Cover Page
Official Title: Evaluation of the Communities of Healing Mentorship/Support Group Program: Assessment of Preliminary Efficacy
NCT number: NCT03317379
Document date: 5/22/2018

Protocol Title:
Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Version Date:
05/22/2018

Protocol Number:
7533

Clinic:
Eating Disorders Clinic

First Approval:
08/29/2017

Expiration Date:
08/20/2018

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Faculty Sponsor:
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Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am proposing an amendment only to an existing protocol

Division & Personnel

Division

What Division/Department does the PI belong to?
Clinical Therapeutics/Psychiatry
Within the division/department, what Center or group are you affiliated with, if any?
Center for Eating Disorders

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

none

Amendment

Describe the change(s) being made

We are requesting three different amendments to our study protocol.

1. The first one regards studying mentors. We would like to consent the mentors matched with a mentee in order to use their data collected as part of the process of becoming a mentor (e.g., interviewing and training). This data assesses general demographic information and, for mentors with a history of an eating disorder, some information about their diagnosis and illness.

2. The second amendment consists of adding an acceptability form to our assessments questionnaires. This form would be completed by mentees at the end of the mentorship intervention (after six months, or sooner if they discontinue their participation prematurely).

3. The third amendment regards modifying the consent form to include information related to the bi-weekly supervision calls our team provides to mentors. We also indicate that if we or their mentor is worried about the mentee's safety, we would be in communication with each other and with the mentee to ensure their safety and help address any pertinent issues.
Provide the rationale for the change(s)
1. The first change would allow us to better understand whether these factors influence the outcomes (e.g., is having the same diagnosis in mentor and mentee important to the success of the peer-mentorship intervention?).

2. The study acceptability questionnaire would be useful to better understand mentees' experience of the study, what they found helpful and what they liked or disliked about the intervention, and how this might influence outcomes.

3. The third change is already in place and the information is already transmitted verbally to participants, but we would like to add it to the consent form for clarity.
Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects

1. There is a risk of unintentional disclosure of confidential information. This is outlined in the consent form and will be reviewed with mentors prior to mentors deciding whether to participate.
2. The proposed changes will not alter or affect the risks/benefits to the subjects.
3. The proposed changes will not alter or affect the risks/benefits to the subjects.

Comment on if the proposed change(s) require a modification to the Consent Form (CF)

1. We added a consent form for mentors

We would like to amend the consent forms to include the language:"Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider)."

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research

✓ Children (ages 13-17)
✓ Adults

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
No
Who is the PI of the grant/contract?
Ranzenhofer, Lisa
Select one of the following
The grant/contract is in preparation
Source of Funding
Foundation
Sponsor
Project HEAL
Select one of the following
Multicenter(NYSPI is not a participating site)
Business Office

RFMH
Does the grant/contract involve a subcontract?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
This protocol describes research conducted by the PI at other facilities/locations
Yes
✓ Community Sources

Community Sources

Type in location(s)

Project Heal has community sites (aka "chapters") in 40 cities across the US including New York, Philadelphia, Los Angeles, San Francisco, Boston, Chicago, and Pittsburg. Interested participants who do not live in the vicinity of an existing Project HEAL site are offered available online peer mentors with whom they may communicate via FaceTime or Skype.

In order to engage in the peer-based interventions, mentor/mentee pairs across various locations in the US will meet in public or semi-public locations, including those on college campuses. Examples of possible meeting locations include libraries, coffee shops, parks, common spaces in residential settings (such as an apartment lobby or meeting room). Many mentor/mentee pairs are anticipated to be members of university communities and may utilize public spaces such as dormitory common areas, meeting rooms, university libraries, or study lounges. If a pair arrives to an arranged meeting location and it is crowded and/or does not appear private, mentors will be trained to say "We may want to meet in a more private space," and mentees will be queried whether they wish to move to an alternative location. Whenever possible, pairs will meet in private spaces.

All research assessments are completed using secure online applications, allowing participants to complete assessments from home or elsewhere.

Uploaded Protocol Summary Form

Upload Document

Select file to upload.
PSF 5.18.18.pdf

Lay Summary of Proposed Research

Lay Summary of Proposed Research
Eating disorders are serious mental illnesses associated with significant morbidity and high relapse rates. Patients are at especially high risk of relapse after leaving structured treatment (e.g., hospitalization). Adjunct interventions targeting patients' motivation and participation in treatment at these times may help more patients recover from eating disorders. Project HEAL is a non-profit organization whose mission is to reduce suffering caused by eating disorders. Project HEAL has developed a intervention in which patients with eating disorders are matched with peers who have previously recovered from an eating disorder, and mentors meet weekly with mentees to provide support, guidance, and serve as a model that recovery is possible. Project HEAL has asked the researchers at Columbia to help them evaluate the feasibility and effects of this intervention. Therefore, the purpose of the current study is to test whether peer-mentorship can help improve patients' eating disorder symptoms above and beyond their traditional treatment. The design of the study is a three-arm randomized controlled trial comparing peer mentorship to an active (social-support) and wait-list control conditions. Participants in the study will be randomized to one of the three conditions for six months. Wait-list participants will subsequently receive peer mentorship. Participants will complete assessments of their eating disorder symptoms at baseline, monthly throughout the course of the study, and one year after beginning the study. Outcomes will be compared between groups.

Description of Subject Population

Sample #1

Specify subject population
Individuals with a DSM-5 eating disorder
Number of completers required to accomplish study aims
80
Projected number of subjects who will be enrolled to obtain required number of completers
100
Age range of subject population
14 - 45

Sample #2

Specify subject population
Individuals serving as Project HEAL mentors
Number of completers required to accomplish study aims
80
Projected number of subjects who will be enrolled to obtain required number of completers
80
Age range of subject population

18 - 75

Gender, Racial and Ethnic Breakdown

Based on epidemiologic studies, AN occurs overwhelmingly more often in women than men (9:1 ratio). Therefore, we expect that our sample will be comprised of 90% female and 10% male. No participants will be excluded on the basis of ethnicity or race. The sample is expected to resemble the demographic composition of the population of patients with anorexia nervosa and bulimia (approx. 60% Caucasian, 20% African-American, 20% Hispanic).

Mentors: Mentors who have recovered from an eating disorder serving as peer mentors are expected to resemble the demographic composition of the population of patients who have eating disorders described above. Mentors who are Project HEAL volunteers who have not personally struggled with an eating disorder are expected to resemble the demographic composition of the general population of the cities they represent.

Description of subject population

Mentees: Participants will be adolescents and adults (ages 14 - 45) with a diagnosis of anorexia nervosa, bulimia nervosa or binge eating disorder who have recently been discharged from treatment at a higher level of care including inpatient/partial hospitalization, residential, or intensive outpatient program. All patients will be involved in outpatient treatment at an appropriate level of care (as documented by the patient's outpatient clinician).

Mentors: Mentors in the peer-mentorship group are adults who have recovered from an eating disorder, while mentors in the social support group are adults who never had an eating disorder. All mentors are individuals recruited and trained by Project Heal to do volunteer work within their organization.

Recruitment Procedures

Describe settings where recruitment will occur
Recruitment will occur using Project HEAL's online and social media platforms and at settings where patients have received treatment for an eating disorder at a higher level of care (hospitalization, partial hospitalization programs, residential, and intensive outpatient programs).
How and by whom will subjects be approached and/or recruited?
Participants who anticipate being discharged from a higher level of care will be provided with information about the study by a member of his/her treatment team. Participants will be provided with EDRU contact information if they are interested in learning more about the study.
How will the study be advertised/publicized?
The study will be advertised using Project HEAL's online and social media platforms including Facebook and web page. Various online platforms also contain information about a variety of additional programs offered by Project HEAL. If a potential participant contacts Project HEAL and expresses interest in the study, they will be asked to contact the EDRU to receive information and, if interested, undergo screening.

Do you have ads/recruitment material requiring review at this time?
No
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT03317379

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
No

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
Yes
Waiver of documentation of consent
Yes
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process

A trained, EDRU research assistant will screen and consent all participants (and, if participant is under 18, their parent/guardian) by telephone. They will first obtain participant's verbal consent to conduct the telephone screening. During the telephone screening, the EDRU research staff member (RA level or higher) will assess inclusion/exclusion criteria including presence of an eating disorder using a standardized measure (the EDA-5). RAs will review eligibility with an EDRU clinician (MD or PhD). Potential participants who are interested will be provided a copy of the consent form. After the participant has received copies, the RA will review the consent (and assent, if applicable) forms, including nature and purpose of study, procedures, potential risks/benefits, and confidentiality, with the participant (and parent/guardian, if applicable). Potential participants will be given an opportunity to ask questions and questions will be answered by the EDRU research staff member (RA level of higher). Participants will

indicate whether they wish to participate and consent will be documented by the EDRU RA. For participants who are 14 – 17 years old, parental consent and adolescent assent will be documented. We have requested a waiver for documentation of consent.

Describe Study Consent Procedures

As described above, potential participants and their parent(s) or legal guardian will hear the details of the screening process and study details described in one conversation.

1. For mentors, we propose to obtain consent by reviewing the consent form during a weekly supervision call with mentors (about 8 mentors participate on the call at one time). The PI will perform the consenting. Prior to this call, the PI will mention the study to mentors (during a *prior* weekly supervision call) and send them a copy of the consent form to view ahead of time. During the call, mentors will be instructed *not* to indicate whether they wish to participate, so that mentors do not feel social pressure to participate if they do not wish. Afterwards, the a trained research assistant or study level clinician will contact each mentor separately to review any questions that the mentor has and find out if the mentor wishes to participate. Verbal consent will be documented for each mentor who chooses to participate.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

Justification for Waiver or Alteration of Consent

Waiver of consent is requested for the following

We are requesting a waiver of consent to conduct telephone screenings.

We are requesting an alteration of consent to verbally review the consent with the participant by telephone and document verbal consent, rather than written consent.

Explain why your research can not be practicably carried out without the waiver or alteration
Contact and initial eligibility information is collected during the phone evaluation. Without access to this information, we would not be able to call a potential participant to arrange the next steps in study evaluation and participation.

Because participants will be located at multiple sites throughout the United States, it is impractical to have participants travel to NYSPI (or have the research team travel to all participant sites) to conduct consent procedures in person. Since having a participant sign and send a written copy of the consent by mail or email poses additional risk to breach of confidentiality, it would minimize risk to document verbal consent instead.

Describe whether and how subjects will be provided with additional pertinent information after participation
n/a

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?
No
Is breach of confidentiality the main study risk?
No
Is consent for this research procedure ordinarily not required outside of the research context? Explain
Participants in the Communities of HEALing support groups (outside of the research study) are not asked to sign a consent form in order to participate.

Assent Procedures

Describe procedures by which subject assent will be assessed and/or recorded
The study procedures will be explained by telephone in general and in age-appropriate terms to the adolescent and his/her parent by an EDRU staff member. The adolescent will have an opportunity to ask questions. The adolescent will understand that participation is voluntary, and if they do not wish to participate, they will not have to. The adolescent will be asked to provide verbal consent by telephone, which will be documented by the person conducting the telephone consent/assent.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Attia, Evelyn, MD
Davis, Haley
Korn, Rachel
Ranzenhofer, Lisa
Rufin, Teresa
Walsh, Emily
Wilhelmy, Mylene
Type in the name(s) not found in the above list
Hochschild, Annabella

Methods to Protect Confidentiality

Will the study be conducted under a certificate of confidentiality?
No

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
No

Uploads

Upload the entire grant application(s)
Upload copy(ies) of unbolded Consent Form(s)
Guardian_consent_Communities_of_HEALing_ 4.11.18 unbolded.pdf
Informed Consent for Participation in Research 4.6.18 unbolded.pdf
Informed Consent for Participation in Research MENTORS 5.3.18.pdf
Upload copy(ies) of bolded Consent Form(s)
Guardian_consent_Communities_of_HEALing_ 4.11.18 bold.pdf
Informed Consent for Participation in Research 4.6.18_Bold.pdf
Upload copy(ies) of unbolded Assent Form(s)
Informed Assent for Participation in Research 4.11.18 unbolded.pdf
Upload copy(ies) of bolded Assent Form(s)
Informed Assent for Participation in Research 4.11.18 bold.pdf
Upload copy(ies) of the HIPAA form
Upload any additional documents that may be related to this study
PSF most recent.pdf
Mentor baseline questionnaire.pdf

Uploaded Protocol Summary Form

Cover Page

Protocol Number: IRB number not yet assigned Draft date: **April 10, 2018**

Protocol Title: Evaluation of the Communities of Healing Mentorship/Support group Program: Assessment of preliminary efficacy

Principal Investigators: Lisa Ranzenhofer PhD

Email: lr2840@cumc.columbia.edu

Telephone: (646) 774-8065

Office: Cell Phone: (240) 671-9040

Lay Summary

This section is intended to provide a basic overview of the study including a description of its purpose, methods, and subject population. The summary should provide a concise overview of the study for non-scientific and scientific members of the IRB. Please avoid medical or technical terminology. In general, the abstract of a grant does not provide a suitable lay summary.

Eating disorders are serious mental illnesses associated with significant morbidity and high relapse rates. Patients are at especially high risk of relapse after leaving structured treatment (e.g., hospitalization). Adjunct interventions targeting patients' motivation and participation in treatment at these times may help more patients recover from eating disorders. Project HEAL is a non-profit organization whose mission is to reduce suffering caused by eating disorders. Project HEAL has developed a intervention in which patient mentees with eating disorders are matched with peer mentors who have previously recovered from an eating disorder, and mentors meet weekly with mentees to provide support, guidance, and serve as a model that recovery is possible. Project HEAL has asked the researchers at the EDRU to help them evaluate the feasibility and effects of this intervention. Therefore, the purpose of the current study is to test whether peer-mentorship can help improve patients' eating disorder symptoms above and beyond their traditional treatment. The design of the study is a three-arm randomized controlled trial comparing peer mentorship to active (social-support) and wait-list control conditions. Participants in the study will be randomized to one of the three conditions for six months. Wait-list participants will subsequently receive either type of mentorship. Participants will complete assessments of their eating disorder symptoms at baseline, monthly throughout the course of the study, and one year after beginning the study. Outcomes will be compared between groups. **We will also evaluate if mentor characteristics influence mentee outcomes.**

Please also paste of a copy of the Lay Summary into the PRISM PSF Form.

Background, Significance, and Rationale

In this section, provide a brief summary of the status quo of the relevant work field, and how the proposed study will advance knowledge. Specifically, identify the gaps in knowledge that your project is intended to fill. If no gaps exist that are obviously and directly related to your project, explain how your proposed research will contribute to the overall understanding of your field. Describe potential impacts of your project within your field of study and in a broader context. Provide a critical evaluation of existing knowledge. The literature review does not have to be exhaustive.

Anorexia nervosa and bulimia nervosa are serious mental illnesses associated with significant morbidity and high relapse rates. AN has the highest mortality rate of any psychiatric illness. Although family-based treatment has led to improved outcomes for adolescent patients, this therapeutic approach has only limited utility in adults. Research suggests that patients with EDs are at greatest risk for relapse in the first six month following discharge from an intensive treatment (e.g. hospitalization or residential). Adjunct, supportive approaches delivered at these high risk times have potential to

improve eating disorder relapse prevention. Adjunct interventions also have potential to promote treatment engagement (attendance, compliance with meal plan, etc.) in patients with high ambivalence.

Project Heal® is a non-profit organization whose primary missions are providing grant funding for individuals with eating disorders who otherwise cannot afford treatment and promoting eating disorder recovery through campaigns and community programming. Project Heal has community sites (aka "chapters") in 40 cities across the US and Canada. Project Heal recently launched a mentorship-based intervention at 12 of it's sites, in which eligible individuals with eating disorders who are receiving treatment from a licensed professional are partnered for six months with peer mentors (individuals who have previously recovered from an eating disorder and who have participated in a general orientation/training program regarding the role of mentor). "Sites" refer to locations across the US and internationally where one or more individuals has established a local Project HEAL chapter. Chapters/"sites" range in size from just a few people to over 50. The Project HEAL national organization has ongoing contact with its sites about many different topics, including the Communities of HEALing program. In the past year, 12 sites have established Communities of HEALing programs, meaning that trained mentors carry out peer mentorship and free community support groups with oversight from a National-level Program Director. As more and more sites established peer mentorship programs, Project HEAL asked us to help them evaluate this intervention.

Moving forward, Project HEAL will continue to communicate with sites/chapters about any number of topics in addition to the Communities of HEALing study. From this point forward, all peer mentorship will take place in the context of the research study (mentorship will not be offered outside of the study). We will communicate with Project HEAL leadership to implement the study. All communication for the purpose of research assessments and data collection will be direct communication between EDRU research staff and study participants. We will provide supervision directly to peer mentors and social support mentors. We communicate directly with participants (and inform Project HEAL) regarding randomization (treatment assignment) and matching.

Project HEAL sites for its mentorship program currently include New York, Philadelphia, Los Angeles, San Francisco, Boston, Chicago, Essex, MA, Southeast Pennsylvania, and Pittsburg. Interested participants who do not live in the vicinity of an existing Project HEAL site are offered available online peer mentors with whom they may communicate via FaceTime or Skype. Peer mentors provide support, guidance, and share personal experiences in order to help mentees cope with challenges to recovery and navigate day-to-day difficulties related to their eating disorder. Peer mentors and their mentees connect once per week in-person (for those from the areas described above) or online (for those who live outside of commutable distance from the identified sites) for one hour. Peer mentor/mentee interactions are focused on the mentee's eating disorder recovery process, and includes structured topics/activities like examining pros and cons of behavior change and challenging eating disorder thoughts. Peer mentorship is *not* designed as a standalone intervention and requires participants in the program to be involved in concurrent treatment with a licensed professional.

Project HEAL's mentorship program is one of the first programs of its kind. Given the project's nascence, its acceptability and effectiveness have not been evaluated, and Project HEAL has asked Drs. Attia and Ranzenhofer and the Columbia Eating Disorders Research Unit (EDRU) to evaluate it by conducting a randomized controlled trail comparing mentorship to two other conditions also carried out by Project HEAL. The two comparison programs are a non-eating disorder-focused social support condition (for six months) and a wait-list control (for six months). In the social support condition, individuals with an eating disorder are matched with a "social support mentor" without a history of an eating disorder. Social support mentors coordinate social activities within Project HEAL and the community, such as participating in advocacy or leisure activities. Participants assigned to this condition engage in an activity per week (lasting approximately one hour) with their social support mentor and in some cases, 1-2 other mentees. Interactions are centered on the week's activity (e.g., writing a letter to a representative, viewing museum exhibit), with an *intentional focus outside the eating disorder*. Wait-list participants engage in treatment with their outpatient providers for six months (as do patients in both active conditions), and then they are offered a mentor for six additional months. They may choose whether they prefer a peer mentor or a social support mentor. Interventions were developed by Project

HEAL and tailored to suit a research context with input from EDRU investigators. Program descriptions and manuals are provided for context.

To evaluate feasibility, we will monitor mentee attendance and acceptability in both active conditions. To evaluate fidelity, mentors and mentees will be asked to complete a brief form (Appendix 1, "weekly report") assessing meeting logistics (e.g., where the meeting occurred, number of contacts per week outside of meeting) and content of the meeting (e.g., topics discussed, activities). Peer mentors will be asked to complete an additional questionnaire assessing adherence to the peer-mentorship manual (Appendix 2, post-meeting mentor rating). Participants' eating disorder symptoms, comorbid psychiatric symptoms, and health care costs and utilization will be assessed at pre- mid- and post-treatment to evaluate preliminary efficacy. Participants' weight and BMI trajectories will also be evaluated by obtaining weight measures from the participant's outpatient provider with participant permission. Outcomes for individuals who participate in the peer mentorship program will be compared with individuals who participate in the social support and wait-list conditions. **We will also evaluate characteristics of individuals participating as peer and social support mentors, including whether demographic characteristics and diagnostic history influence outcome of the mentorship.**

Specific Aims and Hypotheses

Concisely state the objectives of the study and the hypothesis or primary research question(s) being examined. There should be one hypothesis for every major study procedure or intervention. For pilot studies, it is important not to overstate the study's objectives. If there are no study hypotheses, describe broad study goals/aims.

Primary Aims and Hypotheses:

Aim 1. Evaluate the feasibility and acceptability of peer mentorship. Hyp 1a. Peer mentorship will demonstrate greater feasibility, as measured by higher attendance rates, compared to the active control intervention. Hyp 1b. Peer mentorship will demonstrate greater acceptability, as measured by higher acceptability ratings, compared to both control conditions.

Aim 2: Evaluate the impact of intervention condition on eating disorder symptoms. Hyp 2a. Participants in peer mentorship will have greater reductions in eating disorder symptoms, measured using the Eating Disorder Symptom Inventory (EPSI), compared to both control conditions. Hyp2b: For individuals who meet criteria for current or past anorexia nervosa, individuals assigned to peer mentorship will be more likely to achieve or maintain a BMI ≥ 18.5, compared to both control conditions. Hyp2c: For individuals who meet criteria for current or past bulimia nervosa or binge eating disorder, individuals assigned to peer mentorship will be more likely to abstain from bingeing/purging and bingeing episodes, respectively, compared to individuals in either control condition.

Aim 3: Evaluate the impact of intervention condition on total cost for eating disorder treatment. Hyp 3. Estimated total cost for eating disorder treatment, measured using the Healthcare Utilization Survey, will be lower among peer mentorship participants compared to both control groups at (i) post-treatment and (ii) one-year follow up.

Exploratory Aim: Evaluate characteristics of individuals participating as peer and social support mentors. Exploratory hypothesis: Mentor characteristics and similarity between mentee and mentor characteristics will not influence mentee outcomes (acceptability, eating disorder symptoms, and estimated treatment cost).

Inclusion/Exclusion Criteria

This section details your study sample(s) and addresses the requirement for risk minimization.
You may choose to divide your sample by population (healthy controls vs. subjects) or by procedure (subjects who will have an MRI) and then define different sets of criteria for each.

For each sample, create or insert a table to describe detailed criteria for study inclusion and exclusion and the method you will use to ascertain each criterion. The method of ascertainment may describe tests, scales and instruments. When relevant, indicate the level of training of the person who will make the assessment (e.g. clinical interview by a psychiatrist).

Inclusion/Exclusion Criteria needs to be numbered and listed in outline form (see Table template below)

Mentees (Adolescents or adults with anorexia nervosa, bulimia nervosa, or binge eating disorder):

**Note that all EDRU screens will be reviewed with a clinician (MD or PhD level) and if any criteria are in question, the clinician will speak directly with the potential participant by telephone.*

CRITERION	METHOD OF ASCERTAINMENT
Inclusion:	
1. Ages 14 – 45 years	Initial telephone interview with Project HEAL staff, confirmation during telephone screening with EDRU research team member (RA level or higher)*
2. Meets criteria for current or past anorexia nervosa, bulimia nervosa , or binge eating disorder (criteria met either presently or at time of entry into treatment for most recent treatment course)	Eating Disorder Assessment -5 (administered by EDRU RA* during telephone screening)
3. Recent (within past 6 m) discharge from inpatient, residential, or partial hospitalization program (PHP)	Initial telephone interview with Project Heal staff, confirmation during telephone screening with EDRU RA*
4. Involved in outpatient treatment at an appropriate level of care	Telephone screening with EDRU RA* *and* Documentation from primary outpatient clinical provider using Provider Form
5. Medical stability	Telephone screening with EDRU RA* *and* Documentation from primary outpatient clinical provider using Provider Form
6. Access to Smart Phone or computer to complete study assessments	Telephone screening
Exclusion:	
1. Evidence of needing specialized treatment for another medical or mental health condition or substance use	Telephone screening with EDRU RA*

Mentors:

Mentors in the peer-mentorship group are adults who have recovered from an eating disorder, while mentors in the social support group are adults who never had an eating disorder. All mentors are individuals recruited and trained by Project Heal to do volunteer work within their organization.

Inclusion/Exclusion criteria:

CRITERIA	METHOD OF ASCERTAINMENT
Inclusion	
1. Participating as a peer or social support mentor in Project HEAL intervention	**1. Weekly telephone supervision with mentors**
Exclusion	
1. Not being a mentor	**1. Same as above**

Study Procedures

Provide a clear, concise narrative of study procedures with special attention to the subjects' involvement. Detail the overall study timeline and location of study procedures, list all interventions, assessments and interviews, estimate the duration of each procedure, provide dosing schedules, identify study personnel involved in each procedure, and provide credentials for relevant personnel. For complicated study designs, we strongly encourage attaching tables, flow-charts, and study algorithms.

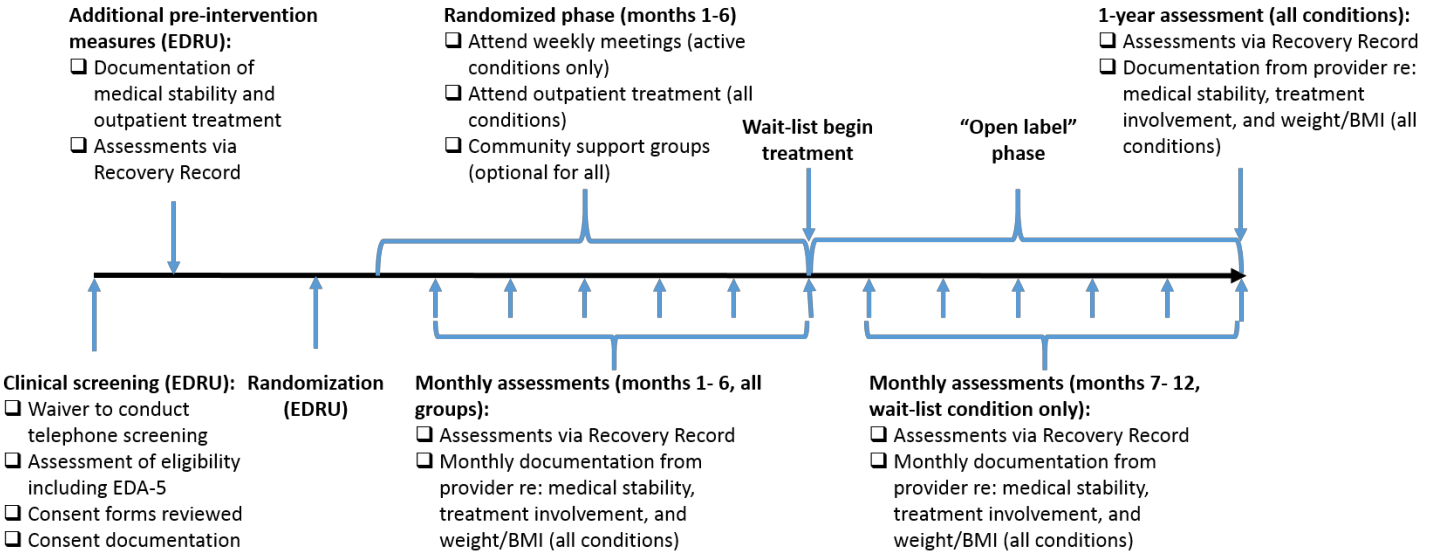
The design of the study is a three-arm, randomized controlled trail comparing peer mentorship to an active control condition that is not focused on eating disorder symptoms (social support), and a wait-list control. Feasibility, as well as preliminary efficacy for improving eating disorder symptoms and reducing health care costs, will be evaluated.

Recruitment of mentees

Participants will be recruited into a study examining the effectiveness of two Communities of Healing adjunct programs, peer mentorship and social support, for promoting eating disorder recovery alongside traditional outpatient eating disorder treatment. Participants with eating disorders (mentees) will be recruited using strategies found to be effective in launching the first Communities of HEALing programs including referrals form providers and utilizing the organizations various online platforms (websites, Facebook). Through Project HEAL's involvement in providing grant funding to patients seeking eating disorders treatment, Project HEAL has established relationships with eating disorder professionals and centers. In the 1-2 weeks preceding patients' discharge from hospital/IOP treatment, providers will inform patients about the study and inquire whether the patient is interested. Interested participants will be given information about the study (according to the attached document "Recruitment messaging for Communities of HEALing") and provided EDRU contact information. EDRU research staff will manage study screening and enrollment. The study will also be advertised through Project HEAL's social media platforms (e.g., website, Facebook) using approved recruitment language (see document "Recruitment messaging for Communities of HEALing").

Procedure

Overview of study flow



EDRU Screening: A trained, EDRU research assistant with a bachelor's degree or higher will screen and consent all participants by telephone. RAs performing telephone consent will have a BA or higher and research ethics/CITI training. Prior to conducting telephone consent, independently, RAs will first observe an investigator or senior-level RA conduct telephone and will be observed by an investigator or senior-RA to ensure competence. They will first obtain participant's verbal consent to conduct the telephone screening. During the telephone screening, the EDRU research staff member (RA level or higher) will assess inclusion/exclusion criteria including presence of an eating disorder using a standardized measure (the EDA-5). RAs will review eligibility with an EDRU clinician (MD or PhD).

Potential participants who are interested will be provided a copy of the consent form by mail or email, according to their stated preference. If mailed, the telephone consent will not be conducted until the participant indicates that they have received the hard copy. After the participant has received copies, the RA will review the consent (and assent, if applicable) forms, including nature and purpose of study, procedures, potential risks/benefits, and confidentiality, with the participant (and parent/guardian, if applicable). All consenters are NYSPI staff. Potential participants will be given an opportunity to ask questions and questions will be answered by the EDRU research staff member (RA level of higher). Participants will indicate whether they wish to participate and consent will be documented by the EDRU RA. For participants who are 14 – 17 years old, parental consent and adolescent assent will be documented. We have requested a waiver for documentation of consent.

Additional pre-intervention procedures: Prior to study enrollment, participants will complete several questionnaires and provide documentation from their treatment team. Questionnaires will be administered using Qualtrics, a HIPAA-compliant application accessible by computer or smart phone, by which participants can access and complete online surveys. Assessment measures are described in detail below in the Assessment Instruments section. They will be used to assess baseline eating disorder symptoms, co-morbid psychiatric symptoms and health care cost and utilization. Participants will provide contact information for their primary provider and document his/her consent to contact his/her primary provider. Similar to consent forms, consent to speak with primary providers will be obtained verbally and signed hard copies will be collected. Primary outpatient treatment providers will be asked to complete a baseline medical evaluation form documenting that, in his/her opinion, the patient is enrolled in treatment *at a sufficient level of care given.* The form on which this information will be document is attached as an addendum (Appendix 3). Treatment providers will also be asked to provide documentation of the patient's medical stability. On a monthly basis, providers will be contacted by EDRU staff and asked to report the participant's height and weight and confirm medical stability and continued treatment engagement.

Interventions:

After a participant has signed consent and completed baseline screening measures, he or she will be randomized to a condition. Randomization schema will be developed and executed by EDRU research team. The participant will then be matched with an available mentor. Matching is based on geographic location and when possible, age, gender, and diagnostic subtype, (e.g., an individual with anorexia nervosa would not be matched with a mentor who has binge eating disorder)). Participants will enter the study on a rolling basis. After a participant is assigned to a condition, he or she will be contacted by Project HEAL staff and informed of treatment assignment. Participants assigned to mentorship or social support will be instructed that he/she will be contacted by his/her mentor/PH volunteer within five days.

Active intervention conditions

Participants in both peer mentorship and social support will have weekly contact with a peer or social support mentor. Mentor/mentee pairs will meet in public or semi-public locations, including those on college campuses. Examples of possible meeting locations include libraries, coffee shops, parks, common spaces in residential settings (such as an apartment lobby or meeting room). Many mentor/mentee pairs are anticipated to be members of university communities and may utilize public spaces such as dormitory common areas, meeting rooms, university libraries, or study lounges. If a pair arrives to an arranged meeting location and it is crowded and/or does not appear private, mentors will be trained to say "We may want to meet in a more private space," and mentees will be queried whether they wish to move to an alternative location. Whenever possible, pairs will meet in private spaces.

Peer Mentorship

The mentorship intervention includes mentorship of patients with an eating disorder by those who have recovered from an eating disorder. All mentors have a history of an eating disorder but no longer meet criteria for an eating disorder. The peer mentorship program being studied was developed by Project HEAL. It is based on a program designed by Carolyn Costin, MA, Med, FAED (Appendix 4). Ms. Costin founded Monte Nido, the first licensed residential eating disorder treatment center. For many years she has provided training in this model to recovered individuals who went on to serve as mentors. Per the Project Heal Mentor Training Handbook (Appendix 4 and 5), mentors will act as a support person and role model for the mentee, through providing interpersonal support, guidance, and sharing of wisdom from personal experiences. Interactions between mentors and mentees are guided by eight core principles used to promote eating disorder recovery, each of which has suggested objectives (e.g., help those still struggling to examine the cost/benefits of recovering) and activities (e.g., write ten goals for treatment, write about a day in my life when I am recovered). The mentors will keep track of which principles, topics, and activities addressed in each mentee meeting using a post-meeting mentor rating form filled out by the mentor after each meeting (Appendix 2). Mentees and mentors connect once per week in person. If both parties agree to exchange contact information, then mentor/mentee pairs may also connect via phone or text. All phone utilization charges are billed to the participant's own phone plan and will not be covered by Project HEAL. Adaptations to Project HEAL's peer mentorship program are solely for the purposes of research.

Social support

Social support mentors (Project HEAL volunteers) will not have a history of an eating disorder. Social support mentors coordinate social activities within Project HEAL and the community, such as participating in advocacy (e.g., writing a letter to a congressperson) or attending a leisure activity (e.g., a museum), as per the social support manual (Appendix 6). Mentees engage in one activity per week (lasting about one hour), with the Project HEAL volunteer, and in some cases, one to three other mentees. Interactions are centered around the week's activity.

Wait-list control

To promote retention, participants will be contacted at two and five months by Project HEAL staff members, who will remind the participant of the study timeline, indicate when the next assessment will be completed, and remind the participant that he/she will be assigned to an active intervention after the 6-month study period.

Addressing mentee/mentor mismatch: There is a 3-step procedure for addressing instances in which a mentee reports a mismatch with his/her mentor. First, the mentor would receive supervision and make attempts to resolve the mismatch. Second, if the mismatch persists, we will match the mentee with a new mentor one time only. If a mentee has a mismatch with their second mentor, they will not be eligible to be re matched and their participation in the study interventions (mentorship) will be discontinued. If the mismatch occurs because the mentee is not abiding by guidelines for participation and this causes the mentor to feel uncomfortable, the PI/Co-I will speak with the mentee to address the issue. If this persists, the mentee's participation in the mentorship component of the study will be discontinued. Mentee guidelines are attached.

Operationalized criteria for early discontinuation of the active intervention: Grounds for discontinuing the active interventions (meaning that the participant is no longer able to meet with his/her mentor) include the following:

(a) Not complying or attending outpatient treatment (defined as mentee or provider indicating that the mentee is not attending treatment for 2 weeks or more) *or* not hearing from the mentee's treatment provider for 2 consecutive months.
(b) Requiring a higher level of care (per the mentee's treatment provider) and choosing not to pursue it.
(c) Missing 3 consecutive sessions with mentor and/or missing >2sessions/month for 2 consecutive months (without calling ahead to reschedule).
(d) Requesting >1 mentor reassignment. If the mentee has a mismatch with >1 mentor, we will not be able to assign a third mentor.

If a mentee is recommended for, and enters, treatment at a higher level of care, he/she may not receive mentorship while receiving treatment at the higher level of care. After discharge, pt may attend any remaining mentorship sessions falling within the study period (months 1 – 6) after providing a new provider clearance form. If the mentee was assigned to the wait list and enters treatment at a higher level of care during months 6 – 12, the same procedure will be followed. We will ask study participants to continue completing questionnaires even if a participant is no longer meeting with his/her mentor (regardless of the reason). Patients may choose whether they wish to continue completing study assessments.

Common intervention components

Recovery Record: Participants in the peer mentorship arm of the study will be asked to utilize Recovery Record®, a HIPPA-compliant smart phone and/or computer application, as a recovery tool only. No data will be collected using this application. The application was designed to provide support to eating disorder patients and includes a number of features aimed to promote recovery, such as a meal tracking record, prompts for completing meals/snacks, tracking for additional symptoms such as stress and mood, motivational messages, information about coping strategies, and capacity to share logged data with clinicians and mentors. Participants in the social support and wait-list control interventions will be informed that Recovery Record® has a number of additional features that they are welcome to explore on their own or in collaboration with their outpatient treatment team. Using the app will not be required if a participant prefers not to use it.

Community support groups: All participants in the study are invited to attend Communities of HEALing support groups, which are offered by Project HEAL but they are not part of the proposed study. Groups may include members of the community who are not involved in research. Participants will be informed at the onset of groups that there are members in the group who are not participating in the research study and it will be up to their discretion whether they choose to attend.

Mentor Training:

Peer mentors: Peer mentors receive 23 hours of training in an online "classroom" which includes completing readings, watching lectures, videos, film clips and role plays, as well as completing writing assignments. Training topics include: general information/history regarding peer mentorship interventions generally and Communities of HEALing specifically,

overview and in depth review of the Carolyn Costin peer mentoring manual (8 keys), crisis responding, and training in human subjects research, including the specifics of the current study.

Social support mentors: Social support mentors receive training in the rational and procedures of the social support intervention, crisis responding, and general and study-specific research training components. Social support mentors do not receive training in core peer mentorship components. Social support mentor training is 4-5 hours.

In both groups, 2.5 hours of the mentor training is devoted to recognizing and responding to urgent/emergency situations. Training is coordinated by Project HEAL staff. The PI and Co-I will develop and lead training regarding research components.

Fidelity monitoring and supervision: Drs. Ranzenhofer or Attia will provide supervision for mentors in both active conditions (peer mentorship, social support mentorship) twice per month. Mentorship and social support supervision will occur separately. Between scheduled supervision, mentors may contact Drs. Ranzenhofer or Attia to discuss emergent questions/concerns. In urgent situations, mentors may contact the EDRU psychiatrist on call. In emergencies, mentors will be told to call 911. Over any period that a leader (mentor or volunteer) is providing the intervention, he/she will be required to attend the bi-monthly supervision and if necessary make up missed sessions. Supervision will focus on both clinical issues that arise during meetings with participants as well as treatment fidelity and adherence to the content of the intervention.

Mentees and all mentors will be asked to submit the "weekly report" form (Appendix 1) each week, to determine number of contacts and session content. Peer mentors only will also be asked to fill out the post-treatment peer mentor rating form (Appendix 2). All fidelity monitoring forms will be reviewed by Drs. Ranzenhofer and Attia on a weekly basis, and the information will be used to guide supervision sessions. This information will also be used to evaluate fidelity to intervention content (for both conditions).

Additional procedures to optimize participant safety:

(1) **Distinguishing between supportive interventions versus treatment:** The distinction between supportive interventions versus treatment (described on pages 64-65 of Communities of HEALing manual) will be underscored throughout screening and intervention procedures. We will identify mentorship and social support as *adjunct,* supportive interventions intended to supplement treatment. We will ensure, through documentation and monthly contact with providers, that patients are concurrently enrolled in treatment with a licensed provider. If a participant stops attending outpatient treatment, the study investigators will discontinue his/her participation in the active interventions (meetings with mentors). This is to ensure that all participants who are meeting with mentors also have outpatient teams. These concepts will be outlined during telephone and in-person screenings, when reviewing study consent, during first meeting between mentor/mentee and at subsequent meetings when deemed necessary, and at the beginning of community support groups.

(2) **Ensuring participants are engaged in outpatient treatment with a licensed provider:** All mentees provide documentation of ongoing engagement in treatment with licensed provider in order to start and continue meeting with a mentor. If a patient misses a doctor form, he/she and his/her mentor will be asked to discontinue meetings until the form is obtained. Once a form is submitted, participants and their mentors may resume meetings for the duration of the six month randomized period. If the research team does not receive any additional forms, participants may continue completing questionnaires if they wish. Because completing surveys via Qualtrics is only minimal risk, we will ask participants to continue completing surveys even if they discontinue mentorship meetings. A patient may decline to continue completing the questionnaires.

If a participant is on the wait list, they *must* submit a provider form for month 6 (the conclusion of the wait-list period) in order to be matched with a mentor. If a participant does not submit a provider form, he/she may not be matched with a mentor, but they may continue completing assessments if they wish.

(3) Training and procedures to address suspected risk to a mentee's health or safety: Participants will provide documentation of permission for their mentor or EDRU research staff to contact their treatment provider in the case of emergent clinical/medical issues. All peer mentors and social support mentors receive training in how to recognize and respond to concerns about a mentee, including potential clinical deterioration, medical instability, or psychiatric instability (e.g., suicidal thoughts or behavior). Specific to suicide risk, this training includes information about signs of suicidal thoughts/behaviors and how to respond to concern about suicidality. Since peers are *not clinicians,* they will be advised to do the following in any case of imminent risk: 1) Contact emergency services 2). Contact EDRU supervisors immediately (Drs. Attia and Ranzenhofer). In cases when the mentor is not concerned about imminent risk: 1). Encourage the mentee to raise the issue with his or her treatment team; 2). Contact EDRU supervisors.

Assessments: All participants will complete monthly assessments of eating disorder symptoms, eating disorder quality of life, and co-morbid psychiatric symptoms throughout the six month randomized phase and then again at a 12-month follow up time point. Participants assigned to the wait-list condition will also complete monthly assessments throughout the "open label" phase in which they are receiving mentorship. On a monthly basis, patients' treatment providers will be contacted in order to obtain the patient's current height/weight from which to calculate BMI. Patient questionnaires will be administered using Qualtrics, a HIPAA-compliant applications accessible by smart phone or computer. If, during participation in an intervention or wait-list condition, a participant is hospitalized or returns to a higher level of care (e.g., residential treatment, partial hospitalization), he/she may resume participation in the mentorship component of the study only with permission from his/her treatment provider (a new letter must be obtained from primary provider). **All participants will complete a questionnaire assessing study acceptability of the study at the end of the 6 months period of mentorship or as soon as their participation in the study ends (e.g., if a participant discontinues after 3 months, they will be asked to complete the survey at that time).**

Mentor Procedures:

Individuals participating as mentors will be asked if they are willing to allow the study team to utilize data previously collected as part of interviewing and training to be a mentor. This data includes demographic information such as age and gender, as well as diagnostic history, for the peer mentors. Mentors will be informed about the study during a supervision call with the PI of the study and Project HEAL staff. Prior to reviewing the consent form during the telephone call with all mentors, all mentors will be sent a copy of the consent form to review ahead of time. Mentors will be asked to then speak individually with one of the study team members (the PI, a trained RA or other study clinician) to indicate whether or not they wish to participate in the study.

The information collected as part of the process of interviewing to be a mentor will be sent in a de-identified format. The code linking mentor information with the identifier will be transmitted by phone to the study team. Mentors will also be asked to fill out a brief 4-question survey using Qualtrics.

Blood and other Biological Samples

Describe how the sample will be used and indicate, when relevant, the amount of the sample. The IRB wants to know that the sample is sufficient for the purposes of the study, but that sampling is limited to what is minimally necessary.

If you've indicated that you intend to store a sample for future use, indicate where the sample will be stored, how long the sample will be stored, and to what purposes the sample will eventually be put. Check the IRB website at http://irb.nyspi.org/irbdnn/Policies/GeneticResearch/tabid/96/Default.aspx for specific guidance and additional information about future use of DNA samples.

Neither blood nor other biological samples will be collected.

Assessment Instruments

List all assessment instruments, indicate who will administer them, and provide an estimate the duration of each. The IRB wants to know that assessments instruments are appropriate measures for the purposes of the study and are no

more burdensome than is necessary. The IRB will consider the burden of assessment instruments (in terms of time, sensitivity of material, etc.) in the risk/benefit analysis. Please attach copies or otherwise provide all non-standard instruments.

Demographic information: Participants will be asked to report general demographic information including birth date, sex, race/ethnicity, and socioeconomic status.

Height and weight: Participants will sign consent giving the research team Project HEAL Program Directors permission to contact their outpatient provider on a monthly basis to receive documentation of height/weight.

Eating Disorder Symptoms: Eating disorder symptoms will be assessed monthly using the Eating Pathology Symptoms Inventory (1). The Eating Pathology Symptoms Inventory (EPSI) is a self-report questionnaire that includes 45 items covering 8 subscales: Body Dissatisfaction, Binge Eating, Cognitive Restraint, Purging, Restricting, Excessive Exercise, Negative Attitudes toward Obesity, and Muscle Building. Each item is scored on a five-point Likert-style scale (0 = Never; 4= Often) to describe how well each item describes the participant's experiences. Scores are derived by summing responses across the questions included in each subscale. The EPSI is part of the Phynx Toolkit, a NHGRI/NIDA-sponsored catalog of recommended standard measures of phenotypes (symptoms) for use in biomedical research. To assess frequency of bingeing and purging episodes, BN and BED patients will be asked to report the average number of episodes/week experienced within the past month on each monthly report of symptoms.

Eating Disorders Quality of Life: Quality of life as related to the patient's eating disorder will be measured using the Eating Disorder Quality of Life assessment survey (2). The EDQOL is a 30-item measure assessing the impact of the eating disorder on psychological, physical/cognitive, financial and work/school domains of life. Participants indicate the extent to which the eating disorder has resulted in a variety of consequences within the past 30 days (e.g., "How often has your eating disorder led to low grades?" on a 5-point scale ranging from 1 = "never" to 5 = "always." Higher scores indicate higher levels of QOL impairment. The measure has been validated and demonstrates good psychometric properties.

Comorbid psychiatric symptoms: Anxiety symptoms will be measured using the State Trait Anxiety Inventory (STAI) (3).The STAI is a well-validated 20-item measure used to assess trait-level anxiety. Each item is rated on a scale of 0 – 2, with total scores ranging from 0 – 40. Depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9), a 9-item self-report questionnaire commonly used in clinical practice. The PHQ has demonstrated good psychometric properties and has high sensitivity and specificity (4).

Health Care cost: Estimated total health care costs related to the patient's eating disorder will be assessed using the Health Care Cost and Utilization Survey, developed by the research team. The survey asks participants to report the types and frequencies of a range of health services received including hospitalizations, residential treatment, outpatient visits (e.g., primary care, registered dietician) and tests (e.g., urine test, blood test), and mental health treatment (e.g., individual therapy, family therapy). Patients are also asked to report information pertaining to their insurance coverage and amount/percentages paid out-of-pocket for various services.

Acceptability of the study: **Acceptability of the mentorship programs will be assessed using the Study Acceptability Form developed by the research team, modified from existing evaluation measures. The questionnaire asks participants to report on their experience with mentorship on dimensions of helpfulness, appropriateness, overall experience, matching expectations, recommend to friend, as well as specific questions pertaining to the alliance with mentor. Participants rate their answers on a 5- or 7-point scale or in open-ended dialogue boxes.**

Research Related Delay to Treatment

Research involving participants who are in need of treatment invariably involves delay to care, and this delay is associated with risk. Scheduling of procedures must be carefully organized to minimize delay. Other delay must involve only that minimally necessary to accomplish the aims of the research while respecting subject well- being and safety. Describe the delay, by virtue of research participation in this study, before a participant can receive treatment of known efficacy or standard care routinely offered in the community.

All participants will be enrolled in treatment with a licensed provider concurrent with their participation in either peer mentorship, social support, or wait-list. The study involves three intervention arms, two of which are active (peer mentorship, social support) and one of which is a wait-list control. For individuals assigned to mentorship or social support, there may be a delay to intervention if a mentor or volunteer is unavailable to meet with the participant at the time that he/she enrolls in the study. For participants assigned to the wait-list, there will be a six-month delay before the participant receives **an active intervention.**

Clinical Treatment Alternatives

Describe what other treatment or assessment options are available to subjects who do not participate in research.

All participants will be required to be engaged in a form of outpatient treatment with a licensed provider in order to be randomized to a condition, and in order to meet with their mentors. Alternatives to participation include not participating. Participants attending Communities of HEALing chapters who choose not to participate in research may still attend support groups offered by Project Heal but they will not have the option of being paired with a mentor.

Risks/Discomforts/Inconveniences

"Risk" is a broad term used to convey the potential for harm, burden, and inconvenience related to research participation. Use this section to provide a comprehensive description of foreseeable physical, psychological, social, interpersonal, and economic risks introduced by the research. Include the source of the information. Consider both the probability and magnitude of harm and its impact. Describe the foreseeable harms associated with the research (untoward effects of a medication) and those related to delay to individualized treatment. Include data from the literature, and local data, if available, on risk rates and subject experiences with research procedures. Describe procedures in place to minimize risk. In general, please create a numbered list of risks/categories of risk, and in general put the list in the order of significance or level of risk, the most significant risks first followed by others.

1. *Psychological assessments* Participants may feel distressed or bored as a result of completing study assessments.

2. *Risk of clinical deterioration* There is a risk that some participants might experience a deterioration of their psychiatric or physical condition over the course of the study.

3. *Risk of unintentional disclosure of confidential information* **This risk applies to both mentees and mentors.** There is a risk that sensitive information collected in the study could become known to individuals not involved in the study.

Procedures in place to minimize risk:

1. *Psychological assessments* If a research participant experiences distress as any part of the screening process, then an EDRU clinician will be available to talk with the participant. Participants will be informed that they should contact a EDRU clinician if they experience distress while filling out assessment questionnaires.

2. *Clinical deterioration* If a participant is suspected to be at risk for relapse or otherwise medically/psychiatrically unstable, mentors and/or EDRU research staff will contact the patients' treatment team and/or emergency services. Mentors in both active intervention conditions will receive training in how to respond to situations in which the participants' medical/psychiatric stability is questionable. Mentors and volunteers will receive ongoing (bi-monthly) supervision by a MD or PhD level EDRU clinician with expertise in the treatment of eating disorders. The risk of clinical deterioration is also minimized by ensuring (through monthly contact with outpatient provider) that all participants, including those on the wait-list, are concurrently enrolled in outpatient treatment, expected to minimize risk of clinical deterioration.

3. *Risk of unintentional disclosure of confidential information* All procedures are consistent with HIPAA requirements, including the completion of online assessments using Qualtrics. Research data will be de identified and stored in locked rooms and computer records will be identifiable only by a participant's deidentified study code. PHI will be available to individuals outside the clinic only if requested in writing and if the participant has signed a release form. Patients will

receive a notice of privacy policies and be asked to sign a HIPAA form in addition to the consent form. **Additionally, data regarding the mentors will be provided to the research team by Project Heal in de-identified form. The key to the codes will be given to the research team by phone in a confidential setting.**

Methods to Protect Confidentiality

Describe the data management plan and the methods you will employ to protect subject privacy and the confidentiality of research data. The section should detail how information will be collected, recorded, coded, stored, transmitted, and as applicable, shared with other investigators so as to minimize risks related to breach of confidentiality. Confirm that identifiers are removed, to the extent possible, from research data, and explain if there are links between subject identity and research data, or if the data is anonymous. Also, indicate where the data is stored, who is responsible for its safekeeping, and who has access to subject identity and codes, if any, which cross-link research data and subject identity. Confirm that identifiable data is not collected, stored, or transmitted by mail, fax, on removable drives, laptops, or via the internet without proper protections, e.g. encryption.

To protect patient confidentiality, all data collected will be kept confidential and used for professional purposes only. Information will be available to the patient's physician or other health services only if directly requested in writing and the participant signs a release form. Identifying information will be kept separate from research records. All patient records at NYSPI will be kept in secure, locked offices within the facilities, and all forms will be identified with only the study code. All electronic data will be stored on computers that are password protected. Only code numbers will appear on any data and documents used for evaluation or statistical analyses. Publications using this data will be done in a manner that fully protects subjects' anonymity.

Direct Benefits to Subjects

Describe only benefits to individual subjects that are likely to accrue during the study itself. Do not include subject compensation or treatment to be provided at the end of the study, as these do not figure into the IRB's risk benefit considerations. Do not describe diagnostic and evaluation components unless subjects receive clinical feedback. Do not describe the anticipated scientific benefits of the research. Some studies offer no direct benefit to subjects.

There are no benefits guaranteed from participation in the study. Participants may benefit from being paired with a mentor and/or from social support unrelated to their eating disorder recovery. Mentorship enable patients to feel an increased sense of support, connection, and accountability. Mentorship also may provide patients with positive role models and a sense of hope that recovery is possible. Social support is expected to promote social connectedness and a sense of purpose beyond the eating disorder. However, the effectiveness of neither group has been previously evaluated, so no direct benefit is guaranteed.

References

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4. Kroenke K., Spitzer R.L., J.B. W. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13.

Parental Permission to Participate in Research

(Parent CF)

Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and Overview

Relapse rates for eating disorders are high and many teens continue to struggle with eating disorder symptoms even when they are in treatment. Project HEAL is a non-profit organization focused on helping individuals with eating disorders find appropriate and affordable treatments and recover from eating disorders. Project HEAL recently developed *Communities of HEALing*, which includes adjunct interventions for eating disorder patients focused on mentorship and social support. The purpose of the current study is to evaluate whether these adjunct interventions can help individuals with eating disorders stay in treatment and achieve lasting recovery. We (the researchers at the Eating Disorders Research Unit at the New York Psychiatric Institute) have agreed to help Project HEAL evaluate if their programs help people who want to recover from an eating disorder. We are the investigators and we will be carrying out the study.

If your teen is being considered for this study, they have recently received treatment for an eating disorder in a structured treatment setting (hospital, residential, partial hospital program (PHP), or intensive outpatient program (IOP)) and they are now in treatment with a licensed professional. If your teen becomes a study participant, they will be randomly assigned to one of three things. Random assignment means that which option your child gets is up to chance, like flipping a coin. We cannot choose which option your child gets, you cannot choose which option your child gets, and your child cannot choose which option they get. Instead, it is chosen totally randomly, using a computer program. Based on the random assignment, your child would receive either six months of peer mentorship from a peer who has recovered from an eating disorder, six months of social support mentorship from someone who has not had an eating disorder, or your child will be asked to be on a wait-list. If your child is on the wait list, they would receive mentorship after six months. Your teen would also be asked to complete interviews and questionnaires about their symptoms.

Voluntary

Participation in this research study is voluntary. If you or your teen decides not to participate, or if they later decide to stop participating, they will not lose any benefits to which they are entitled. If your teen decides not to participate, your teen may still seek treatment at New York

Psychiatric Institute and be involved in Project HEAL in other ways. We will notify you of any significant new findings about this kind of research that may affect your willingness to have your teen participate in this project.

Alternatives to Participation

The alternative to participating is not participating. Your teen may choose to seek peer mentorship or social support through other resources. Your teen cannot be matched with a mentor through Project HEAL unless your teen participates in the research study. The interventions offered as part of this study are not treatment. Even though your child is already in treatment, you can always pursue other treatment options for your child. If you wish, we can provide referrals for eating disorder treatment.

Procedures

If your teen is in the study, they will be randomly assigned (based on chance) to receive one of three things. The first is peer mentorship, in which your teen will meet weekly with a peer over age 18 who has recovered from an eating disorder. During weekly meetings, your teen and their mentor will discuss eating disorder symptoms and how to overcome them. The second is social support mentorship, in which your teen will meet weekly with a peer mentor over age 18 who has not had an eating disorder. During weekly meetings, your teen and their mentor (and 1-3 other group members) will engage in a variety of community, advocacy, and leisure activities. In the third condition, your teen will be on a wait-list for six months, and then they will receive mentorship for six months. All mentors have been interviewed and trained by Project HEAL and have had background checks. **Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider).** Your teen will be expected to exchange contact information with their mentor so they can contact each other between meetings if necessary (for scheduling purposes). If your teen does not have a phone, they may email with their mentor. All charges resulting from phone or data usage are billed to you or your teen and are not covered by Project HEAL and/or Columbia University Medical Center. If you are participating in the study with an online mentor, your teen will be asked to communicate with them using Face Time or Skype.

After each weekly meeting with their mentor, your teen will be asked to answer a few

questions using Qualtrics, a HIPAA-compliant online app, about where the meeting took place, what they talked about, what they did, as well as their symptoms in the past week. If your teen is on the wait-list, these questions will be about their symptoms only. At the beginning of the study and every month throughout the intervention, your teen will be asked to complete several additional questionnaires using the app. The questionnaires are estimated to take 20 minutes to complete each time. If your teen is assigned a peer mentor, they will also be asked to use Recovery Record, a separate, HIPAA-compliant app, designed to provide recovery support (e.g., coping strategies, self-monitoring tools), but we will not collect any data using this tool. While we encourage your teen to use it, it is not required. We will also ask for your permission to contact your teen's primary treatment provider at the beginning of the study and once each month during the study. We will ask your teen's treatment provider to tell us your teen's height and weight and whether they are still involved in treatment. We will also ask your teen and their treatment provider to answer the same questionnaires after 12 months from when your teen began the study.

If we find out from your teen's treatment provider that your teen stopped attending treatment, or if your teen's provider thinks that he or she need more treatment and you choose not to pursue it, or if your teen misses 3 meetings in a row (or 2 meetings per month for 2 months in a row), then your teen will not be able to continue meeting with their mentor. If this happens, we will speak with you and your child and ask if you/your child wish to continue completing the questionnaires. It is entirely up to you and your child whether they do so or not. Even if your child says yes, they can stop at any time. If there is a mismatch with your teen's assigned mentor, we may be able to match your teen with a new mentor one time only. If your teen receives treatment at a higher level of care (e.g., a hospitalization) while participating in the study, your teen may not attend mentorship sessions while in treatment at a higher level of care. After your teen is discharged, he or she may attend remaining mentorship sessions that fall within the study time frame.

Risks and Inconveniences

There is a risk that completing interviews and questionnaires in this study may be distressing. Your teen may always skip a question. If your teen experiences distress as a result of filling out the questionnaires, we will ask them to let us know. We will be available to talk with your teen. There is a risk that your teen's symptoms may worsen when they are participating in an intervention or on the wait list. We will talk with your teen's treatment provider every month to monitor their weight and make sure they are still in treatment. We will not allow your teen to continue attending meetings with their mentor if they have stopped attending treatment. While we will take all measures possible to protect

privacy, there is a risk of disclosure of confidential information. When we suspect that your teen's safety is at risk, their mentor or the study team may talk with you and your teen's treatment provider and/or emergency services if warranted. If we suspect that your teen's safety is at risk, we will talk with you and your teen and help you find appropriate services. Your teen may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

This study was not designed to be of direct benefit to your teen. However, your teen may benefit from working with a peer mentor or social support mentor on your eating disorder symptoms or on other aspects of life. However, the mentorship interventions may not help your teen, and your teen may do worse. Your teen's part may help researchers understand whether adjunct social support and mentorship interventions can help improve eating disorder symptoms.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot disclose this information without your consent. Records will only be available to research staff, and to Federal, State and Institutional regulatory personnel who may review the records as part of routine audits. Your teen's name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Some research information will be stored on computers that are password protected. Information which would allow your teen to be identified (like name, address, social security number) will be stored separately.

Study Compensation

There is no compensation provided for participating in this study.

In Case of Injury

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Ranzenhofer will be available to answer to the best of her ability any questions that may arise now or in the future about the procedures or about your response to the procedures. She can be reached at 646-774-8065.

If you have any questions about your teen's rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at 646-774-7155 during regular office hours.

Documentation of Consent

"I have discussed the proposed research with this parent/guardian and his/her child including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The parent/guardian has had an opportunity to ask questions and in my opinion is capable of freely consenting for his or her child to participate in this research. The parent or guardian voluntarily agrees to have their child participate in the research study and has provided verbal consent."

Print Name: _____
Person Designated to Obtain Assent
Signed: _____
Date: _____

Informed Consent for Participation in Research

Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and Overview

Relapse rates for eating disorders are high and many individuals continue to struggle with eating disorder symptoms even when they are participating in treatment. Project HEAL is a non-profit organization focused on helping individuals with eating disorders find appropriate and affordable treatments and recover from eating disorders. Project HEAL recently developed *Communities of HEALing*, which includes adjunct interventions for eating disorder patients focused on mentorship and social support. The purpose of the current study is to evaluate whether these adjunct interventions can help individuals with eating disorders stay in treatment and achieve lasting recovery. We (the researchers at the Eating Disorders Research Unit at the New York Psychiatric Institute) have agreed to help Project HEAL evaluate if their programs help people who want to recover from an eating disorder. We are the investigators and we will be carrying out the study.

If you are being considered for this study, you have recently received treatment for an eating disorder in a structured treatment setting (hospital, residential, partial hospital program (PHP), or intensive outpatient program (IOP)) and are now in treatment with a licensed professional. If you are a study participant, you will be randomly assigned to one of three things. Random assignment means that which option you get is up to chance, like flipping a coin. We cannot choose which option you get and you cannot choose which one you get. Instead, it is chosen totally randomly, using a computer program. Based on the random assignment, you would receive either six months of peer mentorship from a peer who has recovered from an eating disorder, six months of social support mentorship from someone who has not had an eating disorder, or you will be asked to be on a wait-list. If you are on the wait list, you would receive mentorship after six months. The study also involves completing interviews and questionnaires about your symptoms.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. If you decide not to participate, you may still seek treatment at New York Psychiatric Institute and

you may still be involved in Project HEAL in other ways. You will be notified of any significant new findings about this kind of research that may affect your willingness to continue to participate in this project.

Alternatives to Participation

The alternative to participating is not participating. You may choose to seek peer mentorship or social support through other resources. You cannot be matched with a mentor through Project HEAL unless you participate in the research study. The interventions offered as part of this study are not treatment. Even though you are already in treatment, you can always pursue other treatment options. If you wish, we can provide referrals for eating disorder treatment.

Procedures

If you are in the study, you will be randomly assigned (based on chance) to receive one of three things. The first is peer mentorship, in which you will meet weekly with an adult peer who has recovered from an eating disorder. During weekly meetings, you and your mentor will discuss your eating disorder symptoms and how to overcome them. The second is social support mentorship, in which you will meet weekly with an adult mentor who has not had an eating disorder. During weekly meetings, you and your mentor (and 1-3 other group members) will engage in a variety of community, advocacy, and leisure activities. In the third condition, you will be on a wait-list for six months, and then you will receive mentorship for six months. All mentors have been interviewed and trained by Project HEAL and have had background checks. **Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider).** You will exchange contact information with your mentor so you can contact each other between meetings if necessary (for scheduling purposes). All charges resulting from phone or data usage are billed to you and are not covered by Project HEAL and/or Columbia University Medical Center. If you are participating in the study with an online mentor, you will be asked to communicate with your mentor using Face Time or Skype.

After meetings with your mentor, you will be asked to answer a few questions using Qualtrics, a HIPAA-compliant online app, about where you met, what you talked about, as well as your symptoms in the past week. If you are on the wait-list, these questions will be about your

symptoms only. At the beginning of the study and every month throughout the intervention, you will be asked to complete several additional questionnaires on the app. The questionnaires are estimated to take 20 minutes to complete each time. If you are assigned a peer mentor, you will also be asked to use Recovery Record, a separate HIPAA-compliant online application, designed to provide recovery support (e.g., coping strategies, self-monitoring tools), but we will not collect any data using this tool. While we encourage you to use it, it is not required. We will ask you to give us permission to contact your primary treatment provider at the beginning of the study and once each month during the study. We will ask your treatment provider to tell us your height and weight and whether you are still involved in treatment. We will also ask you and your provider to answer the same questionnaires after 12 months from when you began the study.

If we find out from your treatment provider that you stopped attending treatment, or if your provider thinks that you need more treatment and you choose not to pursue it (e.g., hospitalization), or if you miss 3 meetings in a row (or 2 meetings per month for 2 months in a row), then you will not be able to continue meeting with your mentor. If this happens, we will speak with you and ask if you wish to continue completing the questionnaires. It is entirely up to you whether you do so or not. Even if you say yes, you can stop at any time. If there is a mismatch with your assigned mentor, we may be able to match you with a new mentor one time only. If you receive treatment at a higher level of care while you are in the study, you may not attend mentorship sessions while you are in treatment at a higher level of care. After you are discharged, you may attend remaining mentorship sessions that fall within the study time frame.

Risks and Inconveniences

There is a risk that completing interviews and questionnaires in this study may be distressing. You may always skip a question. If you do experience distress as a result of filling out the questionnaires, we will ask you to let us know. We will be available to talk with you. There is a risk that your symptoms may worsen when you are participating in an intervention or on the wait list. We will talk with your treatment provider every month to monitor your weight and make sure you are still in treatment. We will not allow you to continue attending meetings with your mentor if you discontinue treatment. While we will take all measures possible to protect your privacy, there is a risk of disclosure of confidential information. The procedures associated with risk of disclosure of confidential information include meeting in locations that are not private, such as a coffee shop), and filling out questionnaires using online applications. If we suspect that your safety is at risk, we

will talk with you and help you find appropriate services. You may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

This study was not designed to be of direct benefit to you. However, you may benefit from working with a peer mentor or social support mentor on your eating disorder symptoms or on other aspects of your life. However, the mentorship interventions may not help you, and you may do worse. Your part may help researchers understand whether adjunct social support and mentorship interventions can help improve eating disorder symptoms.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot disclose this information without your consent. Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Some research information will be stored on computers that are password protected. Information which would allow you to be identified (like name, address, social security number) will be stored separately.

Study Compensation

There is no compensation provided for participating in this study.

In Case of Injury

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide.

In addition, we will provide assistance in arranging follow up care in such instances. New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide

compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Ranzenhofer will be available to answer to the best of her ability any questions that may arise now or in the future about the procedures or about your response to the procedures. She can be reached at 646-774-8065.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a
committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at 646-774-7155 during regular office hours.

Documentation of Consent

"I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research. The participant voluntarily agrees to participate in the research study and has provided verbal consent."

Print Name: _____
Person Designated to Obtain Consent

Signed: _____

Date: _____

Informed Assent for Participation in Research
(Child and Adolescent patients)
Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and overview

Recovering from an eating disorder can be very difficult. Some teenagers continue to have trouble even when they are getting treatment. There is an organization called Project HEAL that was started to help people recover from eating disorders. Project HEAL started a new program called Communities of HEALing that includes two programs where people with eating disorders get support from other people to help them recover. The purpose of this research study is to see how well these programs work to help people recover from eating disorders. We (the researchers at the Eating Disorders Research Unit at the New York State Psychiatric Institute) are helping Project HEAL figure out if their programs help people who want to recover from eating disorders.

If we ask you to be in the study, you have recently gotten treatment for an eating disorder in hospital or other program and you are now in treatment with a doctor or therapist. If you participate in the study, you would participate in one of three programs. You would have an equal chance of being in each program. We cannot choose which program you are in and you cannot choose which program you are in. Instead, it is chosen totally randomly, using a computer program. The first program is peer mentorship. In this program, you would meet and talk with someone else (a peer) who has already recovered from an eating disorder. The second program is social support mentorship. In this program, you would do activities not related to the eating disorder with someone who has not had an eating disorder. In the third, you would wait for six months and then get mentorship for six months afterwards. In order to be in the study, you would need to be okay with getting any of the options, since you do not get to pick which one you get. We would also ask you to answer questions about your eating, your thoughts and feelings, and what you do and talk about with your mentor.

Voluntary

You can choose if you want to be in the study. You can stop being in the study any time you want. Even if you say yes now, you can change your mind later. If you decide not to participate, you may still get treatment at New York Psychiatric Institute and you may still be involved in Project HEAL in other ways. We will tell you any new information that may affect whether you want to be in the study.

Alternatives

The alternative to participating is not participating. You may choose to get support from people in other ways. You cannot be matched with a mentor through Project HEAL unless you participate in the research study. The programs offered as part of this study are not treatment. Even though you are already in treatment, you can always go somewhere else for treatment. If you or your parent wants, we can help you find eating disorder treatment.

Procedures

If you are in the study, you will be randomly assigned to one of three things. You would have an equal chance of each one. We cannot choose which option you get and you cannot choose which one you get. Instead, it is chosen totally randomly, using a computer program. The first is peer mentorship. In peer mentorship, you will meet every week with someone (over age 18) who has recovered from an eating disorder. During your meetings, you and your mentor will talk about how to overcome the eating disorder. The second is social support mentorship. In social support mentorship, you will meet every week with someone (over age 18) who has not had an eating disorder. During your meetings, you and your mentor (and 1 - 3 other group members) will do different types of activities in the community, like seeing a movie, going to a museum, doing an art project, or writing letters to help raise money for eating disorder treatment. In the third, you would be on a wait-list for six months, and then you will get mentorship for six months. You may exchange contact information with your mentor so you can call or text between meetings if necessary (for scheduling purposes). If you don't have a phone, you will be asked to email your mentor. If you are in the study with an online mentor, you will be asked to communicate with them using Face Time or Skype. **Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider).**

After meetings with your mentor, we will ask you to answer questions using an app called Qualtrics about where you met, what you talked about, what you did as well as your symptoms in the past week. If you are on the wait-list, these questions will be about your symptoms only. At the beginning of the study and every month while you participate, you will be asked to answer several

additional questions using the app. The questions are about your eating, your thoughts, and your feelings. They take about 20 minutes each time. If you are assigned a peer mentor, we will ask you to use a separate app called Recovery Record. It was designed to provide recovery support (e.g., coping strategies), but we will not collect any data using this tool. While we encourage you to use it, it is not required. We will also ask your parent to say it is okay for us talk with your doctor during the study (once a month). We will ask your doctor to tell us your height and weight and whether you still go to treatment.

If we find out from you doctor or therapist that you stopped going to treatment, or if your doctor thinks that you need more treatment and you do not get it, or if you miss 3 meetings in a row (or 2 meetings per month for 2 months in a row), then you will not be able to continue meeting with your mentor. If this happens, we will speak with you and ask if you wish to complete the weekly questionnaires. It is entirely up to you whether you do so or not. Even if you say yes to filling in the weekly forms initially, you can stop at any time. If you do not get along with the mentor you get, we may be able to match you with a new mentor one time. If you go to the hospital while you are in the study, you may not go to meetings with your mentor while you are in the hospital. After you leave the hospital, you may go to any mentorship sessions that are left until the six months is over.

Risks and Inconveniences

You may feel uncomfortable being asked questions about your thoughts or feelings. We will be able to talk with you if you are upset about any of the questions. You may choose to not answer a question. There is a risk that your eating disorder could get worse while you are in the study. We will talk with your doctor once a month to check your weight and make sure you are still seeing your doctor or therapist. We will not allow you to continue attending meetings with your mentor if you stop going to treatment. There is a risk that your private information could become known to people who are not involved in our study. This is not likely to happen, but it could. The ways this could happen include having meetings with your mentor in locations that are not private, such as a coffee shop, and filling out questionnaires using online applications (Qualtrics). We will do what we can to prevent this. If we find out that you or another child or older person is being hurt, we will let someone know and get you help**.** If we are worried about your health or safety, we will talk with you and your parent and help you figure out what to do. You may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

There are no direct benefits to you for participating. You might benefit from working with a peer mentor or social support mentor, but since it is a research study, we do not know for sure that this will help. The mentorship interventions may not help you, and you may do worse. Your part may help us understand whether mentorship can help people who are trying to recover from an eating disorder.

Confidentiality

At the beginning of the study, you will be assigned a "code name," so we won't use your real name when we look at your data. All of your data will be kept in locked offices and on computers that are protected by passwords. We use a secure app to collect the data that you fill out on a smart phone or computer.

Study Compensation (payment)

There is no compensation (payment) for being in the study.

Questions

If you have questions about this research study, we will try to answer them. If you have questions later on, you can call Dr. Lisa Ranzenhofer at (646) 774-8065.

Documentation of Consent

"I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research. The participant has provided verbal assent to participate in the study."

Person designated to obtain consent:

Print Name: _____

Signed: _____

Date: _____

NYSPI IRB Approved
7533
5/22/2018 -> 8/20/2018

Uploaded Protocol Summary Form

Cover Page

Protocol Number: IRB number not yet assigned Draft date: **April 10, 2018**

Protocol Title: Evaluation of the Communities of Healing Mentorship/Support group Program: Assessment of preliminary efficacy

Principal Investigators: Lisa Ranzenhofer PhD

Email: lr2840@cumc.columbia.edu

Telephone: (646) 774-8065

Office: Cell Phone: (240) 671-9040

Lay Summary

This section is intended to provide a basic overview of the study including a description of its purpose, methods, and subject population. The summary should provide a concise overview of the study for non-scientific and scientific members of the IRB. Please avoid medical or technical terminology. In general, the abstract of a grant does not provide a suitable lay summary.

Eating disorders are serious mental illnesses associated with significant morbidity and high relapse rates. Patients are at especially high risk of relapse after leaving structured treatment (e.g., hospitalization). Adjunct interventions targeting patients' motivation and participation in treatment at these times may help more patients recover from eating disorders. Project HEAL is a non-profit organization whose mission is to reduce suffering caused by eating disorders. Project HEAL has developed a intervention in which patient mentees with eating disorders are matched with peer mentors who have previously recovered from an eating disorder, and mentors meet weekly with mentees to provide support, guidance, and serve as a model that recovery is possible. Project HEAL has asked the researchers at the EDRU to help them evaluate the feasibility and effects of this intervention. Therefore, the purpose of the current study is to test whether peer-mentorship can help improve patients' eating disorder symptoms above and beyond their traditional treatment. The design of the study is a three-arm randomized controlled trial comparing peer mentorship to active (social-support) and wait-list control conditions. Participants in the study will be randomized to one of the three conditions for six months. Wait-list participants will subsequently receive **either type of** mentorship. Participants will complete assessments of their eating disorder symptoms at baseline, monthly throughout the course of the study, and one year after beginning the study. Outcomes will be compared between groups.

Please also paste of a copy of the Lay Summary into the PRISM PSF Form.

Background, Significance, and Rationale

In this section, provide a brief summary of the status quo of the relevant work field, and how the proposed study will advance knowledge. Specifically, identify the gaps in knowledge that your project is intended to fill. If no gaps exist that are obviously and directly related to your project, explain how your proposed research will contribute to the overall understanding of your field. Describe potential impacts of your project within your field of study and in a broader context. Provide a critical evaluation of existing knowledge. The literature review does not have to be exhaustive.

Anorexia nervosa and bulimia nervosa are serious mental illnesses associated with significant morbidity and high relapse rates. AN has the highest mortality rate of any psychiatric illness. Although family-based treatment has led to improved outcomes for adolescent patients, this therapeutic approach has only limited utility in adults. Research suggests that patients with EDs are at greatest risk for relapse in the first six month following discharge from an intensive treatment (e.g. hospitalization or residential). Adjunct, supportive approaches delivered at these high risk times have potential to improve eating disorder relapse prevention. Adjunct interventions also have potential to promote treatment engagement (attendance, compliance with meal plan, etc.) in patients with high ambivalence.

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Project Heal® is a non-profit organization whose primary missions are providing grant funding for individuals with eating disorders who otherwise cannot afford treatment and promoting eating disorder recovery through campaigns and community programming. Project Heal has community sites (aka "chapters") in 40 cities across the US and Canada. Project Heal recently launched a mentorship-based intervention at 12 of it's sites, in which eligible individuals with eating disorders who are receiving treatment from a licensed professional are partnered for six months with peer mentors (individuals who have previously recovered from an eating disorder and who have participated in a general orientation/training program regarding the role of mentor). "Sites" refer to locations across the US and internationally where one or more individuals has established a local Project HEAL chapter. Chapters/"sites" range in size from just a few people to over 50. The Project HEAL national organization has ongoing contact with its sites about many different topics, including the Communities of HEALing program. In the past year, 12 sites have established Communities of HEALing programs, meaning that trained mentors carry out peer mentorship and free community support groups with oversight from a National-level Program Director. As more and more sites established peer mentorship programs, Project HEAL asked us to help them evaluate this intervention.

Moving forward, Project HEAL will continue to communicate with sites/chapters about any number of topics in addition to the Communities of HEALing study. From this point forward, all peer mentorship will take place in the context of the research study (mentorship will not be offered outside of the study). We will communicate with Project HEAL leadership to implement the study. All communication for the purpose of research assessments and data collection will be direct communication between EDRU research staff and study participants. We will provide supervision directly to peer mentors and social support mentors. We communicate directly with participants (and inform Project HEAL) regarding randomization (treatment assignment) and matching.

Project HEAL sites for its mentorship program currently include New York, Philadelphia, Los Angeles, San Francisco, Boston, Chicago, Essex, MA, Southeast Pennsylvania, and Pittsburg. Interested participants who do not live in the vicinity of an existing Project HEAL site are offered available online peer mentors with whom they may communicate via FaceTime or Skype. Peer mentors provide support, guidance, and share personal experiences in order to help mentees cope with challenges to recovery and navigate day-to-day difficulties related to their eating disorder. Peer mentors and their mentees connect once per week in-person (for those from the areas described above) or online (for those who live outside of commutable distance from the identified sites) for one hour. Peer mentor/mentee interactions are focused on the mentee's eating disorder recovery process, and includes structured topics/activities like examining pros and cons of behavior change and challenging eating disorder thoughts. Peer mentorship is *not* designed as a standalone intervention and requires participants in the program to be involved in concurrent treatment with a licensed professional.

Project HEAL's mentorship program is one of the first programs of its kind. Given the project's nascence, its acceptability and effectiveness have not been evaluated, and Project HEAL has asked Drs. Attia and Ranzenhofer and the Columbia Eating Disorders Research Unit (EDRU) to evaluate it by conducting a randomized controlled trail comparing mentorship to two other conditions also carried out by Project HEAL. The two comparison programs are a non-eating disorder-focused social support condition (for six months) and a wait-list control (for six months). In the social support condition, individuals with an eating disorder are matched with a "social support mentor" without a history of an eating disorder. Social support mentors coordinate social activities within Project HEAL and the community, such as participating in advocacy or leisure activities. Participants assigned to this condition engage in an activity per week (lasting approximately one hour) with their social support mentor and in some cases, 1-2 other mentees. Interactions are centered on the week's activity (e.g., writing a letter to a representative, viewing museum exhibit), with an *intentional focus outside the eating disorder*. Wait-list participants engage in treatment with their outpatient providers for six months (as do patients in both active conditions), and then they are offered a mentor for six additional months. They may choose whether they prefer a peer mentor or a social support mentor. Interventions were developed by Project HEAL and tailored to suit a research context with input from EDRU investigators. Program descriptions and manuals are provided for context.

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To evaluate feasibility, we will monitor mentee attendance and acceptability in both active conditions. To evaluate fidelity, mentors and mentees will be asked to complete a brief form (Appendix 1, "weekly report") assessing meeting logistics (e.g., where the meeting occurred, number of contacts per week outside of meeting) and content of the meeting (e.g., topics discussed, activities). Peer mentors will be asked to complete an additional questionnaire assessing adherence to the peer-mentorship manual (Appendix 2, post-meeting mentor rating). Participants' eating disorder symptoms, comorbid psychiatric symptoms, and health care costs and utilization will be assessed at pre- mid- and post-treatment to evaluate preliminary efficacy. Participants' weight and BMI trajectories will also be evaluated by obtaining weight measures from the participant's outpatient provider with participant permission. Outcomes for individuals who participate in the peer mentorship program will be compared with individuals who participate in the social support and wait-list conditions.

Specific Aims and Hypotheses

Concisely state the objectives of the study and the hypothesis or primary research question(s) being examined. There should be one hypothesis for every major study procedure or intervention. For pilot studies, it is important not to overstate the study's objectives. If there are no study hypotheses, describe broad study goals/aims.

Primary Aims and Hypotheses:

Aim 1. Evaluate the feasibility and acceptability of peer mentorship. Hyp 1a. Peer mentorship will demonstrate greater feasibility, as measured by higher attendance rates, compared to the active control intervention. Hyp 1b. Peer mentorship will demonstrate greater acceptability, as measured by higher acceptability ratings, compared to both control conditions.

Aim 2: Evaluate the impact of intervention condition on eating disorder symptoms. Hyp 2a. Participants in peer mentorship will have greater reductions in eating disorder symptoms, measured using the Eating Disorder Symptom Inventory (EPSI), compared to both control conditions. Hyp2b: For individuals who meet criteria for current or past anorexia nervosa, individuals assigned to peer mentorship will be more likely to achieve or maintain a BMI ≥ 18.5, compared to both control conditions. Hyp2c: For individuals who meet criteria for current or past bulimia nervosa or binge eating disorder, individuals assigned to peer mentorship will be more likely to abstain from bingeing/purging and bingeing episodes, respectively, compared to individuals in either control condition.

Aim 3: Evaluate the impact of intervention condition on total cost for eating disorder treatment. Hyp 3. Estimated total cost for eating disorder treatment, measured using the Healthcare Utilization Survey, will be lower among peer mentorship participants compared to both control groups at (i) post-treatment and (ii) one-year follow up.

Inclusion/Exclusion Criteria

This section details your study sample(s) and addresses the requirement for risk minimization.
You may choose to divide your sample by population (healthy controls vs. subjects) or by procedure (subjects who will have an MRI) and then define different sets of criteria for each.

For each sample, create or insert a table to describe detailed criteria for study inclusion and exclusion and the method you will use to ascertain each criterion. The method of ascertainment may describe tests, scales and instruments. When relevant, indicate the level of training of the person who will make the assessment (e.g. clinical interview by a psychiatrist).

Inclusion/Exclusion Criteria needs to be numbered and listed in outline form (see Table template below)

Mentees (Adolescents or adults with anorexia nervosa, bulimia nervosa, or binge eating disorder):

**Note that all EDRU screens will be reviewed with a clinician (MD or PhD level) and if any criteria are in question, the clinician will speak directly with the potential participant by telephone.*

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CRITERION	METHOD OF ASCERTAINMENT
Inclusion:	
1. Ages 14 – 45 years	Initial telephone interview with Project HEAL staff, confirmation during telephone screening with EDRU research team member (RA level or higher)*
2. Meets criteria for current or past anorexia nervosa, bulimia nervosa , or binge eating disorder (criteria met either presently or at time of entry into treatment for most recent treatment course)	Eating Disorder Assessment -5 (administered by EDRU RA* during telephone screening)
3. Recent (within past 6 m) discharge from inpatient, residential, or partial hospitalization program (PHP)	Initial telephone interview with Project Heal staff, confirmation during telephone screening with EDRU RA*
4. Involved in outpatient treatment at an appropriate level of care	Telephone screening with EDRU RA* *and* Documentation from primary outpatient clinical provider using Provider Form
5. Medical stability	Telephone screening with EDRU RA* *and* Documentation from primary outpatient clinical provider using Provider Form
6. Access to Smart Phone or computer to complete study assessments	Telephone screening
Exclusion:	
1. Evidence of needing specialized treatment for another medical or mental health condition or substance use	Telephone screening with EDRU RA*

Mentors:

Mentors in the peer-mentorship group are adults who have recovered from an eating disorder, while mentors in the social support group are adults who never had an eating disorder. All mentors are individuals recruited and trained by Project Heal to do volunteer work within their organization.

Inclusion/Exclusion criteria: n/a.

Study Procedures

Provide a clear, concise narrative of study procedures with special attention to the subjects' involvement. Detail the overall study timeline and location of study procedures, list all interventions, assessments and interviews, estimate the duration of each procedure, provide dosing schedules, identify study personnel involved in each procedure, and provide

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credentials for relevant personnel. For complicated study designs, we strongly encourage attaching tables, flow-charts, and study algorithms.

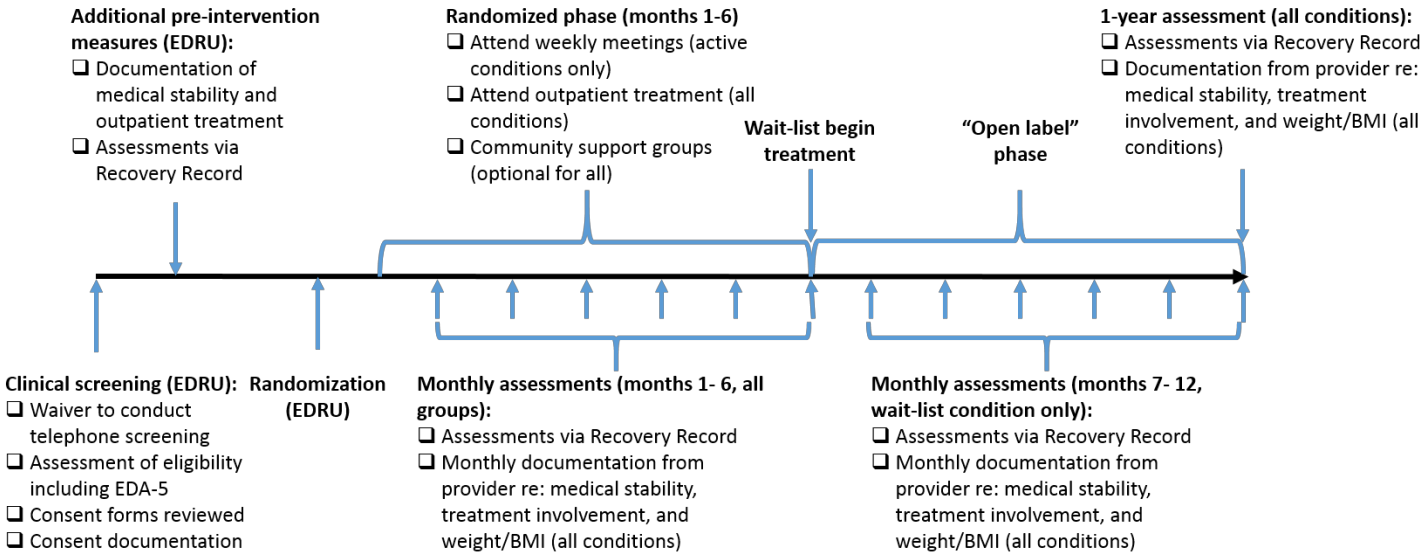
The design of the study is a three-arm, randomized controlled trail comparing peer mentorship to an active control condition that is not focused on eating disorder symptoms (social support), and a wait-list control. Feasibility, as well as preliminary efficacy for improving eating disorder symptoms and reducing health care costs, will be evaluated.

Recruitment

Participants will be recruited into a study examining the effectiveness of two Communities of Healing adjunct programs, peer mentorship and social support, for promoting eating disorder recovery alongside traditional outpatient eating disorder treatment. Participants with eating disorders (mentees) will be recruited using strategies found to be effective in launching the first Communities of HEALing programs including referrals form providers and utilizing the organizations various online platforms (websites, Facebook). Through Project HEAL's involvement in providing grant funding to patients seeking eating disorders treatment, Project HEAL has established relationships with eating disorder professionals and centers. In the 1-2 weeks preceding patients' discharge from hospital/IOP treatment, providers will inform patients about the study and inquire whether the patient is interested. Interested participants will be given information about the study (according to the attached document "Recruitment messaging for Communities of HEALing") and provided EDRU contact information. EDRU research staff will manage study screening and enrollment. The study will also be advertised through Project HEAL's social media platforms (e.g., website, Facebook) using approved recruitment language (see document "Recruitment messaging for Communities of HEALing").

Procedure

Overview of study flow



EDRU Screening: A trained, EDRU research assistant with a bachelor's degree or higher will screen and consent all participants by telephone. RAs performing telephone consent will have a BA or higher and research ethics/CITI training. Prior to conducting telephone consent, independently, RAs will first observe an investigator or senior-level RA conduct telephone and will be observed by an investigator or senior-RA to ensure competence. They will first obtain participant's verbal consent to conduct the telephone screening. During the telephone screening, the EDRU research staff member (RA level or higher) will assess inclusion/exclusion criteria including presence of an eating disorder using a standardized measure (the EDA-5). RAs will review eligibility with an EDRU clinician (MD or PhD).

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Potential participants who are interested will be provided a copy of the consent form by mail or email, according to their stated preference. If mailed, the telephone consent will not be conducted until the participant indicates that they have received the hard copy. After the participant has received copies, the RA will review the consent (and assent, if applicable) forms, including nature and purpose of study, procedures, potential risks/benefits, and confidentiality, with the participant (and parent/guardian, if applicable). All consenters are NYSPI staff. Potential participants will be given an opportunity to ask questions and questions will be answered by the EDRU research staff member (RA level of higher). Participants will indicate whether they wish to participate and consent will be documented by the EDRU RA. For participants who are 14 – 17 years old, parental consent and adolescent assent will be documented. We have requested a waiver for documentation of consent.

Additional pre-intervention procedures: Prior to study enrollment, participants will complete several questionnaires and provide documentation from their treatment team. Questionnaires will be administered using Qualtrics, a HIPAA-compliant application accessible by computer or smart phone, by which participants can access and complete online surveys. Assessment measures are described in detail below in the Assessment Instruments section. They will be used to assess baseline eating disorder symptoms, co-morbid psychiatric symptoms and health care cost and utilization. Participants will provide contact information for their primary provider and document his/her consent to contact his/her primary provider. Similar to consent forms, consent to speak with primary providers will be obtained verbally and signed hard copies will be collected. Primary outpatient treatment providers will be asked to complete a baseline medical evaluation form documenting that, in his/her opinion, the patient is enrolled in treatment *at a sufficient level of care given.* The form on which this information will be document is attached as an addendum (Appendix 3). Treatment providers will also be asked to provide documentation of the patient's medical stability. On a monthly basis, providers will be contacted by EDRU staff and asked to report the participant's height and weight and confirm medical stability and continued treatment engagement.

Interventions:

After a participant has signed consent and completed baseline screening measures, he or she will be randomized to a condition. Randomization schema will be developed and executed by EDRU research team. The participant will then be matched with an available mentor. Matching is based on geographic location and when possible, age, gender, and diagnostic subtype, (e.g., an individual with anorexia nervosa would not be matched with a mentor who has binge eating disorder)). Participants will enter the study on a rolling basis. After a participant is assigned to a condition, he or she will be contacted by Project HEAL staff and informed of treatment assignment. Participants assigned to mentorship or social support will be instructed that he/she will be contacted by his/her mentor/PH volunteer within five days.

Active intervention conditions

Participants in both peer mentorship and social support will have weekly contact with a peer or social support mentor. Mentor/mentee pairs will meet in public or semi-public locations, including those on college campuses. Examples of possible meeting locations include libraries, coffee shops, parks, common spaces in residential settings (such as an apartment lobby or meeting room). Many mentor/mentee pairs are anticipated to be members of university communities and may utilize public spaces such as dormitory common areas, meeting rooms, university libraries, or study lounges. If a pair arrives to an arranged meeting location and it is crowded and/or does not appear private, mentors will be trained to say "We may want to meet in a more private space," and mentees will be queried whether they wish to move to an alternative location. Whenever possible, pairs will meet in private spaces.

Peer Mentorship

The mentorship intervention includes mentorship of patients with an eating disorder by those who have recovered from an eating disorder. All mentors have a history of an eating disorder but no longer meet criteria for an eating disorder. The peer mentorship program being studied was developed by Project HEAL. It is based on a program designed by Carolyn Costin, MA, Med, FAED (Appendix 4). Ms. Costin founded Monte Nido, the first licensed residential eating disorder treatment center. For many years she has provided training in this model to recovered individuals who went on

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to serve as mentors. Per the Project Heal Mentor Training Handbook (Appendix 4 and 5), mentors will act as a support person and role model for the mentee, through providing interpersonal support, guidance, and sharing of wisdom from personal experiences. Interactions between mentors and mentees are guided by eight core principles used to promote eating disorder recovery, each of which has suggested objectives (e.g., help those still struggling to examine the cost/benefits of recovering) and activities (e.g., write ten goals for treatment, write about a day in my life when I am recovered). The mentors will keep track of which principles, topics, and activities addressed in each mentee meeting using a post-meeting mentor rating form filled out by the mentor after each meeting (Appendix 2). Mentees and mentors connect once per week in person. If both parties agree to exchange contact information, then mentor/mentee pairs may also connect via phone or text. All phone utilization charges are billed to the participant's own phone plan and will not be covered by Project HEAL. Adaptations to Project HEAL's peer mentorship program are solely for the purposes of research.

Social support

Social support mentors (Project HEAL volunteers) will not have a history of an eating disorder. Social support mentors coordinate social activities within Project HEAL and the community, such as participating in advocacy (e.g., writing a letter to a congressperson) or attending a leisure activity (e.g., a museum), as per the social support manual (Appendix 6). Mentees engage in one activity per week (lasting about one hour), with the Project HEAL volunteer, and in some cases, one to three other mentees. Interactions are centered around the week's activity.

Wait-list control

To promote retention, participants will be contacted at two and five months by Project HEAL staff members, who will remind the participant of the study timeline, indicate when the next assessment will be completed, and remind the participant that he/she will be assigned to an active intervention after the 6-month study period.

Addressing mentee/mentor mismatch: There is a 3-step procedure for addressing instances in which a mentee reports a mismatch with his/her mentor. First, the mentor would receive supervision and make attempts to resolve the mismatch. Second, if the mismatch persists, we will match the mentee with a new mentor one time only. If a mentee has a mismatch with their second mentor, they will not be eligible to be re matched and their participation in the study interventions (mentorship) will be discontinued. If the mismatch occurs because the mentee is not abiding by guidelines for participation and this causes the mentor to feel uncomfortable, the PI/Co-I will speak with the mentee to address the issue. If this persists, the mentee's participation in the mentorship component of the study will be discontinued. Mentee guidelines are attached.

Operationalized criteria for early discontinuation of the active intervention: Grounds for discontinuing the active interventions (meaning that the participant is no longer able to meet with his/her mentor) include the following:

(a) Not complying or attending outpatient treatment (defined as mentee or provider indicating that the mentee is not attending treatment for 2 weeks or more) *or* not hearing from the mentee's treatment provider for 2 consecutive months.
(b) Requiring a higher level of care (per the mentee's treatment provider) and choosing not to pursue it.
(c) Missing 3 consecutive sessions with mentor and/or missing >2sessions/month for 2 consecutive months (without calling ahead to reschedule).
(d) Requesting >1 mentor reassignment. If the mentee has a mismatch with >1 mentor, we will not be able to assign a third mentor.

If a mentee is recommended for, and enters, treatment at a higher level of care, he/she may not receive mentorship while receiving treatment at the higher level of care. After discharge, pt may attend any remaining mentorship sessions falling within the study period (months 1 – 6) after providing a new provider clearance form. If the mentee was assigned to the wait list and enters treatment at a higher level of care during months 6 – 12, the same procedure will be followed. We will ask study participants to continue completing questionnaires even if a participant is no longer meeting with

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his/her mentor (regardless of the reason). Patients may choose whether they wish to continue completing study assessments.

Common intervention components

Recovery Record: Participants in the peer mentorship arm of the study will be asked to utilize Recovery Record®, a HIPPA-compliant smart phone and/or computer application, as a recovery tool only. No data will be collected using this application. The application was designed to provide support to eating disorder patients and includes a number of features aimed to promote recovery, such as a meal tracking record, prompts for completing meals/snacks, tracking for additional symptoms such as stress and mood, motivational messages, information about coping strategies, and capacity to share logged data with clinicians and mentors. Participants in the social support and wait-list control interventions will be informed that Recovery Record® has a number of additional features that they are welcome to explore on their own or in collaboration with their outpatient treatment team. Using the app will not be required if a participant prefers not to use it.

Community support groups: All participants in the study are invited to attend Communities of HEALing support groups, which are offered by Project HEAL but they are not part of the proposed study. Groups may include members of the community who are not involved in research. Participants will be informed at the onset of groups that there are members in the group who are not participating in the research study and it will be up to their discretion whether they choose to attend.

Mentor Training:

Peer mentors: Peer mentors receive 23 hours of training in an online "classroom" which includes completing readings, watching lectures, videos, film clips and role plays, as well as completing writing assignments. Training topics include: general information/history regarding peer mentorship interventions generally and Communities of HEALing specifically, overview and in depth review of the Carolyn Costin peer mentoring manual (8 keys), crisis responding, and training in human subjects research, including the specifics of the current study.

Social support mentors: Social support mentors receive training in the rational and procedures of the social support intervention, crisis responding, and general and study-specific research training components. Social support mentors do not receive training in core peer mentorship components. Social support mentor training is 4-5 hours.

In both groups, 2.5 hours of the mentor training is devoted to recognizing and responding to urgent/emergency situations. Training is coordinated by Project HEAL staff. The PI and Co-I will develop and lead training regarding research components.

Fidelity monitoring and supervision: Drs. Ranzenhofer or Attia will provide supervision for mentors in both active conditions (peer mentorship, social support mentorship) twice per month. Mentorship and social support supervision will occur separately. Between scheduled supervision, mentors may contact Drs. Ranzenhofer or Attia to discuss emergent questions/concerns. In urgent situations, mentors may contact the EDRU psychiatrist on call. In emergencies, mentors will be told to call 911. Over any period that a leader (mentor or volunteer) is providing the intervention, he/she will be required to attend the bi-monthly supervision and if necessary make up missed sessions. Supervision will focus on both clinical issues that arise during meetings with participants as well as treatment fidelity and adherence to the content of the intervention.

Mentees and all mentors will be asked to submit the "weekly report" form (Appendix 1) each week, to determine number of contacts and session content. Peer mentors only will also be asked to fill out the post-treatment peer mentor rating form (Appendix 2). All fidelity monitoring forms will be reviewed by Drs. Ranzenhofer and Attia on a weekly basis, and the information will be used to guide supervision sessions. This information will also be used to evaluate fidelity to intervention content (for both conditions).

Additional procedures to optimize participant safety:

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(1) **Distinguishing between supportive interventions versus treatment:** The distinction between supportive interventions versus treatment (described on pages 64-65 of Communities of HEALing manual) will be underscored throughout screening and intervention procedures. We will identify mentorship and social support as *adjunct,* supportive interventions intended to supplement treatment. We will ensure, through documentation and monthly contact with providers, that patients are concurrently enrolled in treatment with a licensed provider. If a participant stops attending outpatient treatment, the study investigators will discontinue his/her participation in the active interventions (meetings with mentors). This is to ensure that all participants who are meeting with mentors also have outpatient teams. These concepts will be outlined during telephone and in-person screenings, when reviewing study consent, during first meeting between mentor/mentee and at subsequent meetings when deemed necessary, and at the beginning of community support groups.

(2) **Ensuring participants are engaged in outpatient treatment with a licensed provider:** All mentees provide documentation of ongoing engagement in treatment with licensed provider in order to start and continue meeting with a mentor. If a patient misses a doctor form, he/she and his/her mentor will be asked to discontinue meetings until the form is obtained. Once a form is submitted, participants and their mentors may resume meetings for the duration of the six month randomized period. If the research team does not receive any additional forms, participants may continue completing questionnaires if they wish. Because completing surveys via Qualtrics is only minimal risk, we will ask participants to continue completing surveys even if they discontinue mentorship meetings. A patient may decline to continue completing the questionnaires.

If a participant is on the wait list, they *must* submit a provider form for month 6 (the conclusion of the wait-list period) in order to be matched with a mentor. If a participant does not submit a provider form, he/she may not be matched with a mentor, but they may continue completing assessments if they wish.

(3) Training and procedures to address suspected risk to a mentee's health or safety: Participants will provide documentation of permission for their mentor or EDRU research staff to contact their treatment provider in the case of emergent clinical/medical issues. All peer mentors and social support mentors receive training in how to recognize and respond to concerns about a mentee, including potential clinical deterioration, medical instability, or psychiatric instability (e.g., suicidal thoughts or behavior). Specific to suicide risk, this training includes information about signs of suicidal thoughts/behaviors and how to respond to concern about suicidality. Since peers are *not clinicians,* they will be advised to do the following in any case of imminent risk: 1) Contact emergency services 2). Contact EDRU supervisors immediately (Drs. Attia and Ranzenhofer). In cases when the mentor is not concerned about imminent risk: 1). Encourage the mentee to raise the issue with his or her treatment team; 2). Contact EDRU supervisors.

Assessments: All participants will complete monthly assessments of eating disorder symptoms, eating disorder quality of life, and co-morbid psychiatric symptoms throughout the six month randomized phase and then again at a 12-month follow up time point. Participants assigned to the wait-list condition will also complete monthly assessments throughout the "open label" phase in which they are receiving mentorship. On a monthly basis, patients' treatment providers will be contacted in order to obtain the patient's current height/weight from which to calculate BMI. Patient questionnaires will be administered using Qualtrics, a HIPAA-compliant applications accessible by smart phone or computer. If, during participation in an intervention or wait-list condition, a participant is hospitalized or returns to a higher level of care (e.g., residential treatment, partial hospitalization), he/she may resume participation in the mentorship component of the study only with permission from his/her treatment provider (a new letter must be obtained from primary provider). **All participants will complete a questionnaire assessing study acceptability of the study at the end of the 6 months period of mentorship or as soon as their participation in the study ends (e.g., if a participant discontinues after 3 months, they will be asked to complete the survey at that time).**

Blood and other Biological Samples

Describe how the sample will be used and indicate, when relevant, the amount of the sample. The IRB wants to know that the sample is sufficient for the purposes of the study, but that sampling is limited to what is minimally necessary.

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If you've indicated that you intend to store a sample for future use, indicate where the sample will be stored, how long the sample will be stored, and to what purposes the sample will eventually be put. Check the IRB website at http://irb.nyspi.org/irbdnn/Policies/GeneticResearch/tabid/96/Default.aspx for specific guidance and additional information about future use of DNA samples.

Neither blood nor other biological samples will be collected.

Assessment Instruments

List all assessment instruments, indicate who will administer them, and provide an estimate the duration of each. The IRB wants to know that assessments instruments are appropriate measures for the purposes of the study and are no more burdensome than is necessary. The IRB will consider the burden of assessment instruments (in terms of time, sensitivity of material, etc.) in the risk/benefit analysis. Please attach copies or otherwise provide all non-standard instruments.

Demographic information: Participants will be asked to report general demographic information including birth date, sex, race/ethnicity, and socioeconomic status.

Height and weight: Participants will sign consent giving the research team Project HEAL Program Directors permission to contact their outpatient provider on a monthly basis to receive documentation of height/weight.

Eating Disorder Symptoms: Eating disorder symptoms will be assessed monthly using the Eating Pathology Symptoms Inventory (1). The Eating Pathology Symptoms Inventory (EPSI) is a self-report questionnaire that includes 45 items covering 8 subscales: Body Dissatisfaction, Binge Eating, Cognitive Restraint, Purging, Restricting, Excessive Exercise, Negative Attitudes toward Obesity, and Muscle Building. Each item is scored on a five-point Likert-style scale (0 = Never; 4= Often) to describe how well each item describes the participant's experiences. Scores are derived by summing responses across the questions included in each subscale. The EPSI is part of the Phynx Toolkit, a NHGRI/NIDA-sponsored catalog of recommended standard measures of phenotypes (symptoms) for use in biomedical research. To assess frequency of bingeing and purging episodes, BN and BED patients will be asked to report the average number of episodes/week experienced within the past month on each monthly report of symptoms.

Eating Disorders Quality of Life: Quality of life as related to the patient's eating disorder will be measured using the Eating Disorder Quality of Life assessment survey (2). The EDQOL is a 30-item measure assessing the impact of the eating disorder on psychological, physical/cognitive, financial and work/school domains of life. Participants indicate the extent to which the eating disorder has resulted in a variety of consequences within the past 30 days (e.g., "How often has your eating disorder led to low grades?" on a 5-point scale ranging from 1 = "never" to 5 = "always." Higher scores indicate higher levels of QOL impairment. The measure has been validated and demonstrates good psychometric properties.

Comorbid psychiatric symptoms: Anxiety symptoms will be measured using the State Trait Anxiety Inventory (STAI) (3).The STAI is a well-validated 20-item measure used to assess trait-level anxiety. Each item is rated on a scale of 0 – 2, with total scores ranging from 0 – 40. Depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9), a 9-item self-report questionnaire commonly used in clinical practice. The PHQ has demonstrated good psychometric properties and has high sensitivity and specificity (4).

Health Care cost: Estimated total health care costs related to the patient's eating disorder will be assessed using the Health Care Cost and Utilization Survey, developed by the research team. The survey asks participants to report the types and frequencies of a range of health services received including hospitalizations, residential treatment, outpatient visits (e.g., primary care, registered dietician) and tests (e.g., urine test, blood test), and mental health treatment (e.g., individual therapy, family therapy). Patients are also asked to report information pertaining to their insurance coverage and amount/percentages paid out-of-pocket for various services.

Acceptability of the study: **Acceptability of the mentorship programs will be assessed using the Study Acceptability Form developed by the research team, modified from existing evaluation measures. The questionnaire asks**

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participants to report on their experience with mentorship on dimensions of helpfulness, appropriateness, overall experience, matching expectations, recommend to friend, as well as specific questions pertaining to the alliance with mentor. Participants rate their answers on a 5- or 7-point scale or in open-ended dialogue boxes.

Research Related Delay to Treatment

Research involving participants who are in need of treatment invariably involves delay to care, and this delay is associated with risk. Scheduling of procedures must be carefully organized to minimize delay. Other delay must involve only that minimally necessary to accomplish the aims of the research while respecting subject well- being and safety. Describe the delay, by virtue of research participation in this study, before a participant can receive treatment of known efficacy or standard care routinely offered in the community.

All participants will be enrolled in treatment with a licensed provider concurrent with their participation in either peer mentorship, social support, or wait-list. The study involves three intervention arms, two of which are active (peer mentorship, social support) and one of which is a wait-list control. For individuals assigned to mentorship or social support, there may be a delay to intervention if a mentor or volunteer is unavailable to meet with the participant at the time that he/she enrolls in the study. For participants assigned to the wait-list, there will be a six-month delay before the participant receives **an active intervention.**

Clinical Treatment Alternatives

Describe what other treatment or assessment options are available to subjects who do not participate in research.

All participants will be required to be engaged in a form of outpatient treatment with a licensed provider in order to be randomized to a condition, and in order to meet with their mentors. Alternatives to participation include not participating. Participants attending Communities of HEALing chapters who choose not to participate in research may still attend support groups offered by Project Heal but they will not have the option of being paired with a mentor.

Risks/Discomforts/Inconveniences

"Risk" is a broad term used to convey the potential for harm, burden, and inconvenience related to research participation. Use this section to provide a comprehensive description of foreseeable physical, psychological, social, interpersonal, and economic risks introduced by the research. Include the source of the information. Consider both the probability and magnitude of harm and its impact. Describe the foreseeable harms associated with the research (untoward effects of a medication) and those related to delay to individualized treatment. Include data from the literature, and local data, if available, on risk rates and subject experiences with research procedures. Describe procedures in place to minimize risk. In general, please create a numbered list of risks/categories of risk, and in general put the list in the order of significance or level of risk, the most significant risks first followed by others.

1. *Psychological assessments* Participants may feel distressed or bored as a result of completing study assessments.

2. *Risk of clinical deterioration* There is a risk that some participants might experience a deterioration of their psychiatric or physical condition over the course of the study.

3. *Risk of unintentional disclosure of confidential information* **This risk applies to both mentees and mentors.** There is a risk that sensitive information collected in the study could become known to individuals not involved in the study.

Procedures in place to minimize risk:

1. *Psychological assessments* If a research participant experiences distress as any part of the screening process, then an EDRU clinician will be available to talk with the participant. Participants will be informed that they should contact a EDRU clinician if they experience distress while filling out assessment questionnaires.

2. *Clinical deterioration* If a participant is suspected to be at risk for relapse or otherwise medically/psychiatrically unstable, mentors and/or EDRU research staff will contact the patients' treatment team and/or emergency services.

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Mentors in both active intervention conditions will receive training in how to respond to situations in which the participants' medical/psychiatric stability is questionable. Mentors and volunteers will receive ongoing (bi-monthly) supervision by a MD or PhD level EDRU clinician with expertise in the treatment of eating disorders. The risk of clinical deterioration is also minimized by ensuring (through monthly contact with outpatient provider) that all participants, including those on the wait-list, are concurrently enrolled in outpatient treatment, expected to minimize risk of clinical deterioration.

3. *Risk of unintentional disclosure of confidential information* All procedures are consistent with HIPAA requirements, including the completion of online assessments using Qualtrics. Research data will be de identified and stored in locked rooms and computer records will be identifiable only by a participant's deidentified study code. PHI will be available to individuals outside the clinic only if requested in writing and if the participant has signed a release form. Patients will receive a notice of privacy policies and be asked to sign a HIPAA form in addition to the consent form. **Additionally, data regarding the mentors will be provided to the research team by Project Heal in de-identified form. The key to the codes will be given to the research team by phone in a confidential setting.**

Methods to Protect Confidentiality

Describe the data management plan and the methods you will employ to protect subject privacy and the confidentiality of research data. The section should detail how information will be collected, recorded, coded, stored, transmitted, and as applicable, shared with other investigators so as to minimize risks related to breach of confidentiality. Confirm that identifiers are removed, to the extent possible, from research data, and explain if there are links between subject identity and research data, or if the data is anonymous. Also, indicate where the data is stored, who is responsible for its safekeeping, and who has access to subject identity and codes, if any, which cross-link research data and subject identity. Confirm that identifiable data is not collected, stored, or transmitted by mail, fax, on removable drives, laptops, or via the internet without proper protections, e.g. encryption.

To protect patient confidentiality, all data collected will be kept confidential and used for professional purposes only. Information will be available to the patient's physician or other health services only if directly requested in writing and the participant signs a release form. Identifying information will be kept separate from research records. All patient records at NYSPI will be kept in secure, locked offices within the facilities, and all forms will be identified with only the study code. All electronic data will be stored on computers that are password protected. Only code numbers will appear on any data and documents used for evaluation or statistical analyses. Publications using this data will be done in a manner that fully protects subjects' anonymity.

Direct Benefits to Subjects

Describe only benefits to individual subjects that are likely to accrue during the study itself. Do not include subject compensation or treatment to be provided at the end of the study, as these do not figure into the IRB's risk benefit considerations. Do not describe diagnostic and evaluation components unless subjects receive clinical feedback. Do not describe the anticipated scientific benefits of the research. Some studies offer no direct benefit to subjects.

There are no benefits guaranteed from participation in the study. Participants may benefit from being paired with a mentor and/or from social support unrelated to their eating disorder recovery. Mentorship enable patients to feel an increased sense of support, connection, and accountability. Mentorship also may provide patients with positive role models and a sense of hope that recovery is possible. Social support is expected to promote social connectedness and a sense of purpose beyond the eating disorder. However, the effectiveness of neither group has been previously evaluated, so no direct benefit is guaranteed.

References

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2. Engel SG, Wittrock DA, Crosby RD, Wonderlich SA, Mitchell JE, Kolotkin RL. Development and psychometric validation of an eating disorder-specific health-related quality of life instrument. The International journal of eating disorders. 2006;39(1):62-71. doi: 10.1002/eat.20200. PubMed PMID: 16345055.

3. Spielberger CD, Edwards CD, Lushene RE, Montuori J, Platzek D. STIAC preliminary manual. Palo Alton, CA: Consulting Psychologists Press; 1973.

4. Kroenke K., Spitzer R.L., J.B. W. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13.

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Name:_____

Birthdate:_____

Marital status:

i. Married
ii. Single
iii. Divorced
iv. Widowed
v. Other, please state:_____

Occupation:_____

Level of education:

i. Graduate/Professional Training (or higher)
ii. Undergraduate College Degree
iii. Junior College or at least one year of specialized training
iv. High School/ GED
v. Partial High School

Social support mentors only:

Has a close friend of yours or family member struggled with an eating disorder? If so, please detail your connection to this person and their diagnosis to the best of your ability:

_____
_____
_____

Do you lead a support group?_____

Other current or past experience of mentorship/support role?

_____
_____
_____

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Parental Permission to Participate in Research

(Parent CF)

Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and Overview

Relapse rates for eating disorders are high and many teens continue to struggle with eating disorder symptoms even when they are in treatment. Project HEAL is a non-profit organization focused on helping individuals with eating disorders find appropriate and affordable treatments and recover from eating disorders. Project HEAL recently developed *Communities of HEALing*, which includes adjunct interventions for eating disorder patients focused on mentorship and social support. The purpose of the current study is to evaluate whether these adjunct interventions can help individuals with eating disorders stay in treatment and achieve lasting recovery. We (the researchers at the Eating Disorders Research Unit at the New York Psychiatric Institute) have agreed to help Project HEAL evaluate if their programs help people who want to recover from an eating disorder. We are the investigators and we will be carrying out the study.

If your teen is being considered for this study, they have recently received treatment for an eating disorder in a structured treatment setting (hospital, residential, partial hospital program (PHP), or intensive outpatient program (IOP)) and they are now in treatment with a licensed professional. If your teen becomes a study participant, they will be randomly assigned to one of three things. Random assignment means that which option your child gets is up to chance, like flipping a coin. We cannot choose which option your child gets, you cannot choose which option your child gets, and your child cannot choose which option they get. Instead, it is chosen totally randomly, using a computer program. Based on the random assignment, your child would receive either six months of peer mentorship from a peer who has recovered from an eating disorder, six months of social support mentorship from someone who has not had an eating disorder, or your child will be asked to be on a wait-list. If your child is on the wait list, they would receive mentorship after six months. Your teen would also be asked to complete interviews and questionnaires about their symptoms.

Voluntary

Participation in this research study is voluntary. If you or your teen decides not to participate, or if they later decide to stop participating, they will not lose any benefits to which they are entitled. If your teen decides not to participate, your teen may still seek treatment at New York

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Psychiatric Institute and be involved in Project HEAL in other ways. We will notify you of any significant new findings about this kind of research that may affect your willingness to have your teen participate in this project.

Alternatives to Participation

The alternative to participating is not participating. Your teen may choose to seek peer mentorship or social support through other resources. Your teen cannot be matched with a mentor through Project HEAL unless your teen participates in the research study. The interventions offered as part of this study are not treatment. Even though your child is already in treatment, you can always pursue other treatment options for your child. If you wish, we can provide referrals for eating disorder treatment.

Procedures

If your teen is in the study, they will be randomly assigned (based on chance) to receive one of three things. The first is peer mentorship, in which your teen will meet weekly with a peer over age 18 who has recovered from an eating disorder. During weekly meetings, your teen and their mentor will discuss eating disorder symptoms and how to overcome them. The second is social support mentorship, in which your teen will meet weekly with a peer mentor over age 18 who has not had an eating disorder. During weekly meetings, your teen and their mentor (and 1-3 other group members) will engage in a variety of community, advocacy, and leisure activities. In the third condition, your teen will be on a wait-list for six months, and then they will receive mentorship for six months. All mentors have been interviewed and trained by Project HEAL and have had background checks. Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider). Your teen will be expected to exchange contact information with their mentor so they can contact each other between meetings if necessary (for scheduling purposes). If your teen does not have a phone, they may email with their mentor. All charges resulting from phone or data usage are billed to you or your teen and are not covered by Project HEAL and/or Columbia University Medical Center. If you are participating in the study with an online mentor, your teen will be asked to communicate with them using Face Time or Skype.

After each weekly meeting with their mentor, your teen will be asked to answer a few questions using Qualtrics, a HIPAA-compliant online app, about where the meeting took place, what

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they talked about, what they did, as well as their symptoms in the past week. If your teen is on the wait-list, these questions will be about their symptoms only. At the beginning of the study and every month throughout the intervention, your teen will be asked to complete several additional questionnaires using the app. The questionnaires are estimated to take 20 minutes to complete each time. If your teen is assigned a peer mentor, they will also be asked to use Recovery Record, a separate, HIPAA-compliant app, designed to provide recovery support (e.g., coping strategies, self-monitoring tools), but we will not collect any data using this tool. While we encourage your teen to use it, it is not required. We will also ask for your permission to contact your teen's primary treatment provider at the beginning of the study and once each month during the study. We will ask your teen's treatment provider to tell us your teen's height and weight and whether they are still involved in treatment. We will also ask your teen and their treatment provider to answer the same questionnaires after 12 months from when your teen began the study.

If we find out from your teen's treatment provider that your teen stopped attending treatment, or if your teen's provider thinks that he or she need more treatment and you choose not to pursue it, or if your teen misses 3 meetings in a row (or 2 meetings per month for 2 months in a row), then your teen will not be able to continue meeting with their mentor. If this happens, we will speak with you and your child and ask if you/your child wish to continue completing the questionnaires. It is entirely up to you and your child whether they do so or not. Even if your child says yes, they can stop at any time. If there is a mismatch with your teen's assigned mentor, we may be able to match your teen with a new mentor one time only. If your teen receives treatment at a higher level of care (e.g., a hospitalization) while participating in the study, your teen may not attend mentorship sessions while in treatment at a higher level of care. After your teen is discharged, he or she may attend remaining mentorship sessions that fall within the study time frame.

Risks and Inconveniences

There is a risk that completing interviews and questionnaires in this study may be distressing. Your teen may always skip a question. If your teen experiences distress as a result of filling out the questionnaires, we will ask them to let us know. We will be available to talk with your teen. There is a risk that your teen's symptoms may worsen when they are participating in an intervention or on the wait list. We will talk with your teen's treatment provider every month to monitor their weight and make sure they are still in treatment. We will not allow your teen to continue attending meetings with their mentor if they have stopped attending treatment. While we will take all measures possible to protect privacy, there is a risk of disclosure of confidential information. When we suspect that your teen's safety

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is at risk, their mentor or the study team may talk with you and your teen's treatment provider and/or emergency services if warranted. If we suspect that your teen's safety is at risk, we will talk with you and your teen and help you find appropriate services. Your teen may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

This study was not designed to be of direct benefit to your teen. However, your teen may benefit from working with a peer mentor or social support mentor on your eating disorder symptoms or on other aspects of life. However, the mentorship interventions may not help your teen, and your teen may do worse. Your teen's part may help researchers understand whether adjunct social support and mentorship interventions can help improve eating disorder symptoms.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot disclose this information without your consent. Records will only be available to research staff, and to Federal, State and Institutional regulatory personnel who may review the records as part of routine audits. Your teen's name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Some research information will be stored on computers that are password protected. Information which would allow your teen to be identified (like name, address, social security number) will be stored separately.

Study Compensation

There is no compensation provided for participating in this study.

In Case of Injury

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances. New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide

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compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Ranzenhofer will be available to answer to the best of her ability any questions that may arise now or in the future about the procedures or about your response to the procedures. She can be reached at 646-774-8065.

If you have any questions about your teen's rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at 646-774-7155 during regular office hours.

Documentation of Consent

"I have discussed the proposed research with this parent/guardian and his/her child including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The parent/guardian has had an opportunity to ask questions and in my opinion is capable of freely consenting for his or her child to participate in this research. The parent or guardian voluntarily agrees to have their child participate in the research study and has provided verbal consent."

Print Name: _____
Person Designated to Obtain Assent
Signed: _____
Date: _____

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Informed Consent for Participation in Research

Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and Overview

Relapse rates for eating disorders are high and many individuals continue to struggle with eating disorder symptoms even when they are participating in treatment. Project HEAL is a non-profit organization focused on helping individuals with eating disorders find appropriate and affordable treatments and recover from eating disorders. Project HEAL recently developed *Communities of HEALing*, which includes adjunct interventions for eating disorder patients focused on mentorship and social support. The purpose of the current study is to evaluate whether these adjunct interventions can help individuals with eating disorders stay in treatment and achieve lasting recovery. We (the researchers at the Eating Disorders Research Unit at the New York Psychiatric Institute) have agreed to help Project HEAL evaluate if their programs help people who want to recover from an eating disorder. We are the investigators and we will be carrying out the study.

If you are being considered for this study, you have recently received treatment for an eating disorder in a structured treatment setting (hospital, residential, partial hospital program (PHP), or intensive outpatient program (IOP)) and are now in treatment with a licensed professional. If you are a study participant, you will be randomly assigned to one of three things. Random assignment means that which option you get is up to chance, like flipping a coin. We cannot choose which option you get and you cannot choose which one you get. Instead, it is chosen totally randomly, using a computer program. Based on the random assignment, you would receive either six months of peer mentorship from a peer who has recovered from an eating disorder, six months of social support mentorship from someone who has not had an eating disorder, or you will be asked to be on a wait-list. If you are on the wait list, you would receive mentorship after six months. The study also involves completing interviews and questionnaires about your symptoms.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. If you decide not to participate, you may still seek treatment at New York Psychiatric Institute and

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you may still be involved in Project HEAL in other ways. You will be notified of any significant new findings about this kind of research that may affect your willingness to continue to participate in this project.

Alternatives to Participation

The alternative to participating is not participating. You may choose to seek peer mentorship or social support through other resources. You cannot be matched with a mentor through Project HEAL unless you participate in the research study. The interventions offered as part of this study are not treatment. Even though you are already in treatment, you can always pursue other treatment options. If you wish, we can provide referrals for eating disorder treatment.

Procedures

If you are in the study, you will be randomly assigned (based on chance) to receive one of three things. The first is peer mentorship, in which you will meet weekly with an adult peer who has recovered from an eating disorder. During weekly meetings, you and your mentor will discuss your eating disorder symptoms and how to overcome them. The second is social support mentorship, in which you will meet weekly with an adult mentor who has not had an eating disorder. During weekly meetings, you and your mentor (and 1-3 other group members) will engage in a variety of community, advocacy, and leisure activities. In the third condition, you will be on a wait-list for six months, and then you will receive mentorship for six months. All mentors have been interviewed and trained by Project HEAL and have had background checks. Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider). You will exchange contact information with your mentor so you can contact each other between meetings if necessary (for scheduling purposes). All charges resulting from phone or data usage are billed to you and are not covered by Project HEAL and/or Columbia University Medical Center. If you are participating in the study with an online mentor, you will be asked to communicate with your mentor using Face Time or Skype.

After meetings with your mentor, you will be asked to answer a few questions using Qualtrics, a HIPAA-compliant online app, about where you met, what you talked about, as well as your symptoms in the past week. If you are on the wait-list, these questions will be about your

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symptoms only. At the beginning of the study and every month throughout the intervention, you will be asked to complete several additional questionnaires on the app. The questionnaires are estimated to take 20 minutes to complete each time. If you are assigned a peer mentor, you will also be asked to use Recovery Record, a separate HIPAA-compliant online application, designed to provide recovery support (e.g., coping strategies, self-monitoring tools), but we will not collect any data using this tool. While we encourage you to use it, it is not required. We will ask you to give us permission to contact your primary treatment provider at the beginning of the study and once each month during the study. We will ask your treatment provider to tell us your height and weight and whether you are still involved in treatment. We will also ask you and your provider to answer the same questionnaires after 12 months from when you began the study.

If we find out from your treatment provider that you stopped attending treatment, or if your provider thinks that you need more treatment and you choose not to pursue it (e.g., hospitalization), or if you miss 3 meetings in a row (or 2 meetings per month for 2 months in a row), then you will not be able to **continue meeting with your mentor. If this happens, we will speak with you and ask if you wish to continue completing the questionnaires. It is entirely up to you whether you do so or not. Even if you say yes, you can stop at any time.** If there is a mismatch with your assigned mentor, we may be able to match you with a new mentor one time only. If you receive treatment at a higher level of care while you are in the study, you may not attend mentorship sessions while you are in treatment at a higher level of care. After you are discharged, you may attend remaining mentorship sessions that fall within the study time frame.

Risks and Inconveniences

There is a risk that completing interviews and questionnaires in this study may be distressing. You may always skip a question. If you do experience distress as a result of filling out the questionnaires, we will ask you to let us know. We will be available to talk with you. There is a risk that your symptoms may worsen when you are participating in an intervention or on the wait list. We will talk with your treatment provider every month to monitor your weight and make sure you are still in treatment. . We will not allow you to continue attending meetings with your mentor if you discontinue treatment. While we will take all measures possible to protect your privacy, there is a risk of disclosure of confidential information. The procedures associated with risk of disclosure of confidential information include meeting in locations that are not private, such as a coffee shop), and filling out questionnaires using online applications. If we suspect that your safety is at risk, we

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will talk with you and help you find appropriate services. You may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

This study was not designed to be of direct benefit to you. However, you may benefit from working with a peer mentor or social support mentor on your eating disorder symptoms or on other aspects of your life. However, the mentorship interventions may not help you, and you may do worse. Your part may help researchers understand whether adjunct social support and mentorship interventions can help improve eating disorder symptoms.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot disclose this information without your consent. Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Some research information will be stored on computers that are password protected. Information which would allow you to be identified (like name, address, social security number) will be stored separately.

Study Compensation

There is no compensation provided for participating in this study.

In Case of Injury

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide.

In addition, we will provide assistance in arranging follow up care in such instances. New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide

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compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Ranzenhofer will be available to answer to the best of her ability any questions that may arise now or in the future about the procedures or about your response to the procedures. She can be reached at 646-774-8065.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at 646-774-7155 during regular office hours.

Documentation of Consent

"I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research. The participant voluntarily agrees to participate in the research study and has provided verbal consent."

Print Name: _____
Person Designated to Obtain Consent

Signed: _____

Date: _____

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Protocol #7533 assigned
Questions? Contact Dr. Ranzenhofer at 646-774-8065
Version: 3/14/17

Informed Consent for Participation in Research (Mentor version)

Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and Overview

The purpose of the current study is to evaluate whether different mentorship interventions can help individuals with eating disorders stay in treatment and achieve lasting recovery. We are asking mentors involved in these interventions for permission to use information previously collected as part of interviewing to be a mentor as well as information collected for study fidelity. In addition, we are asking mentors to fill out a short questionnaire.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. You can keep being a mentor whether or not you decide to participate in the study. You will be notified of any significant new findings about this kind of research that may affect your willingness to continue to participate.

Alternatives to Participation

The alternative to participating is not participating.

Procedures

We are asking mentors permission to use data previously collected as part of interviewing to be a mentor, including demographics and diagnosis history, as well as data collected to measure fidelity. We are also asking mentors to fill out a short questionnaire that includes demographic information.

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Risks and Inconveniences

While we will take all measures possible to protect your privacy, there is a risk of disclosure of confidential information. The procedures associated with risk of disclosure of confidential information include filling out questionnaires using online applications. All communication of data among the research team will be done in a deidentified, coded format, in a confidential setting.

Benefits

This study was not designed to be of direct benefit to you.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject records, though they cannot disclose this information without your consent. Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Some research information will be stored on computers that are password protected. Information which would allow you to be identified (like name, address, social security number) will be stored separately.

Study Compensation

There is no compensation provided for participating in this study.

In Case of Injury

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide.

In addition, we will provide assistance in arranging follow up care in such instances. New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide

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compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Ranzenhofer will be available to answer to the best of her ability any questions that may arise now or in the future about the procedures or about your response to the procedures. She can be reached at 646-774-8065.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at 646-774-7155 during regular office hours.

Documentation of Consent

"I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research. The participant voluntarily agrees to participate in the research study and has provided verbal consent."

Print Name: _____

Person Designated to Obtain Consent

Signed: _____

Date: _____

Informed Assent for Participation in Research
(Child and Adolescent patients)
Evaluation of Communities of Healing mentorship and social support programs for individuals with eating disorders: Assessment of feasibility and efficacy

Purpose and overview

Recovering from an eating disorder can be very difficult. Some teenagers continue to have trouble even when they are getting treatment. There is an organization called Project HEAL that was started to help people recover from eating disorders. Project HEAL started a new program called Communities of HEALing that includes two programs where people with eating disorders get support from other people to help them recover. The purpose of this research study is to see how well these programs work to help people recover from eating disorders. We (the researchers at the Eating Disorders Research Unit at the New York State Psychiatric Institute) are helping Project HEAL figure out if their programs help people who want to recover from eating disorders.

If we ask you to be in the study, you have recently gotten treatment for an eating disorder in hospital or other program and you are now in treatment with a doctor or therapist. If you participate in the study, you would participate in one of three programs. You would have an equal chance of being in each program. We cannot choose which program you are in and you cannot choose which program you are in. Instead, it is chosen totally randomly, using a computer program. The first program is peer mentorship. In this program, you would meet and talk with someone else (a peer) who has already recovered from an eating disorder. The second program is social support mentorship. In this program, you would do activities not related to the eating disorder with someone who has not had an eating disorder. In the third, you would wait for six months and then get mentorship for six months afterwards. In order to be in the study, you would need to be okay with getting any of the options, since you do not get to pick which one you get. We would also ask you to answer questions about your eating, your thoughts and feelings, and what you do and talk about with your mentor.

Voluntary

You can choose if you want to be in the study. You can stop being in the study any time you want. Even if you say yes now, you can change your mind later. If you decide not to participate, you may still get treatment at New York Psychiatric Institute and you may still be involved in Project HEAL in other ways. We will tell you any new information that may affect whether you want to be in the study.

Alternatives

The alternative to participating is not participating. You may choose to get support from people in other ways. You cannot be matched with a mentor through Project HEAL unless you participate in the research study. The programs offered as part of this study are not treatment. Even though you are already in treatment, you can always go somewhere else for treatment. If you or your parent wants, we can help you find eating disorder treatment.

Procedures

If you are in the study, you will be randomly assigned to one of three things. You would have an equal chance of each one. We cannot choose which option you get and you cannot choose which one you get. Instead, it is chosen totally randomly, using a computer program. The first is peer mentorship. In peer mentorship, you will meet every week with someone (over age 18) who has recovered from an eating disorder. During your meetings, you and your mentor will talk about how to overcome the eating disorder. The second is social support mentorship. In social support mentorship, you will meet every week with someone (over age 18) who has not had an eating disorder. During your meetings, you and your mentor (and 1 - 3 other group members) will do different types of activities in the community, like seeing a movie, going to a museum, doing an art project, or writing letters to help raise money for eating disorder treatment. In the third, you would be on a wait-list for six months, and then you will get mentorship for six months. You may exchange contact information with your mentor so you can call or text between meetings if necessary (for scheduling purposes). If you don't have a phone, you will be asked to email your mentor. If you are in the study with an online mentor, you will be asked to communicate with them using Face Time or Skype. Mentors attend bi-weekly mandatory phone supervisions with the research team. If your mentor is worried about your safety, they may reach out to us. If we are not able to reach you, we may reach out to your mentor. We may communicate with your mentor to discuss the situation and address an issue (e.g., if we have not heard from your provider).

After meetings with your mentor, we will ask you to answer questions using an app called Qualtrics about where you met, what you talked about, what you did as well as your symptoms in the past week. If you are on the wait-list, these questions will be about your symptoms only. At the beginning of the study and every month while you participate, you will be asked to answer several

additional questions using the app. The questions are about your eating, your thoughts, and your feelings. They take about 20 minutes each time. If you are assigned a peer mentor, we will ask you to use a separate app called Recovery Record. It was designed to provide recovery support (e.g., coping strategies), but we will not collect any data using this tool. While we encourage you to use it, it is not required. We will also ask your parent to say it is okay for us talk with your doctor during the study (once a month). We will ask your doctor to tell us your height and weight and whether you still go to treatment.

If we find out from you doctor or therapist that you stopped going to treatment, or if your doctor thinks that you need more treatment and you do not get it, or if you miss 3 meetings in a row (or 2 meetings per month for 2 months in a row), then you will not be able to continue meeting with your mentor. If this happens, we will speak with you and ask if you wish to complete the weekly questionnaires. It is entirely up to you whether you do so or not. Even if you say yes to filling in the weekly forms initially, you can stop at any time. If you do not get along with the mentor you get, we may be able to match you with a new mentor one time. If you go to the hospital while you are in the study, you may not go to meetings with your mentor while you are in the hospital. After you leave the hospital, you may go to any mentorship sessions that are left until the six months is over.

Risks and Inconveniences

You may feel uncomfortable being asked questions about your thoughts or feelings. We will be able to talk with you if you are upset about any of the questions. You may choose to not answer a question. There is a risk that your eating disorder could get worse while you are in the study. We will talk with your doctor once a month to check your weight and make sure you are still seeing your doctor or therapist. We will not allow you to continue attending meetings with your mentor if you stop going to treatment. There is a risk that your private information could become known to people who are not involved in our study. This is not likely to happen, but it could. The ways this could happen include having meetings with your mentor in locations that are not private, such as a coffee shop, and filling out questionnaires using online applications (Qualtrics). We will do what we can to prevent this. If we find out that you or another child or older person is being hurt, we will let someone know and get you help**.** If we are worried about your health or safety, we will talk with you and your parent and help you figure out what to do. You may be offered hospitalization at the New York State Psychiatric Institute if there is space available.

Benefits

There are no direct benefits to you for participating. You might benefit from working with a peer mentor or social support mentor, but since it is a research study, we do not know for sure that this will help. The mentorship interventions may not help you, and you may do worse. Your part may help us understand whether mentorship can help people who are trying to recover from an eating disorder.

Confidentiality

At the beginning of the study, you will be assigned a "code name," so we won't use your real name when we look at your data. All of your data will be kept in locked offices and on computers that are protected by passwords. We use a secure app to collect the data that you fill out on a smart phone or computer.

Study Compensation (payment)

There is no compensation (payment) for being in the study.

Questions

If you have questions about this research study, we will try to answer them. If you have questions later on, you can call Dr. Lisa Ranzenhofer at (646) 774-8065.

Documentation of Consent

"I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research. The participant has provided verbal assent to participate in the study."

Person designated to obtain consent:

Print Name: _____

Signed: _____

Date: _____