INFORMATION SHEET

Reconnecting for Recovery: A Relational/Motivational Multifamily Therapy Group for Young Adults with Anorexia Nervosa

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This form describes a research study that is being conducted by Mary Tantillo PhD PMHCNS-BC FAED at the University of Rochester School of Nursing (URSON). The purpose of this study is to pilot and evaluate the effectiveness of a new Multifamily Therapy Group (MFTG) treatment for young adults with Anorexia Nervosa. Study participants will be asked to participate in the MFTG treatment, evaluate the effectiveness of the group format, and provide recommendations for any additional improvements in the group format.

If you decide to take part in this study, you will be asked to identify at least one (but can include up to four) adult family member(s) (≥ 18 years old) who are emotionally invested in your recovery and who would agree to participate in all MFTG sessions with you. Your identified family members can include your family of origin (e.g., mother, father, siblings) or your “family of choice” (e.g., partners, close friends, coaches, clergy, etc.). We estimate that approximately 10 young adults (ages 18-40) and their identified family members (up to four per young adult) will take part in this study. The study includes two Multifamily Therapy Groups. Each group will run simultaneously (16 sessions over 26 weeks) and contain five young adults and their families.

If you are found to be eligible for the study after completing a phone screening and initial interviews assessing your eating disorder symptoms and any other mental health conditions, you will also be asked to agree to medical follow-up during the study with study physician, Dr. Richard Kreipe. He will provide customary medical follow-up to you to monitor your medical condition. He will communicate to Dr. Tantillo and the Health Project Coordinator (HPC) any changes in your health status and/or concerns he has about your medical stability and ability to continue in the study treatment. Continued medical stability
is required for your continued participation. If you should require inpatient care any time during the study, Dr. Tantillo and Dr. Kreipe will help arrange this for you. Your consent will be needed to allow exchange of medical information between Dr. Kreipe, Dr. Tantillo, and the study’s HPC. The only medical information obtained from Dr. Kreipe that will be recorded in your research record by HPC, is your height, weight, and medication use. All other medical information will be verbally exchanged with regard to any changes in your health status that might affect your continued participation. Additionally, you will be asked to agree to pay for costs of customary medical care including but not limited to physical examinations, lab work, EKG as indicated, and medications received during the study. You will also be asked not to receive other eating disorder treatments during the duration of the study (i.e., including the 26 week group cycle and the time leading up to the 6 month group follow-up).

If you agree to participate in this study, as stated above, you will be asked to complete an interview (2 hours) at the URSON to assess your eating disorder symptoms (including obtaining your weight and height) and other mental health conditions. You also will be asked to complete 6 surveys (60 minutes) that include questions about your demographics (age, education, etc.) eating disorder symptoms, mood/emotions, and relationships. Your identified family members will also be scheduled for an interview with the HPC who will obtain their consent for study participation and ask them to complete demographic surveys. Additionally, you and your family members will be asked to complete a brief survey (5-10 minutes completion time) regarding the helpfulness of group sessions at the end of each group session. You will also be asked to participate in a one hour interview and complete the 5 of the 6 surveys again at the mid-point of the group, end of treatment (session 16), and 6 month follow-up group. The demographic survey will be completed again at the 6 month group follow-up.

If you agree to participate in this study, you and your family members will be asked for permission to videotape all MFTG sessions including the 6 month follow-up group. These videotapes will assist with data analysis because each session will be transcribed and analyzed. Seeing group member non-verbal and verbal responses contributes to a clearer picture of what is transpiring in the group sessions instead of relying on an audiotape and/or transcription alone.

Some of the survey questions in this study may be upsetting or make you feel uncomfortable. You also may feel uncomfortable during or after a MFTG session. You can skip any of the questions you do not want to answer on the surveys, and you have control over what you share during the MFTG sessions. You can obtain support from the MFTG therapist after the session if you or your family members feel uncomfortable. There are no expected benefits associated with this study other than participating in the development of a new model of treatment that may help future patients with AN and their families.
Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will not store any directly identifiable information about you with your survey responses. All of the information we collect will be stored in a secure manner and only study team members will have access to it. There are no other expected risks other than discomfort you may feel during a MFTG session.

You may withdraw at any time during the study and receive referral to an eating disorder therapist in the community or to an outpatient therapist at Strong Behavioral Health. Dr. Tantillo can contact the Western NY Comprehensive Care Center for Eating Disorders Care Manager and work together with her to make a referral.

The University of Rochester is receiving payment from Hilda and Preston Davis Foundation for conducting this research study. You will not be paid for participating in this study. However, you will receive four movie vouchers for your participation, two after the end of MFTG treatment (session 16) and two after the 6 month follow-up group. There will be no cost to you to participate in this study, other than the medical costs incurred during your medical follow-up with Dr. Kreipe during the duration of the study. You will be responsible for paying the costs of customary medical care with Dr. Kreipe including but not limited to physical examinations, lab work, EKG as indicated, and medications received during the study (throughout MFTG treatment and up to the time of the 6 month follow-up group).

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, study information will be stored in locked records maintained by Dr. Tantillo and the health project coordinator at the University of Rochester School of Nursing. Information outside of medical information received from Dr. Kreipe will be coded by number only. Participant data will be identified in the research data set with random sequential numbering. No names or medical record numbers will be recorded in any data collection. Persons involved in the study will be instructed on the nature of confidentiality and their responsibility to maintain it. All study materials including videotapes of interview assessments, MFTG sessions, end of treatment and 6 month follow-up focus groups will be stored in a locked cabinet in the locked offices of the PI or HPC. All videotapes, except videotape clippings for future training of therapists, will be destroyed at the end of the study. Only the HPC and PI will have access to the list linking code numbers and participant contact information. The study team members and data entry staff at the URSON, Center for Research and Evidence-Based Practice will have access to study measures and the study team members and transcriptionist will have access to the videotapes. The participants will be asked to only use their first names when introducing themselves and all participants will be asked to keep information discussed in MFTG confidential.
Quantitative data will be reported in aggregate form. Qualitative data will identify themes and if any individual data is reported, e.g., data analysis regarding a particular member’s (ss) responses, this will be de-identified in reporting the narrative findings. Any storage of electronic files will comply with University IT policies and be adequately encrypted.

Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

In order to collect study information, we have to get your permission to use and give out your personal health information. We will use your research record, screening logs, case report forms, the weight/height and medications provided by Dr. Kreipe, survey forms, MFTG videotapes and transcripts, to conduct this study.

Your permission to use your health information for this study will expire at the end of this study (after the 6 month follow-up group). All videotapes, except videotape clippings for future training of therapists, will be destroyed at the end of the study.

**Your participation in this study is completely voluntary.** You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are otherwise entitled.

For more information or questions about this research you may call Dr. Mary Tantillo at 585-703-3403. Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.