

5. Multi-site Research Design and Study Procedures

This section summarizes the logistical and implementation concerns addressed by the Logistics Subcommittee. For a more complete discussion of the issues and concerns leading up to the final decisions made by the Steering Committee, please refer to Steering Committee teleconference minutes and face-to-face notes. This section draws heavily from the work of Sally Rogers, Chair of the Logistics Subcommittee and Joseph Sonnefeld, co-chair of the Logistics Subcommittee.

5.1 Target Conditions

Study participants are defined as persons age 18 and over who currently or at any time over the past year have had a diagnosable mental, behavioral, or emotional disorder of sufficient duration to meet diagnostic criteria specified within the DSM-IV that has resulted in functional impairment which substantially interferes with or limits one or more major life activities.

5.2 Recruitment Materials and Procedures

All recruitment materials and procedures should be developed with caution so as not to alert potential participants to the hypotheses under study. Potential participants must be fully informed about the study, its risks and benefits and the intent of the data collection. But it is important not to alert them to the specific hypotheses under study in any written materials, group presentations, screening meetings, or subsequent contact. Doing so could create demand characteristics that subtly suggest to the participants

that they answer the questions in the CP in a particular way. It is also very important that there not be an imbalance between the experimental condition (COS + TMHS) and the control condition (TMHS only) in terms of this information or these demand characteristics. For example, we would not want one group to be singled out and have high expectations for the gain communicated to them.

5.3 Exclusion and Inclusion Criteria

5.3.1 Exclusion Criteria: Involvement in Consumer Operated Services (COS)

More than minimal involvement in the past 6 months in a COS similar to the ones under study (i.e., drop-in centers, education and advocacy programs and peer support programs) results in exclusion from the study. “Minimal involvement” is defined as more than three visits/meetings at COSP like those under study. In order to qualify as a COS, the program has to meet the definition of COSP using the first three common ingredients structural criteria (see Appendix B).

There was some discussion of whether involvement in “COSP-like” programs would make the person ineligible for participation in the study, and decided that only programs that meet the criteria set forth by the Common Ingredients Committee would be considered COS programs.

5.3.2 Inclusion Criteria: Involvement in Traditional Mental Health Services

To be included in the study, the GFA states a potential participant must be a recipient of

traditional mental health services for at least one year. The individual does not need to be a recipient of services with the same TMHS provider, but must have been on a TMHS roster during that period. *The traditional mental health services involvement must meet three core criteria: recency, longevity, and intensity.*

Recency of Involvement: An individual coming into the study would have to have had received services within the past 4 months prior to the date of “application” to the study;

Longevity: An individual coming into the study would have had to be involved with a TMHS provider for a full 12 months prior to the date of application to the study;

Frequency: An individual coming into the study would have to have received services at least 4 times in the past year, for example, 4 visits with a case manager, 4 visits for medication checks, etc..

5.3.3 Diagnosis

Participants in this study must meet the diagnostic criteria in the GFA which states that individuals must have a serious mental illness. The participant must have a DSM-IV Axis I diagnosis of serious mental illness. Co-occurring substance abuse disorders are acceptable for entrance as long as the person has a mental health diagnosis in addition to their substance abuse diagnosis. Severe mental illness is usually defined as meeting three criteria: diagnosis, duration, and disability. Certain DSM-IV diagnoses are usually associated with severe disability: schizophrenia, schizo-affective disorders, any diagnosis with

psychotic features, major depression, and some personality disorders. In addition, duration is usually a factor in determining disability, with two years being the commonly accepted cutoff. Finally, functional impairment (disability) as a result of the diagnosis is needed. Criteria two and three (duration and disability) are difficult to ascertain when simply screening for entry. Therefore, we must rely on diagnosis for inclusion.

Diagnosis will generally be ascertained after enrollment in the study, utilizing records from the participating traditional mental health services sites.

Sites may impose additional inclusion and exclusion criteria as long as they do not conflict with these basic criteria.

5.4 Consumer Assessments

5.4.1 Screening

It was determined that sites will sample/recruit consumers receiving services at TMHS provider who express sufficient interest in motivation for project and who go through a common induction procedure including explanation of what a COSP is. There were efforts to develop a common screening questionnaire that would implement the inclusion and exclusion criteria (See Exhibit 5-1).

Although there was considerable discussion of the merits of attempting maximize generalizability by

attempting to enroll a representative sample of consumers receiving services in each of the sites, it was eventually agreed that enrolling substantial numbers of study participants who were unlikely to utilize COS programs or who would participate only minimally would degrade the power of the study, undermining the ability of the study to demonstrate the effectiveness of COS programs. It was recognized that, prior to the COSP multi-site initiative, the 8 participating COSPs differed in significant ways that were related to the means that they employ to recruit participants, the characteristics of the individuals the COSPs targeted, and the services and programs they provided. For example, the application process to get into AU in Connecticut is a distinctive part of AU. Similarly, the restriction of Friends Connection in Pennsylvania to persons with both psychiatric and substance abuse concerns is a fundamental part of both recruitment and program design, which focuses on persons with dual diagnoses. Although reducing cross-site variability in participant characteristics would allow greater confidence in pooling data within clusters and possibly across all COSPs, it was recognized that imposing uniform screening requirements for participant characteristics would run the risk of fundamentally change programs that may have developed in delicate balance.

Screening for Exclusion and Inclusion Criteria

Exhibit 5-1 contains a copy of a Screening Questionnaire that can be used by sites to insure that they are screening in and screening out people who might not be eligible for the study based on the criteria in the GFA. Use of this Screening Questionnaire is not mandatory, however, each site must have a way of tracking the screening criteria on the last page of the Questionnaire for reporting to the CC.

Exhibit 5-1: Draft Screening Questionnaire

DRAFT SCREENING QUESTIONNAIRE

Person completing form: _____

Applicant Name: _____

___/___/___ Date Form Completed

INSTRUCTIONS TO PERSON COMPLETING FORM: This form is designed to be completed using information from the applicant directly, using information from available records, your general knowledge about the applicant's circumstances, or any combination of these sources. By "applicant" we mean an individual who has expressed interest in participating in the COSP study. The purpose of this form is to determine if the individual meets the requirements for coming into the study. If there are any questions about the applicant's eligibility, please contact: _____.

1. *Is the applicant over the age of 18?* ___Yes ___No

2. *Is the applicant already a participant of the study, or has he/she applied to the study in the past?*

___Yes ___No

If yes, please explain: _____

3. *Is there a compelling reason to believe that the applicant cannot give informed consent?*

___Yes ___No

4. *Is there a compelling reason to believe that the applicant cannot give reliable or valid responses to questions on the CP?*

___Yes ___No

5. *Does this person's current diagnosis meet the inclusion criteria for the study (i.e., the applicant has a diagnosis of major mental illness)?*

___Yes ___No

If yes, what is the applicant's diagnosis: _____

Does the applicant meet the TMHS inclusion criteria:

6a. Does he/she currently receive mental health services such as case management, residential services, or help with medications?

___Yes ___No

6b. Write in the applicant's mental health provider (or providers if there is more than one provider)?

6c. How many times in the past year (one year from today) has the applicant received services from this mental health provider(s) (that is, how many times have they had a visit with a case manager, or any mental health provider. If applicant lives in a residential program that is run by a mental health provider, check that option)?

- 1) Not at all
- 2) 1-3 times
- 3) 4 times or more
- 4) Applicant lives in a residential program that is run by a mental health provider
- 5) Information not available or applicant does not know

6d. Estimate how long ago applicant's last contact was with someone from the mental health provider/program?

- 1) No contact
- 2) more than 4 months from today
- 3) less than 4 months ago
- 4) Applicant lives in a residential program run by a mental health provider or goes to day treatment and has contact almost every day
- 5) Information not available or applicant does not know

6e. How long has applicant been involved with this program (or any other mental health provider)?

- 1) Never involved
- 2) for the past 1-6 months from today
- 3) for the past 6-11 months from today
- 4) for more than the past year
- 5) Information not available or applicant does not know

Does the applicant meet the COSP inclusion criteria?

7a. Has the applicant participated in a COSP program (that is a peer support program, a drop in center, or an education and advocacy program that is run by consumers and meets other CI structural criteria) in the past 6 months?

Yes No

If yes, please record the name of the program(s): _____

7b. If yes, how many times in the past 6 months has the applicant participated in/visited this program?

- 1) Not at all
- 2) 1-3 times
- 3) 4 times or more
- 4) Information not available or applicant does not know

Summary of Inclusion/Exclusion Criteria:

1. Applicant is at least 18 years of age? ___Yes ___No

2. Individual is currently enrolled in the study/or has been in study ___Yes ___No

3. Is there a compelling reason to believe that the individual cannot give informed consent?
 ___Yes ___No

4. Is there a compelling reason to believe that the individual cannot participate in the research interviews?
 ___Yes ___No

5. Individual has a diagnosis of major mental illness? ___Yes ___No

6. Individual meets TMHS criteria for inclusion? ___Yes ___No
(Individual has been involved with a Traditional Mental Health service provider in the past 12 months and demonstrates recency, longevity and intensity of involvement-that is has had at least 4 services in the past 12 months with any traditional mental health provider; the most recent contact had to be 4 months ago or less)

7. Individual meets COSP criteria for exclusion? ___Yes ___No
(Individual has had more than minimal involvement in a COSP program, that is, he or she has had more than 3 visits/meetings in the past 6 months)

A Yes to Questions 1, 5, and 6 and a no to Question 2, 3, 4, 3 and 7 are necessary for the applicant to be enrolled in the study.

Was the individual enrolled in the study? ___Yes ___No

Screening Form Reviewed by Research Staff Person: _____ Date: ___/___/___

5.4.2 Assessments

A baseline Common Protocol was developed over the course of the first year of the project. This development process is fully described in Section 8 and the Common Protocol is provided in the Appendix. In addition, sites planned to administer a variety of additional instruments.

It was agreed that there would be a translation of common protocol into Spanish only. It was further agreed that all data collection would take place in face-to-face interviews rather than paper-and-pencil administration, because of concerns about literacy. Several sites were planning to use laptop CAPI versions of the common protocol.

5.4.3 Timing of Consumer Assessments

It was agreed that the Common Protocol would be administered at baseline (just before or at approximately the same time as assignment to condition) and at 4, 8, and 12 months post-baseline. The 12-month assessment was regarded as being highly recommended, but two sites anticipated problems and continued to explore options for funding and logistical adjustments that would permit them to include the 12-month follow-up within the grant period.

The SC agreed that an acceptable “window” around assessments would be one month. Follow-up interviews not completed within the window would be classified as lost to follow-up for the purposes of cross-site analysis.

5.5 Placement of Site-specific Measures

The logistics committee recommended that the common Protocol be kept intact insofar as possible. It was agreed that isolated site-specific items might be placed in a site-specific protocol if they would be out of place at the end. It was agreed, however, that all site-specific additional instruments or blocks of questions from existing instruments would be placed at the end of the common-protocol assessment.

5.6 Common Induction and Sampling Procedures

The sampling procedure we agreed upon involves sampling/recruitment of consumers who are receiving services at a TMHS provider who express sufficient interest in motivation for project and who go through a common induction procedure.

The common induction process will fully inform prospective study participants about randomization and what is expected of them.

The essential elements of the common induction procedure include the following:

- ◆ Informing potential participants that this study is part of a multisite SAMHSA study
- ◆ Informing individuals that the basic purpose of the study is to study the effectiveness of consumer operated programs when compared to traditional mental health services alone
- ◆ Informing people that they have a 50-50 chance of being randomized to the COS + TMHS group or

the TMHS alone group, and the importance to the study of this randomization

- ◆ Informing people that if they are randomized to the TMHS group and go to services at a COS, they are essentially dropping out of the study.

A common induction process also requires that:

- ◆ Randomization occur after or coincident with baseline
- ◆ Sites overlay any further induction process on top of the common process; and that
- ◆ Each site that does overlay such a process must spell this out in detail.

It was decided that this common process would not in general be part of the informed consent, but would occur before it and separately so that sites would not have to revise their previously developed informed consent procedures.

5.7 Informed Consent and Confidentiality Certificate

It was agreed that each site will develop its own informed consent and that draft Informed Consent materials shared with other sites.

Confidentiality Certificate: Every site is expected to apply for a Confidentiality Certificate from SAMHSA.

The Certificate provides some protection for participants in research studies to help keep the information they provide confidential and prevent it from being summoned by a court of law if the research participant is involved

in a criminal justice proceeding. Each site must apply for the Confidentiality Certificate when their local IRB's have signed off on the project and on the Informed Consent. Please note that there is specific language that is required in an Informed Consent to obtain a Confidentiality Certificate.

5.8 Randomization Procedures

Randomization to the experimental (COS + TMHS) and control (TMHS only) will occur after the baseline CP is administered or co-incident with it. Co-incident means randomization will occur within one working day.

A multi-site randomization process was not agreed upon, however sites will block on gender and will generate their own randomization schedules based on gender. Sites are free to add blocking variables to the randomization process as long as they document their randomization procedures for the CC. Sites should carefully guard against any attempts to influence the random assignment of participants by having the PI closely monitor the random assignment process, by taking the random assignment out of the hands of the interviewers, and by developing procedures that are “game-proof”.

Any site needing technical assistance to carry out their randomization procedures should contact ROW Sciences. Any site needing a randomization schedule can contact Sally Rogers at Boston University.

Individual sites posed several different approaches to random assignment and for some sites, the actual mechanics of the random assignment was at first unclear (how they would form the pool for RA, whether they had planned to flip a coin or use a random number generator, etc.). There was some discussion of whether we

it was necessary or desirable to move to uniformity on the random assignment process--perhaps adopting a single centralized randomization procedure that would provide all assignments via an 800 number operated 24-hours a day--or allow sites to proceed as they had originally planned. Issues related to how well random assignment can work in small waves (which several sites will have) and whether any blocking should occur so that the random assignment is more likely to result in balanced groups on certain key variables, were discussed.

It was agreed that no site would conduct random assignment with a coin flip, and that all reasonable efforts would be made to remove any pressure on interviewers over the assignment by having assignments made centrally at each site. It was agreed that all sites would block by gender and some sites planned to use additional blocking factors including race.

5.9 Intention-to-Serve Analysis

The overall study approach agreed upon was an “intention-to-serve” design where all individuals enrolled in the study will be tracked regardless of the amount of each condition they receive. This approach has power implications (i.e., the more individuals who are randomized to the COS condition that don’t participate in it, the less likely we will see a difference between the COS + TMHS and the TMHS group alone).

Therefore, it is important that each site emphasize strategies to maximize the retention of study participants in the respective conditions. Secondly, whatever each site can do within ethical constraints to keep crossover to a minimum will help preserve the power of the study. If individuals refuse to participate in a scheduled follow-up

interview, the interviewer must assess whether the individual simply does not want to participate on that day, or is refusing participation for the duration of the study. The interviewer should make several attempts (being sensitive to the individual's wishes and rights as a research participant) to complete a follow-up interview, unless the individual emphatically refuses.

“Administrative withdrawals” are individuals who cannot participate in the study condition to which they are assigned (e.g., they are arrested shortly after random assignment and would not be able to receive either COS or the TMHS service). For these individuals we can do early replacement of them in the study, meaning we can treat them as though they were never in the study and randomly assign someone else to take their place. We cannot do any other kind of replacement of participants since we are using an “intention to serve” approach. Some sites may over-sample to insure they have sufficient power, but they will still track every person entered into the study.

If individuals want to re-enter the study after an administrative withdrawal they will not be allowed to. If an individual withdraws from the service component, they will still be a research participant. If a participant wants to withdraw from the research *and* the services, he or she can do that and request that their data be destroyed. In that case, locally held data should be destroyed and Matthew Hile should be instructed to delete data from the repository.

Any withdrawal or re-entry scenario that does not fit the above description should be posted to the Logistics Subcommittee listserv for comment and final decision making so that we can keep a log and a protocol for these unusual situations.

5.10 Mode of Data Collection

All interviews be conducted in a face-to-face mode rather than self-administered because of concerns about literacy. Either paper-and-pencil CP instruments provided by the CC can be used, or computer-assisted interviewing can be performed. Tom Summerfelt, PI of the TN site has the Access program for the computer-assisted interviewing. Using computer-assisted interviewing conserves resources for data entry, but special steps need to be taken to preserve and back up the data and to verify the data entry. Contact Joe Sonnefeld of ROW for procedures for data verification with the computer assisted interviewing, and Matthew Hile at the CC at MIMH for the data verification protocol for regular data entry.

5.11 Tracking of Participants

The tracking of study applicants needs to occur to provide the information that will be requested by the CC each quarter. Tom Summerfelt, PI of the TN site has an Access database and screen program that will track these data elements and generate the reports needed to CMHS. This tracking software can also be used as a tickler system to help plan and manage the interviews. Managing the interviews is critical for having complete datasets.

Each site is strongly encouraged to contact Tom to preview this software and to consider using it for reporting to the CC. Rise Goldstein at ROW is the contact person for questions pertaining to tracking.

We will not track any demographic items on potential participants because they will not have given their permission at that point. It was generally agreed that people who refuse to participate in the study not be asked “why” they refuse. They might be asked if they are willing to share why they refused, and then if the information is volunteered, it can be used to help improve future recruitment. Sites can keep track of that information if they choose, but it is not mandatory.