Title: Comparison of E-Health vs. In-Person Delivered Family Psychoeducation Treatment

NCT ID: NCT02032680

Document date: September 20, 2018

1.0. Research Study methods

This project will conduct a randomized comparative effectiveness clinical trial with 89 Veterans with schizophrenia or schizoaffective disorder (SZ/SZA). In addition family members or other informal support persons will be invited to formally join the study with each Veteran with SZ/SZA who consents to join the study. These subjects will be randomized into one of two study arms: 1) the Daily Support Website (DSW), this group will receive access to the DSW intervention that includes three facilitated group forums, Ask Our Experts Your Questions, the Questions and Answers Library of previously asked and answered questions, educational materials, tutorials and self-help guides, libraries, and community resources lists; and 2) in-person Multi-Family Group (MFG). This is the standard in-person method for providing multi-family psycho-education to veterans with schizophrenia and their supporters (e.g., family members) in the VA. This group will receive the standard and manualized MFG treatment provided by the VA, it will be provided by trained clinicians, and supervised by those who provide supervision in the VA. In both study arms, participants will receive all treatment as usual (TAU). In the DSWDSWDSW arm, as needed Veterans can receive a new or refurbished computer and Internet access at home.

All Investigators and staff on the research team will have completed educational training required by the VA.

Recruitment

Veterans will be recruited from the two VA campuses in the Pittsburgh area, University Drive, and H.J.Heinz, and five Community Based Outpatient Clinics (CBOCs). Veterans will be randomly assigned to the two treatment arms, and will be stratify by: distance from/difficulty traveling to the VA medical center (<40 min. or do not have significant transportation barriers, vs. >=40 min. or have significant transportation barriers); number of prior psychiatric hospitalizations (<5 vs. ≥5); and gender. The study statistician will generate randomization tables prior to beginning recruitment, and these will be used to assign participants to one of the arms. Flyers describing the study will be available at each site.

Staff at the two VA campuses in the Pittsburgh area, University Drive, and H.J.Heinz, will inform eligible/potentially eligible Veterans and family about the study. If a Veteran is interested, the Veteran can call a recruiter, a staff member can provide a study recruiter with contact information if a waiver is authorized by the Veteran, and the recruiter will follow-up with the Veteran, or alternatively a Veteran could set a time to meet with a recruiter to learn more about the study. Participants will also be recruited through clinician referrals and review of clinic rosters. A partial Health Insurance Portability and Accountability Act waiver will be obtained to allow review of individuals' charts in order to determine potential eligibility prior to a Veteran's clinic appointment. The charts of potentially eligible Veterans will be reviewed to confirm that each meets study criteria. Eligible individuals will then be approached at their clinic appointments to discuss the study.

During recruitment a research staff member will review and eligibility criteria with veterans. These are: have a DSM-V diagnosis of schizophrenia or schizoaffective disorder; are 18-70 years old; are not in another family treatment, and; are able to speak and read English at the 5th grade level.

To enhance recruitment of Veterans we will utilize the REORDER intervention (HSR&D grant IIR 04-255, Dr. Dixon PI and consultant to this project, and Dr. Glynn a Co-Investigator on the REORDER study, and a Co-Investigator on this project). REORDER is a method that is used during the recruitment process, prior to consent. It has been shown to increase recruitment of veterans with a severe mental illness (SMI) into treatment studies and increase their willingness to agree to have their family join the treatment as well. REORDER has two phases: the first focuses on the Veteran, the second involves meetings with the family. We will utilize the first or Veteran phase, with the option to also use the second or "family phase" as needed, for example, depending on whether it is needed to encourage a family to join treatment with a veteran. In Phase I, which can have three or more sessions, a Veteran meets with an appropriately trained research staff member who provides evidence about family involvement in treatment, and helps the veteran to consider the role of family involvement in his/her recovery. In this phase the research staff member will identify the resources of in-person MFG or DSW that might help the Veteran achieve his/her goals. This should improve the acceptability of receiving treatment, and willingness to invite family to participate. In Phase 2, the same information and approach is used when meeting with family members.

Consenting

Consenting will occur in face-to-face meetings between a study staff recruiter and a veteran, a veteran's family member/supporter or a Veteran and his/her family member/supporter. During the consenting process, if a potential participant decides that one or more of the conditions of the study are unacceptable, we will note the issues for which a person voiced concern to allow us to track the various types of concerns voiced during recruitment. These data will allow us to explore the acceptability of the two treatment methods and various components of the interventions, problem areas for Veterans, and areas where possible adjustments might lead to more widespread acceptability of both of these two approaches to providing this treatment. This information could be valuable to the design of both in-person and e-health models of treatment delivery.

Identification of Family member/Support person for study participation and data collection

A standard question will be asked of the Veteran to identify the person who is their primary family supporter or other primary support person. To verify this, a similar question will be asked of the support person identified. If there is a tie between two or more support persons (e.g., family members), it will be the person who spends the most face-to-face time with the Veteran who will be used as the "primary" support person for data collection.

Recruitment of Family/Support persons

To recruit family members and support persons, the Veteran will be asked to identify appropriate persons (family, other support persons). A brochure explaining the study will be sent to such persons, either by mail or the Veteran will provide it to him or her. Staff will also tell family about the study when they see them at a clinic, or talk with them as part of standard clinical care over the telephone. Family and support persons will be provided with a number and contact information of a study recruited, who they can get in touch with for additional information concerning the study. If they are interested in participating they will be formally consented to join the study by research staff. The primary support person/family member for the veteran must be ≥18 years old and able to speak and read English at the 5th grade level.

1. After consenting, and then baseline data collection, participants will be assigned to one of two treatment arms. Those in each arm will receive a different form of multi-family psychoeducation treatment. One arm will receive Multi-

Family Group (MFG). This treatment is provided in in-person group meetings that occur every other week for one year. The other arm will receive the treatment for one year via the Daily Support Website.

a. Multi-Family Group (MFG). Participants assigned to the Multi-Family Group arm will receive the standard Multi-Family Group treatment provided by the VA. The treatment includes: individual participant and individual family meetings with the study clinician(s) who is providing the MFG treatment, using in-person and phone meetings; attending a multi-family group educational meeting (the Psychoeducational Survival Skills Workshop) that will be attended by the veterans and supporters who will be in a particular group, the clinicians leading the treatment, and potentially other experts who have specific content expertise and will provide brief presentations on a particular educational topic (e.g., how medications act to treat schizophrenia); and bi-weekly meetings of the group that will be led by the two clinicians. The study clinicians will be supervised by the study Investigators.

The MFG model begins with two participant engagement activities. The first activity is joining sessions where the therapist meets with each individual participant (veteran, and when present supporter), to develop a collaborative relationship and discuss MFG. These meetings can involve both individual participant meetings as well as joint family meetings (i.e., veteran and his/her supporters). The number of meetings varies by individual and family need (as jointly determined by the therapist and the participants). Following these meetings with the participants who will form an individual in-person group, a Psychoeducational Survival Skills Workshop (PSSW) is held. The PSSW varies in length from 2 to 7 hours, depending on the educational needs of the participants and the amount of time they are able to tolerate a meeting. The PSSW includes educational presentations on schizophrenia, and group discussions. The specific educational topics are chosen and adapted based on the needs of the participants as determined by the therapists during the joining sessions. Once the PSSW is held the multi-family treatment sessions begin on a bi-weekly basis. Each meeting is structured around reviewing the results of a previous meeting's effort to solve a member's problem and then identifying one new problem of a group member to be solved via the group problem solving process.

b. Daily Support Website (DSW). Participants assigned to be in the Daily Support Website arm will receive access to this website and its associated functionalities. The DSW provides the following five resources. (1) Three on-line group forums. One for persons with SZ/SZA only (the SZ/SZA peer group), one for family/supporters only, and a combined group for both persons with SZ/SZA and support persons. In each group the therapists emphasized discussions that focus on problem-solving, alleviating stresses, and encouraging peer interactions. (2) Educational materials and tutorials. (3) A section to ask questions and receive an answer from the therapists associated with the project. (4) A library of previously asked and answered questions. (5) A list of community resources. Those who do not have a computer will have a computer (e.g., laptop, touch pad, or chrome book) provided to them, and Internet service, both free of charge to allow them to participate in the intervention. After their participation is over they will return the equipment.

The DSW treatment begins with two participant engagement activities. The first activity is joining sessions where the study therapist(s) meets with each individual participant (veteran, and when present supporter). These meetings can be in-person, via phone or over the internet. The purposes of the meetings are to develop a collaborative relationship, discuss the DSW, facilitate comfort with the e-health approach to receiving treatment, and develop an individual goal or identify a current 'issue' or 'complaint' that is bothering the individual. These meetings can involve both individual participant meetings as well as joint family meetings (i.e., veteran and his/her family/supporters). The number of meetings varies by

individual and family need (as jointly determined by the therapist and the participants). During the initial treatment period a therapist or research staff member may call a participant to ensure there are no issues with accessing the DSW, such as problems with equipment or lack of understanding of one or more aspects of using the DSW.

2. Participant Data collection. Outcomes data will be collected at scheduled time points of baseline (0), 6, 12, and 15 months. Each of these sessions is estimated to take about 2 hours. The data to be collected is described in Table 4.1.

Table 1.1. Data collection

Information	Measure
1.1. Collected Only On Veterans	
Patient symptom severity (positive, negative) & relapse	SANS, SAPS (Primary Veteran Outcome)
Hospitalizations & ED visits	Medical records, provider verification
Community participation	Community Participation Measure
1.2. Collected On Veterans and their Primary Family Member/Supporter	
Health services utilization	Question, Services utilization check list, CPRS, or billing data
Medication adherence (of patient)	Standardized structured interview
Social support & loneliness	MOS & Social Loneliness Scale questionnaires
Stress	Perceived Stress Scale (PSS)
Quality of life	Quality of Life interview
Knowledge of SZ/SZA	Knowledge about Schizophrenia Interview
Coping style/problem solving skills	Social Problem Solving Inventory
Sociodemographics, background, technology experience	Questionnaire
Cognitive function	RBANS
Treatment satisfaction	CSQ-8
Participant treatment exposure	Records/logs and computer server logs
Treatment: initiation, engagement, attendance, drop-out	Records/logs and computer server logs
DSW usage	Usage automatically collected by server
Commitment to DSW	Online Community Commitment Survey (OCCS)
DSW website evaluation	Web Evaluation Instrument (Appendix 8)
Participant treatment contact time	Clinician & staff logs, DSW server logs (includes video use)

Time providing each treatment	Detailed logs and CPRS progress notes
1.3. Collected Only On Primary Family Caregiver/Support Person	
Psychological distress/burden	Caregiver burden (primary family member outcome)
1.4. Collected On Therapists and Research Staff Providing the Treatments	
Therapist & staff contact time	Records/logs
Therapist & staff time to provide treatments	Records/logs
1.5. Inform Future Implementation Efforts: Collected from Clinicians and Participants	
Semi-structured interviews	Based on Getting To Outcomes implementation framework

1.1. Collected Only on Veterans with SZ/SZA

1.1.1. Symptom severity and Relapse (SANS, SAPS, BPRS). Illness symptom severity will be assessed using the Scale for the Assessment of Positive Symptoms (SAPS) (the primary patient positive symptoms outcome) and the Scale for the Assessment of Negative Symptoms (SANS) (the primary patient negative symptoms outcome). The SAPS and SANS have high internal consistency (Cronbach's >= 0.66-0.83). The summary SAPS score has high inter-rater reliability (>0.90) for our trained raters, as has the SANS (>0.80), which are comparable to published inter-rater reliabilities for these scales. We will also administer the Brief Psychiatric Rating Scale (BPRS). Relapse or 'significant exacerbation' will be defined on the basis of the standard BPRS criteria.

1.1.2. Hospitalizations & Emergency Department (ED) Visits. We will measure both the number of times that a patient has an ED visit, or is hospitalized for a psychiatric reason, and the number of days for each hospitalization. We will identify this information via self-report and collect CPRS records, or if not a VA facility, the medical records from the provider via a release of information from the participant.

1.1.3. Community Participation Outcomes. The Community Participation Measure is designed to measure changes in participation in 26 community activities (e.g., shopping, going to a coffee shop, church, or movie). It has good internal consistency (Cronbach's alpha=0.9) and test-retest reliability (r>0.7). We have norms available from Dr. Mark Salzer (personal communication).

1.2. Collected On Both Veterans with SZ/SZA and their Family Members

1.2.1. Health Services Utilization. These will be gathered from two sources: 1) the electronic medical records of the VA and affiliated sites, and; 2) for outside providers a checklist that we have used in previous studies will collect simple counts of utilization and provider information, for which we will obtain a release of medical records from subjects and collect utilization data from each provider. Utilization will be treated as both an outcome measure and for behavioral health visits outside of the study as mediators of improvement.

1.2.2. Antipsychotic Medication Adherence. Medication adherence will be assessed using relatively standard methods that involve obtaining self-report information on medication adherence from a patient and their primary family caregiver. Patients are asked about the extent to which they took their medication as prescribed since the last interview, or at baseline, in the past 3-months, using a five point scale from "1) never missed taking my medication" to "5) I stopped taking the medication altogether." The primary family caregiver will also be asked the question about the patient. If there

is disagreement the accepted procedure is to take the lower of the two ratings as the patient's degree of adherence.

1.2.3. Social Support & Loneliness. The MOS Social Support Survey will be used to assess perceived and actual social support. It has excellent internal consistency (Cronbach's alpha from .90 to .97) and composite reliability (ranging from .93 to .97), and is relatively brief (19 items).The Revised UCLA Social Loneliness Scale will assess subjective feelings of loneliness and isolation. It has high internal consistency (α=.89-.94), good test-retest reliability (r=0.73), and convergent and construct validity.

1.2.4. Perceived Stress. Perceived stress will be measured with the 14 item Perceived Stress Scale. The scale has good internal reliability (α=0.85) and test-retest correlation (r=0.85).

1.2.5. Quality of Life, Functioning. The Quality of Life Interview (QOLI) contains both subjective and objective measures of quality of life including, living situation, daily activities and functioning, family-related quality of life, social relations, work, personal safety and health as well as a global rating of life satisfaction. The QOLI has been shown to have good test-retest reliability (median *r*=0.72), internal consistency (median >= .85) among its subjective subscales, fair retest reliability (median *r* = .65). It is one of the most widely used measure of QOL with psychiatric populations.

1.2.6. Knowledge of SZ/SZA. The Knowledge about Schizophrenia Interview (KASI), which we used previously, will be used to assess patient and family knowledge about SZ/SZA. The KASI is widely used and has good validity and inter-rater reliability (80% to 100%).

1.2.7. Problem Solving & Coping Style. The Social Problem Solving Inventory-Revised will be used to measure coping style. It has good test-retest reliability (0.73-0.86), internal consistency (0.65-0.9), and criterion validity, and is a common measure of coping style.

1.2.8. General Background, Sociodemographic Information, and Experience with Technology. Background and sociodemographic information will be collected from patients and family using a standard instrument. We will collect information on computer experience, distance from the VA medical center and difficulties traveling to receive treatment, the average amount of weekly face-to-face contact Veteran has with family, and friends, and so forth. We will also use a relatively questionnaire that we have used in previous studies to assess experience with relevant technologies (PCs, internet, web-browsing, smart phone, etc.), and skills with these technologies (e.g., use a mouse, use a printer, make own web-page, etc.).

1.2.9. Repeatable Battery for the Assessment of Neuropsychological Status (RBANS). The RBANS is a general measure of the severity of neurocognitive impairment. It has been shown to have high convergent validity as indicated by correlation with the WAIS-III full-scale IQ (r=0.73), and a composite z score derived from 22 standard measures of IQ, memory, language, motor, attention, and executive function (r=0.79).

1.2.10. Treatment Satisfaction. The Client Satisfaction Questionnaire (CSQ-8) will be used to assess satisfaction with treatment. The CSQ-8 is used worldwide to assess client/patient satisfaction with services. It has good internal consistency (coefficient alpha 0 .86 to 0.94) and concurrent validity.

1.2.11. Participant Treatment Exposure. We will log each subject's contact with treatment in each study arm. In the in-person arm this will include session attendance and any other contact with the therapists relevant to the treatment outside of the sessions. The same will be done for the DSW arm. This will also include any usage of the website, which will be logged on the server for each participant.

1.1.12. Intervention Initiation: DSW and in-person MFG. Treatment initiation will be defined as those that consent to participate in the study and then begin treatment. For both treatments two components of initiation will be tracked. First, will be participating in the Joining Sessions, then will be participation in the PSSW.

1.1.13. Intervention Engagement: DSW and in-person MFG. We will assess the number of Veterans who become engaged in the two treatments. Based on established standards for defining therapeutic treatment engagement as returning for treatment after the intake or initial session, we have previously defined initial engagement in DSW as participating in the PSSW and then using DSW to participate in an on-line group forum (e.g., logging on to the website and posting a 'new member' introduction) and an educational activity (e.g., reading an article). For in-person MFG intervention engagement will also be participating in the PSSW and then attending a first in-person group meeting.

1.1.14. Intervention Attendance/Commitment: DSW and in-person MFG. The number of weeks that participants attend each treatment will be assessed. For DSW this is defined as logging on to the website for at least 15 minutes in a week. For in-person MFG meetings are every other week, so each attendance covers two weeks.

1.1.15. Intervention Drop-out: DSW and in-person MFG. We will track the number of participants who drop-out of treatment in both arms. We will track those who officially drop-out of the study, and those who indicate that they no longer wish to receive treatment, though they may not drop-out of the study.

1.3. Collected Only On Primary Family Caregiver/Support Person

1.3.1. Family member psychological burden: Caregiver Burden Scale. We will measure psychological burden using an instrument we have experience with that was specifically developed for family members of those with SMI. The global score has good reliability (alpha=0.85), and the 6-subscales have good construct validity and reliability (the average alpha reliability score is 0.82).

1.4. Collected Only on DSW Users

1.4.1. DSW website Usage. The programming of the DSW application will automatically identify each user who enters DSW and track every page used, the amount of time spent on each page, any video interactions a user is involved with, and the time of day. It will also identify whether access was via mobile phone or personal computer. By the use of cookies we will determine whether access was from a subject's registered home computer or another computer. These data will allow us to describe subjects' complete usage patterns, and will allow us to break the usage down by each content or page of DSW.

1.4.2. DSW Commitment: Online Community Commitment Survey (OCCS). This 15-item survey measures three distinct forms of on-line commitment (using 7-point Likert scales ranging from "strongly disagree" to "strongly agree"): continuance (e.g., "the content of this site is too valuable for me to stop using"); normative ("this site deserves my loyalty"); and affective ("I feel like a part of the group at this site"). These commitment constructs and scales have been used in prior studies of user behavior in online groups.

1.4.3. Website Evaluation Instrument (WEI). Subjects' satisfaction with, and reactions to, DSW will be assessed using the WEI. Our research team developed and has used the instrument in our prior web studies. It was developed from several standard instruments, and measures helpfulness, understandability, value, ease of use, users' preferences for each of the on-line modules versus obtaining each service using traditional in-person methods, problems, suggested changes, and so forth.

1.5. Collected On Therapists and Research Staff Providing DSW and In-Person MFG

1.5.1. Therapist/staff Contact Time. All therapists will keep a log of all contacts they have with participants in both arms of the study. This will include the date, amount of time and purpose of the contact. For the in-person MFG treatment this will also include time in the sessions. Research staff will also keep track of all contact with participants in all arms and the reasons for the contact.

1.5.2. Therapists & Research Staff Time Providing the Treatments. All therapists will keep detailed records of all activities and the time involved with each activity to provide each of the two treatments, including preparation time, any calling of participants and meetings, time on DSW, etc. This will allow analyses of the clinician time requirements for each treatment. In addition, we will track research staff time involved with each treatment to identify the types and amount of potential "overhead" effort involved in providing each treatment.

1.6. Data Management

The PI will oversee all aspects of data management. The MIRECC Data Center (DC), PI, data manager, and study coordinator will develop a Manual of Operations (MOP) to standardize all staff training and procedures. Study forms will be paper. Completed forms will be stored in a locked file cabinet where only select research team members will have access.

1.8. Power, Sample Size, with Estimation of Missing Subjects Follow-up

The primary Veteran outcomes are SAPS and SANS, and family outcome is caregiver burden. Note, for these outcome measures higher scores indicate worse symptoms. The equivalence ratio that will be tested is the mean of DSW/mean of in-person MFG. For both Veterans and family members we plan for the study to detect equivalence ratios of 1.2 for the two measures of psychotic symptoms (SAPS and SANS) and caregiver burden. In these hypotheses tests the null hypotheses are that DSW outcome means are inferior to MFG. The 'alternative' hypotheses are that outcomes means in the DSW arm are equivalent to outcomes in the in-person MFG arm. If as an example, the symptoms are higher in the DSW arm, and thus the ratio of the mean of the DSW arm to the mean of the in-person MFG arm exceeds 1.2 (i.e. mean of DSW > mean in-person MFG by 20% or more) we will accept the null hypothesis that the mean of DSW > mean of in-person MFG, and that DSW is not as effective as in-person MFG. Any ratio of DSW/MFG that is < 1.2 will cause us to reject the null hypothesis and accept the alternative that they are equivalent. For the caregiver burden scale the equivalence ratio that leads to rejection is slightly smaller, it is 1.17 because there is only 1 primary measure. With 42 subjects per treatment arm, power is >80% with one tailed alpha =0.025 to detect equivalence ratios of 1.2 (and above). For testing whether DSW is superior to in-person MFG on the illness symptom measures we can reverse the ratio and test whether (mean of in-person MFG/mean DSW) is > 1.20. For these sample size calculation we used reported data to estimate the coefficients of variation (CV) of the scales. CVs commonly range from 0.3-0.5 and within this range there were differences in the calculated equivalence ratios. For alpha =0.025, and CV equal to 0.3 the equivalence ratio bound was 1.20 with an increase to 1.29 for a CV of 0.5.

For the in-person MFG arm a correction for nesting of subjects in a group is needed, which increases the number of subjects required. If it is assumed that this dependency is 0.01 and groups are of size 6-8 then variance inflation factor is on the order of 10%, resulting in 46-47 subjects being needed for the in-person MFG arm. Because DSW is available separately for each Veteran and family member it is not necessary to increase the 42 subjects needed for this group. The

42 and 47 subjects per treatment arm respectively (n=89 total) represent the number of Veterans that need to complete their assigned interventions. We expect that the non-completion rate for the in-person MFG arm to be ≤33% and DSW arm to be ≤10%. Given these estimates 70 in person MFG subjects will be enrolled and 47 DSW subjects, for a total of 117 to account for attrition and non-completers. Sample size calculations used PASS (2008, NCSS, LLC, Kaysville Utah.).

1.7. Data Analysis

Overview. Initially we will assess whether our stratified randomization procedures yielded groups equivalent in groups on the stratification factors and other demographic and clinical variables. These analyses will be completed with chi-square statistics for categorical variables (or Fisher Exact statistics as needed for small ns) and t-tests for continuous measures (or Kruskal-Wallace tests if there are serious deviations from normality on these variables). Our initial analyses of the primary dependent measures for Veterans, the SAPS and SANS, and for family members/supporters, Caregiver Burden, will test the mean ratios at time points 12 and 15 months to test for non-inferiority. Then the analyses will be move to mixed effect regressions with the primary effects of interest the interaction between time of measurement and treatment group. The use of mixed effect regression allows us to include subjects with partially complete data, e.g. missing the 6 month interview but have baseline, and 12 month interview data available (see below). Prior to the regression analyses we will also check to insure that the continuous measures (SAPS, SANS, Caregiver Burden) are normally distributed. If these assumptions are violated we will identify appropriate transformations to normalize these outcomes or use different forms of the outcome variables and regression techniques that do not require normality to be appropriate. Also of interest will be differences between completers vs. non-completers across the 2 groups as well as within groups (see specifics below under Aims 1 and 2).

1.7.1. Specific Aim 1

We will conduct a 2-arm, non-inferiority randomized comparative effectiveness trial of DSW and in-person multi-family MFG. We will compare changes in severity of Veterans' of psychiatric symptoms (i.e., positive and negative symptoms), and caregiver psychological burden, during the treatment period and then 3-months post-treatment.

Hypothesis 1.1. Veterans participating in DSW will do as well or better than those participating in in person MFG with an equivalence ratio of 1.20-1.47 (depending on the coefficients of variance of the measures assessed) at time points 12 and 15 months.

Hypothesis 1. 2. Family caregivers participating in DSW will do as well as or better than those participating in in-person MFG with an equivalence ratio of 1.17-1.29 (depending the coefficient of variance of the measure assessed) at time points 12 and 15 months.

Hypotheses 1.3. When compared to in-person MFG, Veterans and family members receiving DSW will have higher treatment initiation, engagement, attendance, lower drop-out, and higher perceived social support.

1.7.2. Specific Aim 2

We will conduct exploratory analyses to identify Veteran and family characteristics that are associated with severity of psychiatric symptoms and caregiver burden across both treatment arms. Analyses will look for important moderators (e.g. baseline symptom level, distance from hospital, age, technology expertise) as well as mediators (e.g., in-person meeting attendance, amount of DSW usage).

These analyses will be completed by supplementing the mixed effect regressions with demographic (age, race education), pre-study computer experience, support (living situation) and clinical characteristics (symptom severity, severity of cognitive impairment) of subjects that affect the relationships between the treatment and outcomes. Analyses will be carried out across both arms and then for each arm separately. While it is possible to test the treatment X non-treatment moderators with interaction terms the number of subjects precludes analyses that include all factors and interactions.

Mediating effects of the different intervention components and different patterns of attendance and engagement are likely to occur in this study and will also be identified with mixed effect regressions. To test for mediating effects we will compare the relationships between treatment and outcomes and these potential mediating variables and outcomes. We assume that exposure, i.e., increased numbers of in-person session attendance, or more usage of DSW, will lead to greater improvements. These will help us to identify whether it is the amount of time spent on the materials/in treatment, or the duration of time one is exposed to treatment. Those in DSW and in-person MFG could have up to 1 year exposer, but usage patterns will identify the actual period of time over which Veterans were actually exposed to MFG materials, and the amount of time they used those materials. Thus, though the duration is the same in both treatments, the actual amount of exposure is not necessarily the same in both. For these analyses with 80 subjects in a multivariable regression with treatment included the detectable R^2 difference of an additional variable is 0.06 with 3 added variables it is 0.09 and with as many as 8 additional variables (or degrees of freedom) the detectable difference in R^2 is 0.12 (alpha=0.05, power=80%). The usual rule of thumb is to include at most n/(8-10) variables in a multivariable regression, thus the analyses will be limited to 8 variables including the treatment variable.