7. Chapter 7: Adherence, Retention and Drop-Out Recovery

7.1 Overview

Adherence, retention, and recovery of possible drop-outs from the study are essential to the scientific credibility of the study. Without sufficient adherence to the intervention, sufficient changes in depression and/or social isolation may not be obtained among participants to judge the impact of decreasing depression and/or social isolation upon morbidity and mortality. Without sufficient retention of participants in the arms of the study, the generalizability of the study’s findings to the usual depressed and/or socially isolated post-MI patient may not be possible. Additionally, differential retention between the intervention and usual care arms of the study may severely bias the interpretation of the efficacy of the interventions. Thus, it is essential that methods be systematically implemented to promote adherence and retention and recover as many participants who drop out as possible.

ENRICHD will adopt a variety of approaches to promote adherence and retention during the study, and to aid in drop-out recovery. The first set of strategies consists of commonly used methods of assisting participants in adhering to the study protocol, and will be described as general adherence strategies in Section 1. that follows. In addition, we will use motivational interview methods from the moment of recruitment in order to reinforce adherence during the study as previously described in Chapter 3, and further discussed in Section 7.2. below. Finally, we will describe strategies aimed specifically at recovering drop-outs, either due to a failure to return to follow-up assessments or failure to return to intervention sessions (Section 7.3. below).

7.2 Approaches to Adherence

Three general strategies will be used to facilitate adherence to the intervention follow-up assessments, and to retain study subjects throughout follow-up. These strategies include logistical assistance, reminders, and involvement by family and/or friends and are discussed further below.

• logistical assistance/support

As previously discussed in Chapter 3, the Case Coordinator (CC) will ensure that participants have sufficient logistical assistance to attend first screening visits and then intervention and assessment sessions once they are randomized. Issues that we anticipate commonly being addressed with patients include providing assistance with transportation, offering meals during return visits to the hospital, and arranging for child-care and other family obligations. The CC will also try to schedule visits at times least likely to interfere with other social or work activities.

• reminders

We also plan to provide all study participants with calendars indicating intervention and/or assessment sessions, and to send them reminders in advance of follow-up assessments. A newsletter will also be developed and sent to both intervention and usual care participants in order to
encourage continued involvement in the study. Appropriate care will be taken to ensure, however, that the newsletter content does not address issues related to either depression or social isolation.

- eliciting support from family/friends

Lack of support is a common barrier to participation for all participants, but may be a particularly common issue among low-SES participants, minorities and women. This may be especially the case with a study which focuses on psychosocial issues where there may be less cultural acceptance of these factors than among more affluent or non-minority groups. We will thus plan to inform family and/or friends of participants during the recruitment phase and to solicit their support and involvement (see Chapter 3). Fortunately, a focus of intervention will be on developing skills to increase social support which should be sufficient for those participants assigned to the active intervention to deal with these issues that may affect participation. For those participants assigned to usual care, however, it will be essential for the CC to facilitate participants addressing social support barriers to participation without actually providing them with much support. For these usual care participants, issues concerning social support barriers to participation will be addressed through developed text materials to be sent to participants and newsletter articles.

### 7.3 Motivational Interviewing Methods

Motivational interviewing is an approach to assessment and intervention based on Stages of Change Theory which is designed to augment an individual’s motivation to change behavior. This approach to health-promotion interventions emphasizes the use of individualized risk appraisal, identification of potential risk-reduction strategies, techniques to increase self-efficacy for behavior change, and strategies to prevent relapse and promote retention. It incorporates several strategies to facilitate transition from one stage to the next, thereby preparing an individual to initiate and/or maintain a recommended behavior. Objective feedback is provided and ambivalence about behavior change explored, with specific attention to eliciting an individual’s personal goals and self-motivational statements, formulating personal goals in behavioral terms and problem-solving barriers to change. Reflective listening skills are particularly effective as a method of interaction with patients in eliciting and clarifying their personal goals and self-motivational statements. Motivational interviewing seeks to evaluate the discrepancy between participants' stated goals and their current behaviors in a style that increases motivation for change.

Motivational interviewing methods will be incorporated in the earliest stages of recruitment as previously described in Chapter 4, Section 4.3.2. However, these methods will be extended throughout activities of ENRICHD to encompass interactions of participants with CCs, interview and clinic follow-up staff. Our experience has been that these methods, when used consistently across contacts, are extremely effective in promoting active participation.

Training in motivational interviewing methods will be incorporated into the national training for study staff. Additionally, the supervising psychologist at each site will ensure the training of all staff in motivational interviewing methods to supplement the national training, and staff experience with motivational interviewing methods will be reviewed during staff meetings and supplemented with role-playing as needed to train staff on an on-going basis to use these methods effectively.
7.4 Drop-out Recovery

Drop-out recovery methods have been demonstrated in clinical trials to re-engage participants who have become inactive when applied systematically (Probstfield, Russell, Insull, & Yusuf, 1990). While not originally conceptualized in this manner, this approach incorporates the use of good reflective-listening and directive skills to elicit barriers to participation from subjects. This information is then used to problem-solve with participants for methods to overcome the identified participation barriers. Finally, an essential component of drop-out recovery is the application of motivational interviewing methods in an attempt to further elicit and clarify participants’ personal reason for continued participation.

The general approach to drop-out recovery will involve contact by the CC in an attempt to: 1) identify barriers to participation; 2) problem-solve for solutions to overcome identified barriers; and 3) apply motivational interviewing methods as discussed above. These efforts will be discussed and reviewed during Case Management Review sessions by the CCs, therapists, and behavioral investigators. If the CC is not successful in re-engaging the participant, then contact will be initiated by a therapist or investigative team member at the discretion of the Case Management Team. Often, contact by a new member of the staff results in new perspectives and is to be encouraged in drop-out recovery.

In general, drop-out may be seen from clinic follow-up visits for all enrolled participants. It is common, though, for participants assigned to active intervention to see drop-outs selectively from either clinic follow-up or intervention sessions; some intervention participants will, of course, drop out from both intervention and clinic follow-up. Drop-out recovery of intervention participants thus requires close coordination and sharing of information between intervention and clinic staffs.

7.4.1 Specific Methods for Drop-Out Recovery

The approach to drop-out recovery will involve the following steps: 1) contact the patient; 2) identify reasons for withdrawal; 3) negotiate solutions to overcome barriers; and 4) apply motivational interview methods. Motivational interviewing methods are discussed in Section 7.3 above. The other steps are discussed below.

7.4.1.1 Contact the patient:

Attempt to contact patient - When a patient has missed one intervention session without advanced warning, then the therapist will inform the CC, who will try to contact the patient. The CC will first attempt to contact the patient directly by phone. If patient has an unlisted telephone number, then an attempt should be made to contact the proxy of the patient. The proxy may be asked to have the patient contact study staff, or to find out whether patient is still in the area and his/her vital status. The CC may also send a letter by certified mail, asking the patient to contact the study staff. Record the results of all attempts to contact the patient either by phone or by mail on follow-up form (to be developed).
Attempt to contact the patient’s physician - Record the result of the attempt to contact the patient’s personal physician, by letter or by phone, for the patient’s current address and/or vital status. Other staff in the physician’s office, such as the nurse, may also be asked to provide this information.

Other sources of contact to find out about the patient’s whereabouts include patient’s employer, Social service agencies, the Department of Motor Vehicles, the Police Department, etc. In each instance record the results of the inquiry.

### 7.4.1.2 Identify reasons for withdrawal

Patient has died - record date of death and how date of death information is obtained.

Patient is lost to follow-up - All efforts to locate patient have failed. Record whether patient’s vital status is known or unknown, and last date of known contact with ENRICHD.

Patient has moved away - The patient has moved away and cannot or will not return for intervention sessions and any scheduled follow-up visits. [optional: If the patient has moved to another ENRICHD center area, it may be possible to keep patient in trial for follow-up visits. The Coordinating Center should be contacted for instructions on how to transfer patient from one center to another.

Physician refuses to continue patient in study - Contact the physician’s office and record reasons/circumstances which have influenced the physician’s refusal for the patient to continue in the study.

Patient refuses to continue in study - Identify reasons for withdrawal and register whether barriers to participation are solvable. It is important to use good reflective-listening and directive skills to elicit barriers to participation from patient. To the extent possible, to determine willingness of patient to work on solutions to overcome barriers to participation. Record patient reason’s for withdrawal and willingness to return (potentially willing vs absolutely unwilling). If patient has dropped out of treatment and is absolutely unwilling to return, negotiate continued participation in follow-up assessment visits.

### 7.4.1.3 Negotiate solutions to overcome barriers

**Logistical obstacles** - When major barriers to participation involve logistical obstacles, first try to identify alternative strategies that the patient may use to overcome these obstacles. If these alternative strategies fall short or are not available, then offer reasonable logistical assistance provided by study resources.

**Lack of motivation** - Use motivational interviewing techniques to encourage patient reconsidering the decision to withdraw. Suggest an in-home visit to discuss re-entry into study with patient. If family members play in role in decision to drop-out, then try to schedule a phone call or home visit with family members present. Also, contact therapist to discuss motivational problems on the part of the patient.
Recurrent event - If patient is temporarily hospitalized, or otherwise unable to continue intervention sessions because of recurrent event or other health condition, discuss importance of returning to interventions after recovery. Conduct weekly follow-up phone calls to determine status of patient.

7.5 References

Appendix: Sample Form for Drop-out Registry

Patient ID:

COMPLETE THIS FORM IF PATIENT HAS DROPPED OUT FROM INTERVENTION OR IS NO LONGER PARTICIPATING IN THE STUDY

1) Date of last ENRICHD contact (mo/day/yr)

2) Reason for Patient Withdrawal
   1: Patient is lost to followup
   2: Patient has moved away
   3: Patient refuses to continue (go to 4)
   4: Physician refuses to continue patient in the study
   5: Other (specify)

3) List reasons/circumstances of patient's drop-out

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

4) Vital Status
   1: Alive
   2: Dead (record date of death plus where information was obtained)
   3: Unknown

5) Evaluation of patient's willingness to re-enter:
   1: perhaps willing
   2: absolutely unwilling

6) Outcome of drop-out recovery effort:
   1: patient re-entered
   2: patient refused to re-enter