7. ENHANCING RETENTION AND CONVERSION OF RELUCTANCE

7.1 DEFINITIONS

The following definitions should be used when discussing participation level in ENRICHD participants who are randomized to receive counseling.

1. Reluctant Participants: Those who:
   - repeatedly cancel appointments;
   - repeatedly do not show up for appointments;
   - repeatedly indicate that now is “not a good time”;
   - screen calls and do not respond to messages.

2. Hard Refusals: Those who state, in no uncertain terms, that they DO NOT WANT to participate in the study and DO NOT WANT any further contacts with anyone associated with the project.

3. Integrated Participants: Those who faithfully follow through and attend appointments or, if they cancel, follow through and attend the next appointment. Integrated is defined only in terms of contact; not in terms of success with goals of treatment.

7.2 REASONS FOR PARTICIPATION

There are possibly four main reasons why the participant originally agreed to participate in the trial:

1. He/She perceived possible benefits from treatment and wanted to feel less depressed and more supported;

2. His/Her spouse, significant other, family, etc. wanted him/her to participate;

3. He/She agreed for reasons other than personal benefit, such as contributing to science, pleasing the recruiting RN, benefiting future patients, etc.;

4. He/She did not really understand what he/she was signing on to.

Reluctance may be due to the fact that the original reason is no longer compelling or valid. As such, an understanding of the reason for current reluctance can be aided by determining why the participant initially agreed to participate. The recruiting case coordinator is an excellent source of information about this and should be consulted very early. Moreover, it is a good idea to meet
family members and discuss the goals and requirements of participation before beginning treatment.

7.3 COMMON BARRIERS TO PARTICIPATION

It is useful to keep in mind that the participant’s stated reasons are not necessarily THE reason, i.e., the basis for which the participant does not intend to continue. Thus, “I don’t have the time” may be a cover for “I am embarrassed that I need this.” A convenient way to think about this is the following:

His/Her reason (the stated reason);

A reason (a reason that partly explains the participant’s reluctance, but is not the only reason);

THE reason(s) (the actual reason or reasons why the participant is refusing).

We must strive to understand THE reason in order to know how to intervene. Among the various reasons that could fall into any of these categories and thus serve as barriers to participation are the following.

1. Distrust of:

   -- research and researchers: may be selling something; may jeopardize insurance; Tuskeegee (in African Americans);

   -- strangers, projects they have never heard of before;

   -- doctors/health care providers, carried over from this, or previous, encounters with health care or mental health system

2. “Price” of treatment is greater than perceived benefits. Among the “prices” are:

   -- Competing obligations or interests (e.g., being “too busy”, going back to work);

   -- Embarrassment, emotional stress of counseling

3. Never participates in “things like this”

4. Friends, family, doctor advised against it, or are unsupportive

5. Lack of information; unwillingness of hear information

6. Dislike of counseling/therapy, anything “messing with head”
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7. Loss of faith that the counseling can do anything to help, despite the continued existence of depression, low social support

8. Do not see the need:
   --don’t believe that feelings have anything to do with the heart;
   --don’t experience any distress and thus have no keenly-felt goals;
   --avoidant coping style leads to suppression/denial of distress; participant does not feel comfortable talking about problems;
   --”rugged individualist” does not accept help from anyone;
   --denies occurrence of heart attack.
   --no longer feels depressed or unsupported and thus no longer needs help.

9. Logistical problems in getting to the treatment setting

10. Won’t tell you what the barriers are

11. Uncomfortable in groups

12. Co-morbidity:
   --psychiatric co-morbidity interferes with therapeutic engagement; borderline personality types find something wrong with whatever you say or do
   --physical comorbidities/symptoms result in feeling ill, preoccupation with physical problems, not up to participating in behavioral treatment

13. Did not understand:
   --that this was a trial
   --what was required of them

14. Does not want to be reminded of the MI and would rather focus on return to “normal”.

15. Counselor discomfort with the process of reluctance conversion.

7.4 CONCEPTUALIZATION

The following conceptualization guides the suggested approaches to converting reluctant participants.
1. Reluctance is conceptualized in ENRICHD as a set of attitudes and behaviors that lead the participant to draw away from involvement in the trial. Reluctance is influenced by multiple factors including, for example, participant attitudes/behaviors, counselor attitudes/behaviors, an inability to establish the therapeutic alliance, and environmental/logistical problems.

2. Reluctance conversion is conceptualized as efforts to increase participant involvement in the trial by:

   --identifying and addressing participant attitudes/behaviors associated with reluctance;

   --identifying and addressing counselor attitudes/behaviors associated with difficulties in converting reluctance;

   --extending time spent in the cultivation of the therapeutic alliance;

   --identifying and solving environmental/logistical barriers to receipt of treatment.

7.5 BASIC APPROACHES TO RELUCTANCE CONVERSION

Here are some strategies to try. This is a fluid situation and the best approach is based upon the counselor’s judgment of efficacy, given the unique characteristics of the participant and the situation.

7.5.1 Foster A Relationship (Barrier: Distrust)

a. Engage in supportive, non-directive contacts characterized by unconditional positive regard for the participant. Listen, reflect feeling, reflect content, make eye contact (if possible). Note: eye contact may not be desirable in some cultures, such as the Asian cultures. Be sure to use cultural sensitivity.

b. Try to find a commonality in experience

c. Maximize chance to have a face-to-face contact

d. Meet them on their own terms. Go with their agenda; not your own. Try to understand their concerns FROM THEIR PERSPECTIVE. Practice the listening skills we are using to teach patients to garner more social support (see 1a.). Keep quiet until they finish, use body language that conveys your interest in what they have to say, reflect back what you’ve heard (to be sure you’ve got it right), and, BE PREPARED TO BE CHANGED BY WHAT YOU HEAR.

e. Use time as a friend; not as an enemy. Be patient and use it to your advantage

f. Keep the door open at the end of any contact (e.g., “Would it be O.K. if I checked in on you in 1-2 weeks?” “Could I send you some literature about this program?”)
g. Use flexibility in ways to approach participant. Vary time of contact, type of contact, counselor who does the contact, reason for contact, etc.

Note: Be sensitive to the number of people with whom the participant interacts with. Too many individuals can be dysfunctional.

h. Work toward name recognition in the community, via news media, talk shows, etc.

i. Look for the “buying” question, e.g., “How long will this take?”

j. Do not make a follow-up contact too soon. Going back too soon will result in a closed door.

7.5.2 Provide Information (Barrier: Information)

a. Provide information in very small, understandable pieces

b. Explain confidentiality, what is going to be done with private information

c. Take advantage of opportunities to educate about mind-body connections, e.g., “When you feel sad (lonely, angry) like this, it is bad for your heart”

7.5.3 Obtain Support (Barrier: Others advised against it or are unsupportive; Counselor discomfort)

a. Involve family/friends/doctor. While a discussion with family members may be helpful, such a decision must be made carefully, with consideration of confidentiality and how the participant might react to such a contact. Foster good relationships with family and significant others by taking a moment to chat with them before or after appointments, when they answer the telephone, etc. If you do not have a relationship with the family, or if your are concerned about confidentiality issues, offending the participant, etc., consider asking the recruiting RN to talk to them.

b. Use the problem-solving module to problem-solve with other counselors, case managers, or other staff on how to approach the participant

c. Guard against low counselor morale by obtaining emotional support from fellow counselors, other staff members, PI, other co-investigators. Be sure to plan “morale boosting” activities such as lunches, happy hours, etc.

7.5.4 De-Pathologize Treatment (Barrier: Dislike of therapy; avoidant coping; not wanting to be reminded of the MI)

a. Focus on recovery; not on feelings. Ask open questions about risk factors, visits to the MD, symptoms, etc.
b. Present the trial in a way that is something like this:

“We are not seeing you in this study because there’s something WRONG with you, but because we believe that anyone who has had a heart attack can benefit from training that will help you deal with negative emotions and build stronger, more supportive relationships. It’s the same principle that leads us to suggest physical exercise and good diet. We know it helps build up your body, heart, and blood vessel’s ability to function more healthily. In the same way, we are trying to build up your mental/emotional abilities to handle stress better. By providing you with this mental/emotional TRAINING, we believe it will also help to build up your body, heart, and blood vessel’s ability to function more healthily and help you to recover better.”

c. Focus on other areas of the participant’s life that are not related to the MI to avoid reminding him/her of the event.

7.5.5 Empathizing (Paradoxical Intention). (Barrier: Don’t see the need)

Give the participant space to disagree. Say something like, “This trial is very demanding and takes a lot of time. You really have to be ready to participate in it. Some people know that they are just not ready at this time to make that type of commitment right now. I am really glad that you shared the fact that you are not ready right now to take part. If at some time in the future, you find that you get to the point where you are ready to participate, you can let us know by contacting us at . . . . I will probably check in with you after a little while to see how you are doing. Once again, thanks for letting us know that you are just not ready to participate right now.”

Then call them back, as soon as you believe it is most opportune, to see where things stand. If their status is unchanged, repeat the statement above. Caveat: Be careful using this strategy. For effectiveness, the counselor must believe that the participant really does want to get involved.

7.5.6 The Direct Approach (Barrier: Never participates in “things like this”; Won’t tell you what the barriers are)

A direct approach can be a fresh, helpful one in some cases, and can encourage the participant to be direct with you. For example, “You were so interested in being in this trial initially, but I sense a reluctance now. What accounts for that?” or “I sense that it is hard for you to do the things we are asking of you. What would make it easier or doable?”

7.5.7 Recall Original Motivation To Participate (Barrier: Don’t see the need)

The participant was “sold” on the idea initially, and it may be possible to do so again by reminding him/her what he/she expected to gain.
a. If the participant believes he/she is no longer depressed or unsupported, and therefore no longer in need of treatment, discuss relapse and emphasize the value of “overlearning” as a way to inoculate oneself against possible harmful effects of future stressful events on the heart.

b. If the participant no longer receives encouragement from the family, discuss with family members the participant’s plan to drop out. Restate the goals and benefits of participation and encourage them to discuss this with the participant. If you are reluctant to contact family members because of confidentiality concerns, consider asking the recruiting RN to call them. Suggest a meeting with key family members and the participant to discuss the planned drop out.

c. If the participant originally decided to participate for altruistic reasons, but now no longer finds these reasons compelling in light of the perceived costs, explain the importance of the trial and how the dropout hurts the ability of the trial to achieve it’s goals. Explain that a dropout is a potential “waste” of his/her, and others’, tax dollars. Appeal to the participant’s ethical, moral, religious, humanitarian side. Remind him/her that he/she made a commitment to participate and encourage him/her to follow through.

7.5.8 Alter Counselor Attitudes and Feelings (Barrier: Counselor Discomfort)

a. Leave participant reluctance at THEIR door. Each new contact should be approached with a fresh, optimistic outlook.

b. It is unpredictable when a participant may convert. Conversion is a function of the number of reluctant participants contacted. Thus, success at reluctance conversion goes hand and hand with making many contacts with those who do not convert.

c. A basic principle in reluctance conversion is “You will spend the majority of your time on the minority who are reluctant.” This investment is time well spent if you are successful in converting even a small percentage of this minority

7.5.9 When To Quit

In a clinical trial, intention-to-treat analysis is the standard approach to determination of treatment effects on the primary outcome. Regardless of whether counseling was delivered or not, outcomes for an intervention participant will be analyzed as if they had actually received treatment. Thus, the study is penalized whenever a counselor “gives up” on a participant.

Here are some guidelines for when to quit attempting to convert a reluctant participant.

a. Quit when you receive a hard refusal, e.g., “I do NOT want to hear from you again.

   Please do not call, send any information, or attempt to see me again.”
Instinctively, you will know when you have received a hard refusal. Hard refusals are uncommon.

b. When 6 months from time of randomization have elapsed.

c. In situations where the participant shows by his/her behaviors that he/she does not want to participate, but is unwilling/unable to give a hard refusal, keep trying the strategies above, at intervals that are negotiated with the participant. Conversion of reluctance is frequently unpredictable and related to circumstances in the participant’s own life of which the counselor is unaware (e.g., new stressors; having a good day; downturn in his/her physical condition, etc.).