1. ENRICHED PSYCHOSOCIAL INTERVENTION

1.1 OVERVIEW

The goal of the ENRICHED psychosocial intervention is to reduce mortality and morbidity following acute myocardial infarction by reducing depression and/or improving perceived social (emotional) support in participants who are at risk based upon these factors. The intervention combines a proven, state-of-the-art individual treatment for depression, a newly-developed individual treatment for low social (emotional) support that integrates elements from a number of established treatments, and a group treatment, applicable to participants who experience either depression and low perceived emotional support.

This Manual of Operations will outline separately, and in detail, the basic elements of the individual treatments for depression and social (emotional) support, and the group intervention. This Overview aims to integrate these treatments by highlighting the most critical common elements and focusing on their implementation across the three treatments.

1.2 THEORETICAL MODEL

The ENRICHED intervention is rooted in cognitive behavior therapy (CBT), as described by Beck and colleagues (1979) and refined by J. Beck (1995). This model hypothesizes that peoples’ emotions and behaviors are influenced by their perception of events. It is not only the situation that determines how people feel, but the way in which they construe the situation. As such, a central task of the ENRICHED psychosocial treatment is to help the participant understand that automatic thoughts exist, influence feelings, can be altered, and, if altered, can have a beneficial impact on feelings. To accomplish this, CBT utilizes three basic strategies that are central to the ENRICHED intervention: behavioral activation, alteration of automatic thoughts, and active problem-solving.

The individual depression intervention follows a standard CBT approach in which depressed feelings are hypothesized to be a function of irrational automatic thoughts. CBT was chosen because it has demonstrated efficacy, across a rich database, at reducing both major and minor depression. In cases of severe or unremitting depression, however, it may not be possible to alleviate the depression with CBT alone. Thus, pharmacological therapy will be used as an adjunct to CBT to achieve treatment goals.

The individual social support intervention and the group intervention are also rooted in CBT but in addition draw on principles from social cognitive theory (Bandura, 1986). In this model, five interacting sources of influence--cognitive, behavioral, emotional, physiological, and environmental--are hypothesized to direct human behavior in dynamic, reciprocal interactions. Targeting any or all of these sources of influence is an appropriate route to behavior change since change in one will promote change in the others. This augments the CBT model by
suggesting that ultimate targets for behavior change include not only the CBT targets of cognitions, behaviors and emotions, but also the individual’s physiological arousal and his/her social environment.

The theoretical underpinning of the individual social support intervention is that low perceived emotional support increases risk for cardiac recurrence. It may emerge in several ways. It may reflect cognitive deficits and thus be well suited to CBT approaches. It may reflect behavioral deficits, such as poor communication skills, and require behavioral skills training. It may have little to do with intrapersonal deficits but instead reflect a true environmental deficit characterized by social isolation, in which case work to mobilize one or more potential support-givers is required.

The theoretical underpinning of the group intervention is that a versatile repertoire of self-management skills is associated with continued improvement in depression and low perceived emotional support and maintenance of positive changes over time. This repertoire includes self-management skills across all five sources of influence. It reinforces and extends the principles of CBT, works in the environmental domain by using other group members to offer and receive emotional support for change, and works in the physiological domain by using relaxation skills to teach mind-body connections. In the group, it is possible to observe directly the dynamic, unfolding process of reciprocally interacting sources of influence: how thoughts influence feelings and behaviors, how feelings influence physiology, how behaviors influence environmental reactions, and how environmental reactions influence thoughts and feelings. It is also possible to observe directly the impact of change in any one source of influence on change in a number of others.

1.3 CRITERIA FOR SUCCESSFUL COUNSELING

The ENRICHD clinical trial is designed to evaluate results using all participants who have been randomized to receive the intervention, regardless of their individual success at behavior change. However, designation of individuals who have been successful at achieving therapeutic goals is important because they comprise the subgroup in whom greatest reduction in risk of recurrent events is hypothesized to occur.

Therapeutic success is judged by the counselor based upon several criteria that vary slightly depending upon the baseline diagnosis of depression, low social support, or both.

The first criterion for success is that there is an observed reduction in the relevant psychosocial risk factor. Reduction in risk in depression is defined as two consecutive scores of 7 or less on the Beck Depression Inventory. Reduction in risk in low perceived emotional support is defined as 2 consecutive scores of 2 or more items scored at 4 or greater on the Modified Duke Social Support Scale.
The second criterion is that the participant receives a minimum of 6 sessions of either individual or group therapy. This insures a minimum exposure to basic principles deemed important in ENRICHD.

The third criterion is that the participant demonstrates an ability to apply CBT skills by independently engaging in self therapy in which automatic thoughts leading to unwanted feelings are identified and altered. This criterion is met by attaining a perfect score of 12 on the CBT Performance Criteria Scale.

The fourth criterion, applying only to participants who screened in on low social support, is that the participant must be connected with at least one satisfying and supportive relationship. This is defined as a score of 3 or more on the Social Relationship Criterion Scale.

The counselor is expected to monitor each participant on each of these criteria after each treatment contact, on the Treatment Process Data Log (See Appendix). A copy of this Log, for each participant receiving active treatment, is sent to the Coordinating Center by the counselor every two weeks.

1.4 STRUCTURE

Since data on the relationship between these psychosocial factors and recurrence indicates that they exert an immediate adverse effect on prognosis, the individual intervention begins as soon as possible after randomization occurs. A hospital visit to the participant is strongly encouraged, if randomization occurs during the hospital stay. Individual counseling continues as long as it is needed but no longer than 6 months. Referral to group treatment occurs whenever a group becomes available if the participant has had at least 3 sessions of individual counseling and there are no contraindications to group counseling. There is an onus to refer participants who screened in on low social support to group as quickly as possible because the group provides a particularly powerful context for improving low perceived emotional support.

Participants should be terminated from active treatment when the criteria for successful counseling (Section 1.3) have been met. The duration of individual counseling is based upon the counselor’s judgment, but the duration of group counseling is fixed at 12 sessions. Since referral to group counseling is, to a large extent, based upon the logistics of forming a group, participants may be seen in both individual and group counseling simultaneously. If a participant has had a group experience and has met criteria for successful counseling, individual counseling should be terminated. Individual counseling can be terminated if all criteria for successful counseling have been met except a score of 12 on the CBT Performance Criterion Scale if the participant scores at least 5 and the counselor and supervisor agree that further progress on this criterion is unlikely.

Group treatment follows a partially open group format. A group begins as soon as there are at least 3 reliable participants available to join, and continues for 12 sessions. Enrollment is open to any other participants who may become available at any time during the 12-week group. A
participant can enter a group at any time up through his/her 6-month anniversary of randomization. If, for example, a participant begins a group at his/her anniversary date, his/her counseling will continue through 9 months post-randomization.

Psychosocial treatment concludes after a maximum of 6 months of counseling, and pharmacotherapy concludes after a maximum of one year of counseling. At the conclusion of active treatment, all participants are called each month on the phone to assess relapse, using the BDI and the Modified Duke. Calls end at month 7 from the time of randomization, with further calls being the exception and conducted only in unusual circumstances. If relapse has occurred within the 6-month window, the participant may be called back in for individual counseling. If relapse has occurred outside of the 6-month window, the participant may be referred to a community therapist.

1.5 RATIONALE FOR INDIVIDUAL AND GROUP MODALITIES

The ENRICHD intervention has to be powerful enough not only to promote change during treatment, but also maintenance of change after treatment has been discontinued for up to 3.5 years. The power of individual CBT for reduction of depression is supported by a consistent and extensive database. When combined with adjunctive pharmacotherapy for extreme cases, this represents the most powerful existing treatment approach for depression. When combined with maintenance sessions, only 10-20% can be expected to relapse.

The efficacy of the individual counseling designed for ENRICHD for improvement in social support is unknown, however its rationale is to accomplish two key treatment aims. First, the counselor quickly establishes a therapeutic alliance characterized by the provision of emotional support and unconditional positive regard. This is intended to provide an immediate alleviation of the feelings of low emotional support. Second, through interactions with the participant, the counselor can identify the reasons for feelings of low emotional support which could be due to deficits in communication skills, cognitions, and/or the social network. In the latter case, individual work makes it possible to examine the social network with the aim of identifying someone who could be involved in the counseling and ultimately replace the counselor as primary support-giver after counseling is discontinued.

Group counseling also lends to the power of the intervention. Of seven studies of behavioral interventions that have successfully reduced post-MI risk, six used a group intervention. Although the specific reasons for the success of groups with post-MI patients are not clear, some of the advantages are:

Groups make it possible for the therapist to step out of discussions and observe the dynamic process of reciprocally interacting sources of influence unfold. The therapist is provided with an objective view of interactional styles that is not filtered through any one participant’s view of reality, and is afforded the opportunity to make “in vivo” observations on interpersonal dynamics.
Groups provide a context in which to practice new skills. New behavioral competencies are acquired when four criteria are satisfied: (1) knowledge--the individual knows what the skills are; (2) performance--the individual provides evidence that he/she can perform the skills; (3) generalization--the individual can apply the skills to a new situation; and (4) maintenance--the individual retains the skills after the treatment is discontinued. Whereas the individual treatment focuses on development of knowledge and an ability to perform the skill with the counselor, the group treatment provides the opportunity to generalize the learning to a new context.

Groups make it possible to learn vicariously. One of the most powerful opportunities afforded by the group is not the learning that occurs from counselor to participant, but the learning that occurs from participant to participant. An ability to see oneself in the experience of others fosters vicarious learning.

Groups provide the opportunity to receive and offer trust and support from peers. A well running group, characterized by an atmosphere of safety, acceptance, support, and positive feedback, makes it possible to experience the benefits of being more trustful and of helping others. Such an experience can challenge intrapersonal beliefs of helplessness and hopelessness, challenge interpersonal beliefs of cynicism and distrust, and build self-esteem, self-worth and self-efficacy.

1.6 CRITICAL COMMON ELEMENTS

The most important elements of treatment that are common across all parts of the intervention are the following.

1. The format of individual sessions should be consistent regardless of the particular part of the intervention one is in. The similarity in format makes sessions predictable for participants. This general format is:

   a) Setting the agenda;

   b) Introduction, including such things as engaging in a supportive interactions, checking mood, review of the events of the week, reactions to last session, and/or relaxation practice;

   c) Review of homework;

   d) Presentation of new material;

   e) Assignment of new homework;

   f) Summarization of the session;

   g) Feedback about the session.
2. The therapeutic alliance is critical across all parts of the intervention. In individual counseling, this alliance is between the counselor and the participant and it is the counselor’s job to foster an atmosphere of intimacy and trust. For the individual social support intervention, this alliance is so critical that it has been elevated to one of the key treatment goals. The concomitant in group therapy is the creation of a cohesive group characterized by interpersonal trust. Group discussions will be difficult until the group coalesces. With the development of trust and a highly cohesive group, core cognitive structures can be identified and systematically changed.

3. The principles taught in individual and group counseling must be clearly connected. These principles include cognitive restructuring, communication skills training, problem-solving, network development, coping with negative affect, and relapse prevention. It is the counselor’s responsibility to continually demonstrate the connection between learning in the group and that accomplished individually.

4. The counselor must always remain flexible and open to critical learning opportunities. Participants will bring to the session powerful experiences and their struggles to deal with them. The personal and powerful nature of these experiences can be associated with important insights, if given time and attention at the moment they arise. To do so may require that the counselor “switch gears” away from a planned topic. This is a particular problem in group therapy where there is a sequential set of topics to present. The counselor must exercise judgment to be able to respond to these moments while at the same time sticking to the protocol.

5. Common assessment tools between individual and group treatment will make the overall treatment more understandable to the participant. The key common tool is The Daily Log. This Log can be used to assess thoughts, feelings, situations, outcomes, and behaviors, or any combination of these, depending upon the work to be accomplished at any particular session. It is generalizable across the two individual interventions and across the individual and group interventions.