthly staff meetings for training and supervision. Participate in the development of general goals for the research project and in the planning of the field work

DEPT MINIMUM QUALS:
Master's in Nursing is required Excellent interpersonal skills.

DESIRED QUALS:
Past experience in longitudinal human subjects research studies is helpful. Background in Psych-Mental Health or Family Nursing is desired.

NOTE:
8 hours per week
Must have own transportation (mileage for research trips to be reimbursed.)
Must be willing to have a flexible work schedule and be available for some evening and weekend work.

MINIMUM QUALIFICATIONS:
Requires the academic knowledge of a health science discipline, such as public health, microbiology, biochemistry, anatomy, pathology, nursing, dental hygiene or medical technology, including advanced study or demonstrated capacity for health science research that is generally associated with a Master's degree or an equivalent combination of education and progressively responsible work experience.