A randomized controlled trial of Illness Management and Recovery with an active control condition

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Disclosures

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Abstract

Objective: The purpose of the current study was to rigorously test Illness Management and Recovery (IMR) against an active control group in a sample that included Veterans. *Methods:* Participants with schizophrenia-spectrum disorders (N = 118) were randomly assigned to an IMR group or a weekly problem solving group intervention. Blinded assessments were conducted at baseline, 9 months, and 18 months on measures of symptoms, functioning, illness self-management, medication adherence, subjective recovery experiences, and service utilization. *Results:* Study participants improved significantly over time in symptom severity, illness management, and quality of life, and had reduced emergency room visits, but there were no differences between IMR and support groups. However, participation rates in both interventions were low. *Conclusions:* This is the first negative trial of IMR. Given the inclusion of an active control group and the low participation rates, further research is needed to understand factors affecting IMR effectiveness. Increased attention may need to be paid to facilitate more active participation in IMR, such as individual follow-up with consumers and the integration of IMR with ongoing treatment.

The Illness Management and Recovery (IMR) program is a curriculum-based approach to helping consumers with severe mental illness set and achieve personal recovery goals and acquire the knowledge and skills to better manage illnesses (1). IMR has been tested in multiple quasi-experimental studies (2-7) and three randomized controlled trials (8-10). A growing body of research has also addressed implementation and adaptations of IMR (11), illustrating its widespread popularity.

IMR was explicitly developed to incorporate effective strategies for managing illnesses like schizophrenia (12), including psychoeducation, cognitive-behavioral approaches to medication adherence, relapse prevention, social skills training, and coping skills training. The information and skills taught in IMR are conceptually organized around the stress-vulnerability model (13, 14), and are aimed at improving illness through reducing biological vulnerability (e.g., increasing medication adherence, reducing substance abuse), reducing the impact of stress (e.g., coping skills training, facilitating meaningful activities), and increasing social support (e.g., improving relationships). The IMR curriculum includes 10 topic modules taught individually or in groups. By learning to effectively manage mental illness and work towards personal goals, IMR seeks to help consumers become more active in treatment, to make progress in recovery, including both subjective (e.g., hopefulness) and objective aspects of recovery (e.g., improved role functioning), and to reduce use of inpatient and crisis services.

Research on IMR as a package has demonstrated the program's effectiveness, particularly regarding increased illness management and symptom reduction (11). The randomized trials have been conducted in very different settings: thirteen community agencies in Israel (8), three supportive housing settings in New York City (9), and six Swedish psychosocial rehabilitation centers (10). Each of these studies used a "treatment as usual" condition that varied substantially; however, common elements

included case management, medication management, and access to other rehabilitation services. Though not consistent across outcome domains, these trials all produced positive results showing advantages for IMR participants. However, no studies have compared IMR to equally intensive interventions to control for non-specific treatment factors, such a clinician attention. More rigorous evaluation of the benefits of the curriculum and teaching methods above and beyond non-specific therapeutic factors is needed.

In addition, none of the prior published work on IMR has addressed the needs of Veterans. The Department of Veterans Affairs (VA) is investing resources to improve mental health treatment for Veterans, including evidence-based community mental health programming (15) and an increased emphasis on recovery-oriented care (16). Despite these initiatives, Veterans' needs are still great. For example, in 2004, the average length of inpatient psychiatric hospitalization was 13 days; however, rates of readmission were high, with 31% readmitted within 6 months (17). One study directly comparing Veteran with non-Veteran consumers with schizophrenia found similar levels of subjective recovery (e.g., hope, satisfaction with life, and empowerment), but lower perceived knowledge about illness management among Veterans (18). Taken together, these findings suggest the need for interventions that can help Veterans take greater control of their illness and rely less on costly mental health services.

The purpose of the current study was to rigorously test IMR in a sample of Veterans and non-Veterans with schizophrenia-spectrum disorders to determine if IMR improves outcomes above the effects of an active control group. We hypothesized that IMR would lead to greater improvements in symptoms, functioning, illness management, medication adherence, subjective experiences of recovery, and reduced utilization of crisis and hospital services.

Methods

A randomized controlled trial compared group-based IMR to an equally intensive problem solving (PS) control group offered weekly for 9 months. All participants continued to receive other usual treatment, which could include medication management, case management, individual or group therapy, and other psychosocial treatment. The study took place at a VA Medical Center Psychosocial Rehabilitation and Recovery Center and at a community mental health center (CMHC) in the same city. Recruitment occurred between September 2008 and October 2010, with assessments conducted at baseline, 9 months, and 18 months. Procedures were approved by the Institutional Review Board at [xxx] university and the Research and Development committee of the [xxx] VA Medical Center.

Participants

Inclusion criteria were: currently receiving (or newly admitted to) mental health services at the VA or CMHC; age 18 or older; diagnosis of schizophrenia or schizoaffective disorder; and willingness and ability to give informed consent. Exclusion criteria were: medical condition limiting participation in an 18-month study (e.g., end stage renal disease), or evidence of severe cognitive impairment based on a screener (19). All participants of the VA were Veterans (N=52) and 4 of the 66 CMHC participants were Veterans.

Participants were recruited through clinician referrals, self-referral, and a registry of individuals who had participated in previous research. Members of the research team attended clinical team meetings to describe the study and distribute brochures, which were then given to consumers and posted in treatment areas. As shown in the study flow chart (See Figure 1 in supplemental materials), 118 participants were recruited and randomly assigned to either IMR (N = 60) or PS (N = 58).

Program models

Illness Management and Recovery was offered in small groups (less than 8), co-facilitated by either an experienced masters level clinician or a doctoral level psychologist and by a doctoral student in clinical psychology. The initial facilitator was trained directly by Susan Gingerich and participated in biweekly phone supervision for several months. Through the rest of the study, facilitators met regularly for peer supervision. Facilitators used the IMR curriculum (20), incorporating psychoeducation, cognitive-behavioral approaches, relapse prevention, social skills training, and coping skills training. Facilitators worked with group members to set personal recovery goals and address progress towards those goals throughout the intervention. Home assignments helped participants apply newly learned skills and/or make progress on goals. Groups were open to rolling admission across the study period.

Problem Solving was used to control for attention and time in groups. Participants were encouraged to discuss current concerns and receive group support for solving problems, but we did not use structured problem solving tasks. These groups were led by the same facilitators described above, who helped establish group expectations (attendance, confidentiality), encouraged participation, and provided process-oriented observations; there was no formal curriculum, goal setting, or homework assignments.

Fidelity assessment. To ensure that the experimental condition was following the IMR model and that the control condition was not, we audiotaped all sessions and rated fidelity using the IMR Treatment Integrity Scale (IT-IS) (21), a 16-item, behaviorally anchored scale. We randomly selected 60 IMR and 20 control sessions to rate. Raters were four graduate students with experience providing IMR and trained to make fidelity ratings, and were not told which condition they were rating. On a 5-point scale, mean total scale scores were significantly higher for IMR sessions (3.4±.8) than for PS

sessions (2.2±.3), $t = 11.68$, $p < .001$. Means for each of the items were higher for IMR than PS, except “enlisting mutual support” which was similar across conditions.

Measures

Participants were interviewed at baseline, 9 months, and 18 months by trained raters blinded to study condition. Participants were paid $20 for each interview. We obtained data on emergency room and hospital utilization through medical records. At baseline, diagnoses were assessed with the psychosis modules of the Structured Clinical Interview for DSM-IV (SCID) (22) administered by either a clinical psychologist or trained doctoral student. Because IMR was designed to help consumers become more active in their own treatment and to make progress in recovery, we included a range of measures to tap activation and both subjective and objective indices of recovery.

Psychiatric symptomatology was assessed by the Positive and Negative Syndrome Scale (PANSS; (23)), a widely-used, 30-item interview-based rating scale. The PANSS has demonstrated satisfactory internal consistency, test-retest reliability, and validity (23). Raters were trained to an inter-rater reliability of .80 prior to interviewing participants. We examined the total score and five factors comprised of Positive symptoms, Negative symptoms, Emotional discomfort, Hostility or poor impulse control, and Cognitive symptoms (24).

Quality of life was assessed with an abbreviated version of the Quality of Life Scale (25), commonly used in schizophrenia. The QLS includes questions and objective indicators for interviewers to rate social and occupational functioning during the prior 4 weeks. The abbreviated version includes 7 of the original 21 items, providing a reliable, brief measure (26).

Illness self-management was assessed with the consumer-rated Illness Management and Recovery Scale (27). Items are rated on a 5-point behaviorally

anchored scale, and the mean across all 15 items forms an overall score, with higher scores indicating better self-management. The IMR Scales have shown internal consistency, stability, sensitivity to change over time, and correlations with indices of functioning, symptoms, and recovery (28-30).

Patient activation was assessed with the short form, mental health version of the Patient Activation Measure (31). Scores have a possible range of 0 (least activation) to 100 (highest activation). The 13-item mental health version has been shown to have strong reliability in Rasch analyses, test-retest reliability, and correlates with related constructs (32), and has been used in other samples with schizophrenia (33-35).

Medication adherence was assessed with the Morisky Scale, a 4-item scale with adequate reliability and validity across populations (36), including severe mental illness (37). Participants answered “yes” or “no” to items related to medication adherence; a score sums the number of “yes” responses, with a *lower* score indicating better adherence.

Perceived recovery was assessed using the total score of the Recovery Assessment Scale (38). Respondents endorse 41 items (e.g., "I have a desire to succeed.") on a scale from 1 ("strongly disagree") to 5 ("strongly agree"). RAS total score has shown good test-retest reliability, internal consistency, and correlates with measures of self-esteem, empowerment, and quality of life (38).

Hope was assessed using the 6-item Adult State Hope Scale (39), which has high internal consistency and convergent and discriminant validity (39). The scale has also been used in individuals with schizophrenia (40, 41).

Service utilization was extracted from medical records, including number of visits to the emergency room and number of admissions and length of stay in inpatient units of the respective settings. Data were extracted for 9 months prior to baseline, baseline to 9 months, and 9 to 18 months.

Data analysis

We compared IMR and PS on background and outcome variables using X^2 for categorical variables and *t*-tests for continuous variables. Intent-to-treat analyses compared changes in IMR and PS groups over time on the outcome measures. To explore whether outcomes differed among consumers who had some engagement in their assigned intervention, we also conducted analyses comparing those randomized who attended at least one group. These analyses produced similar results as the intent-to-treat analyses, and are not presented.

We followed a similar analysis approach of recent RCTs using mixed effects regression analyses of mean response profiles (42, 43). We included the baseline measure for a given outcome variable as a covariate, as well as site, and fit adjusted mean response profile models (44) using SAS PROC MIXED for continuous outcomes (interview data) and SAS PROC GENMOD (Poisson regression) for count outcomes (service data). This approach can accommodate correlated residuals by selecting appropriate covariance structures as well as missing data with maximum likelihood estimation (45). The group main effects in this model (i.e., the difference in group mean response profiles between the IMR and problem solving interventions at post-treatment and follow-up) were the primary test of the study hypotheses. To evaluate changes over time across the outcome measures from baseline to 9 and 18 months, we performed similar analyses, but included all measurement occasions as dependent variables using SAS PROC MIXED and SAS PROC GENMOD. Finally, we examined if rates of intervention exposure (% of attendance for the intervention) were related to changes in outcomes over time. We employed the significance level at a *p* value of .05 or less.

Results

Participants assigned to IMR did not differ significantly from those assigned to PS on baseline measures (See Table 1). Participants were predominantly male (80%),

African American (61%), and living independently (70%). The mean age was 47.7±8.9. Most were unemployed (86%) and reported an annual income of less than $10,000 (63%).

Rates of treatment participation were low for both groups, but did not significantly differ. For IMR, 14 (23%) attended no sessions, 29 (48%) attended fewer than half the scheduled sessions, and 17 (28%) attended half or more. For PS, 20 (34%) attended no sessions, 28 (48%) attended fewer than half the scheduled sessions, and 10 (17%) attended half or more. Older age, lower hostility, fewer psychotic symptoms, and more education were associated with higher attendance in both conditions (see (AuthorCite) for more details).

Outcomes across time are shown in Table 2. The mean response profile analyses revealed no group differences between IMR and PS on any of the outcomes. Time effects showed improvements in several variables, including all symptom domains (Cohen's d >.5), functioning on the Abbreviated Quality of Life Scale (Cohen's d =.4), self-reported illness management (Cohen's d = .4), and emergency room visits (Cohen's d = .3). There were main site effects with consumers from the VA having lower scores on some of the outcome variables (i.e., self-reported illness management [$p<.05$], total RAS scores [$p<.05$]), but there were no site by group interactions. Additional analyses accounting for percent of sessions attended indicated that treatment exposure did not explain the variance in outcomes.

Discussion

Participants in both groups improved significantly in a number of domains related to illness management, including symptoms, psychosocial functioning, self-rated illness management, and emergency room use. However, in contrast to three other randomized trials showing some advantages for IMR (8-10) over usual care, there were

no significant differences between IMR and the problem-solving group on any outcomes. We speculate on several possible reasons for these findings.

This was the first randomized trial of IMR that controlled for non-specific treatment factors with an active, equally intensive intervention, rather than usual services. While the control intervention did not take a structured approach to teaching problem solving, it did provide a forum to discuss problems and concerns with experienced clinicians and to receive support from group members, which have been identified as effective components of group interventions (47, 48). Our fidelity ratings showed no differences between the IMR and problem solving groups in enlisting mutual support. Thus, it is possible that the benefits of IMR over usual services shown in previous studies are primarily due to non-specific therapeutic factors in IMR groups, rather than the specific curriculum, teaching methods, and recovery orientation of IMR. A recent Cochrane review of cognitive behavioral therapies for schizophrenia showed similar lack of findings when compared to active controls (49). However, there are important alternative explanations to consider related to implementation and participation of the group interventions.

Participation rates in both the IMR and problem solving groups were lower than desired, which could have limited the effect of intervention. Only 28% of consumers assigned to IMR, and 17% of those assigned to problem solving, participated in more than half of the scheduled groups, and 23% and 34% assigned to each respective group attended no sessions. Although percentage of sessions attended did not account for outcomes in our analyses for either group, it is conceivable that a minimum threshold of exposure to IMR is necessary to detect treatment benefits, and potentially even higher levels of exposure are necessary to distinguish specific from non-specific effects of IMR.

Our rates of exposure to IMR are lower than those reported in the previous three controlled trials of IMR. One study in a residential setting (9) reported that 54% of

consumers (almost twice our rate) attended at least half of the sessions. Participants in Färdig's (10) sample attended an average of 30 out of 40 sessions, and all attended at least half; however, participants were recruited based on consistent attendance in prior mental health services and implementation of IMR focused heavily on consumer engagement (Färdig, personal communication, 12/19/12). The controlled trial that took place in Israel reported 7% were dropped from analyses for not participating, but completion rates for IMR were not reported.

In our study, participants were asked to attend weekly for 9 months. Although group leaders attempted to facilitate attendance with reminders and phone calls, assertive outreach was not feasible. This may represent a common scenario in community mental health and suggests that additional engagement strategies may be needed to engage participants in a weekly intervention for the better part of a year. A possible limitation in our study design was rolling admission into groups. This was done so that participants would not wait long between recruitment and intervention; however, rolling admission may have led to less group cohesion or mutual accountability, which could have impacted participation. In addition, in both settings there was a lack of integration of IMR with other services and with documentation in medical records. The lack of integration may have limited the ability of other treatment providers to facilitate consumers' work on recovery goals, encourage IMR attendance, and reinforce skills learned in the program.

In addition to the integration with other treatment, the interaction of IMR with other services is poorly understood and may have affected responsiveness in the current trial. Veterans participating in the current trial generally had received extensive services prior to participating in IMR, including psychoeducation, coping skills, and relapse prevention groups. It is unclear from previous IMR trials how many participants accessed other rehabilitation services concurrently or previously. Although we did control for site in

the analyses, more work is needed in the VA context, particularly as illness management is a required component of recovery-oriented care in VA psychosocial and recovery centers (50). Finally, our available sample sizes were somewhat smaller than our a priori power calculation (n=62 for each group assuming 20% attrition), while attrition was higher resulting in slightly less overall power to detect moderate effects.

Conclusions

This study highlights important areas for future study of IMR effectiveness. Although IMR did not have an advantage, participants across groups experienced improvements in several domains. Issues of treatment exposure, potency, context, and population served may have all impacted outcomes and serve as important targets for future study.

Table 1: Descriptive statistics of participant background characteristics.

	IMR (N=60)		PS (N=58)		Total (N=118)	
Variable	**N**	**%**	**N**	**%**	**N**	**%**
Site:						
VA	25	42	27	47	52	44
CMHC	35	58	31	53	66	56
Gender:						
Male	46	77	48	83	94	80
Female	14	23	10	17	24	20
Ethnicity:						
African American	32	53	40	69	72	61
White	22	37	18	31	40	34
More than one race	6	10	0	0	6	5
Diagnosis:						
Schizophrenia	27	45	27	47	54	46
Schizoaffective	33	55	31	53	64	54
Marital Status:						
Not Married	52	87	47	81	99	84
Married/ Living with partner	6	10	10	17	16	14
Missing	2	3	1	2	3	3
Housing:						
Non-independent	17	28	14	24	31	26
Independent	40	80	42	72	82	70
Homeless	2	3	0	0	2	2
Missing	1	2	2	3	3	3
Educational Attainment:						
Less than high school	20	33	20	35	40	34
High school/GED	20	33	19	33	39	33
College and above	19	32	18	31	36	31
Missing	1	2	1	2	2	2
Employment Status:						
Employed	9	15	6	10	9	13
Unemployed	50	83	51	88	101	86
Missing	1	2	1	2	2	2
Annual Income Level:						
$0 to < $10,000	44	73	30	52	74	63
$10,000 to < $20,000	10	17	15	26	25	21
$20,000 to < $30,000	0	0	3	5	3	3
$30,000 or higher	3	5.	5	9	8	7
Missing	3	5.	5	9	8	7

Table 2. Descriptive Statistics, Group Effects, and Time Effects

	IMR						PS											
	Baseline (N=59)		9 MO. (N=44)		18 MO. (N=37)		Baseline (N=57)		9 MO. (N=40)		18 MO. (N=33)		Group Effect			Time Effect		
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	*df*	*F*	*sig*	*df*	*F*	*sig.*
Interview-based measures																		
PANSS TOTAL	75.1	16.1	68.5	18.5	61.9	17.1	76.1	15.3	66.6	14.9	65.3	19.6	1, 82.7	.95	n.s	2, 79.8	24.29	p<.001
Positive Symptoms	16.3	5.3	14.1	6.2	13.5	5.2	15.2	4.5	12.6	4.9	13.0	5.3	1, 81.8	.59	n.s	2, 78.9	15.93	p<.001
Negative Symptoms	18.7	5.8	18.5	5.8	16.7	6.8	19.5	5.3	17.9	6.2	18.5	6.7	1, 80.2	.31	n.s	2, 80.6	3.16	p<.05
Emotional Discomfort	12.4	4.6	10.8	5.1	10.6	4.7	12.8	4.6	10.6	4.1	10.7	4.4	1, 82.7	.24	n.s	2, 80.0	8.75	p<.001
Hostility	8.4	3.2	7.3	2.9	4.9	1.7	8.9	3.2	7.8	2.4	5.8	2.4	1, 74.8	1.04	n.s	2, 85.8	40.70	p<.001
Cognitive Symptoms	17.1	5.3	15.7	6.0	14.1	5.5	17.2	5.8	15.6	5.7	15.5	6.6	1, 84.6	1.10	n.s	2, 79.7	14.23	p<.001
QLS	3.1	1.1	3.3	1.1	3.5	1.0	2.8	1.0	3.3	1.1	3.3	1.3	1, 76.1	.08	n.s	2, 81.6	7.06	p<.01
Illness Management and Recovery	3.5	.5	3.5	.6	3.6	.5	3.3	.5	3.6	.6	3.5	.6	1, 77.6	.02	n.s	2, 80.4	3.55	p<.05
Patient Activation	53.2	15.3	55.1	15.1	56.7	15.5	55.2	17.4	57.9	18.1	58.2	17.3	1, 80.3	.22	n.s	2, 82.9	1.11	n.s
Medication Adherence	1.4	1.3	1.3	1.3	1.1	1.3	1.7	1.2	1.2	1.1	1.3	1.1	1, 82.4	.11	n.s	2, 82.1	3.01	n.s
RAS TOTAL	3.1	.4	3.1	.4	3.1	.4	3.0	.4	3.1	.4	3.1	.5	1, 76.5	.50	n.s	2, 77.0	2.53	n.s
Hope	3.0	.6	3.0	.6	2.9	.6	2.9	.7	3.0	.7	3.0	.7	1, 83.8	.38	n.s	2, 84.1	.50	n.s
Service utilization													*df*	x^2	*sig.*	*df*	x^2	*sig.*
ER visit	2.3	4.1	1.9	3.6	1.3	2.6	2.4	3.6	1.3	1.9	1.3	2.5	1	1.06	n.s	1	5.87	p<.05
Psych ER visit	.4	1.1	.3	.9	.2	.6	.5	1.2	.2	.6	.3	1.0	1	1.16	n.s	1	2.35	n.s
Inpatient admissions	.4	.8	.4	.8	.4	.7	.7	1.1	.4	.7	.3	.6	1	.70	n.s	1	.71	n.s
Inpatient psych admissions	.3	.6	.3	.5	.3	.7	.4	.8	.2	.5	.2	.6	1	.72	n.s	1	.75	n.s
Length of stay in hospital	6.9	17.1	3.7	16.5	6.1	15.1	7.8	15.0	3.3	17.2	5.5	15.6	1	.84	n.s	1	.69	n.s
Length of stay in psych hospital	6.2	16.9	4.5	10.8	5.7	15.1	5.7	14.0	4.4	11.6	4.7	15.6	1	.74	n.s	1	.72	n.s

Note: Descriptive statistics are simple statistics for means without any covariates adjusted, but group and time effects were tested for the mean differences adjusting for the covariates (i.e., baseline scores and site) and accounting for the missing data.

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