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ORIGINAL ARTICLE

Participants' and staffs' evaluation of the Illness Management and Recovery program: a randomized clinical trial

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Abstract

Background: Psychoeducational interventions for people with severe mental illness are developed to enable them to manage their illness effectively to improve prognosis and recovery.
Aim: The aim was to investigate the benefits and harms of the Illness Management and Recovery (IMR) program among people with severe mental illness in Denmark. IMR builds among other approaches on a psychoeducational approach.
Methods: A randomized, multi-center, clinical trial of the IMR program compared with treatment as usual among 198 participants with schizophrenia or bipolar disorder investigating outcomes related to illness self-management assessed by the IMR scale, recovery, hope and participants' satisfaction at the end of the 9 months intervention period.
Results: No statistical differences were seen between the two groups regarding illness self-management, hope, recovery, or satisfaction with treatment.
Conclusions: IMR appears not to be better than treatment as usual in any of the outcomes. Further studies with a longer follow-up period, better assessments of recovery and a systematic review of the existing trials are needed to assess if the program is effective.

Keywords

Recovery, psychoeducation, Illness Management and Recovery, hope

History

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Introduction

Psychoeducational programs for people suffering from severe mental illness have been developed to enable them to cope with and manage their illness more effectively in order to improve prognosis and recovery (Xia et al., 2011). The Illness Management and Recovery (IMR) program combines psychoeducation, self-management approaches, techniques from motivational interviewing and cognitive behavioral therapy, and is every-day life focused with the option of including the participant's family (Mueser et al., 2006). IMR is aiming at improving the participant's recovery by learning illness management skills. The IMR program consists of 11 modules: Recovery Strategies, Practical Facts about Mental Illness, The Stress-Vulnerability Model, Building Social Support, Using Medication Effectively, Drug and Alcohol Use, Reducing Relapses, Healthy Lifestyle, Coping with Stress, Coping with Problems and Symptoms, and Having Your Needs Met in the Mental Health System. The first module ''Recovery Strategies'' sets the agenda for the whole program. It focuses uniquely on what recovery means to the individual participant and what his or her personal recovery goals are. These recovery goals are in focus during each session and the goals are broken down into smaller steps and perhaps changed by the participant to make them more desirable and obtainable. Recovery in mental illness is defined in numerous ways (Roe et al., 2011; Silverstein & Bellack, 2008), and a common definition separates clinical and personal recovery (Macpherson et al., 2016). Clinical recovery consists of a decrease in symptoms, increase in function, and prolonged remission, whereas personal recovery is a unique process involving hope, gaining empowerment, autonomy, quality of life and participation in meaningful activities (Anthony, 1993; Davidson & Roe, 2007; Davidson et al., 2008; Deegan, 2007; Noiseux et al., 2010). The rationale of the IMR program is that it will improve the aspects of clinical recovery and have effects in terms of personal recovery aspects. IMR may have a positive effect on aspects of personal recovery and

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self-management skills (Färdig et al., 2011; Hasson-Ohayon et al., 2007; Levitt et al., 2009). However, this is still disputed as two out of the five randomized clinical trials conclude that IMR has no effect on aspects of personal recovery (Salyers et al., 2010, 2014). Thus, there is a need for a large randomized clinical trial with a solid methodological approach to investigate the effects of personal recovery of IMR. The current trial aimed at investigating the benefits and harms of IMR versus treatment as usual. The hypothesis is that IMR will improve aspects of illness self-management and aspects of personal recovery for participants assigned to IMR and treatment as usual compared to participants assigned to treatment as usual alone. Effects on illness management are proximal outcomes of IMR, detectable shortly after participating in the program whereas aspects of personal recovery as well as clinical recovery are considered to be distal outcomes that can only be assessed after a while (Mueser et al., 2006). In this paper, we report results regarding the illness self-management and personal recovery outcomes by scales assessing illness self-management, personal recovery and hope. In the IMR program, aspects of reaching personal recovery goals and effectively being able to manage one's mental illness are closely related. Results regarding clinical recovery outcomes such as the level of functioning and symptoms will be presented elsewhere (Dalum et al., 2014).

Methods

Design

This trial was designed as a randomized, multi-center, clinical trial investigating the IMR program compared with treatment as usual. The design has previously been reported in detail (Dalum et al., 2011). The trial was conducted from February 2011 to December 2013 in three community mental health centers (CMHC) in the Capital Region of Denmark.

Participants

Included participants were diagnosed with schizophrenia or bipolar disorder according to the ICD-10 criteria and verified by the Present State Examination (Cooper et al., 1977) by a psychiatrist or clinical psychologist; some participants were clinically stable and some were unstable; aged 18 years or older; referred to an included CMHC; speaking and understanding Danish; and giving informed consent. Exclusion criteria were having a guardian or getting forensic care; having dementia or mental retardation defined by the ICD-10 criteria; having a large-scale substance abuse; living in supported housing; being involved in psychoeducation at the time of inclusion; or not giving informed consent.

Randomization procedure

The participants were randomly allocated 1:1 to receive IMR in groups plus individual treatment as usual or to continue individual treatment as usual. The allocation sequence was computer-generated using permuted blocks in varying sizes of 6, 8 and 10 and stratified by diagnosis and CMHC. To secure concealment of the allocation sequence and block size, the randomization was central and telephone-based by an administrative office outside the research team.

Assessments and blinding

Due to the nature of the intervention, neither participants nor staff members were blinded to allocation during the intervention. Outcomes reported in this paper were self-assessed, and thus it was not possible to be blind to allocation. However, the statistical analyses were conducted blinded with the two intervention groups coded as A and B, and the Steering Committee drew the conclusions with the blinding still intact.

Interventions

Illness Management and Recovery

IMR was provided in a group format with ten participants in each group and each group was facilitated by two mental health practitioners from the CHMC. It was expected that some participants would leave the group during the course of the program. Therefore, the group size of 10 participants was decided so that an eventual drop out would not ruin the desired group dynamics. The IMR program lasted nine months with one weekly session of one hour during the day at the CMHC.

The staff facilitating IMR experienced mental health professionals with a minimum of three days course of teaching IMR. Two days of training was given to all staff prior to the intervention. After six months, one day of training was given to all staff to keep focus on the IMR curriculum and motivational interviewing. One year after the prior training, some of the IMR staff were given an additional day of training to brush up their knowledge before facilitating their own group. All training was provided by a well-experienced IMR educator from the USA (The Mental Health Center of Greater Manchester, New Hampshire).

Staff facilitating IMR received monthly supervision and met in an IMR network across the three participating CMHCs to share experiences and help each other implement the program. The well-experienced IMR educator from the USA, who taught the IMR curriculum to the staff, provided the first six months of implementation supervision in each CMHC. After the first six months, supervision was carried out under the auspices of each CMHC. To ensure that staff members in the CMHCs were following the principles of treatment as usual when meeting participants in the control groups, the staff members could consult and get advised by a well-experienced psychiatrist only performing treatment as usual. A more detailed description of the IMR program and the implementation in the CMHC can be found elsewhere (Dalum et al., 2011).

Treatment as usual

The treatment as usual consisted of an individually adapted interdisciplinary treatment in the CMHC or in the participant's own home. The treatment included medication, individual case-manager support, individual and group therapy, unstandardized psychoeducation, and psychiatric or psychological counseling. Each participant had a case manager who in cooperation with the participant planned the individualized treatment. The case manager's average caseload was 30 patients. The participant met with the case manager or

attended other activities at the CMHC once a week on average.

Outcomes

All outcomes were assessed at baseline and at the end of intervention, 9 months after randomization. For this trial, the outcome scales were translated into Danish and then independently translated back into English, but not validated in Danish. In this paper, the outcomes of Illness Management and Recovery Scales (IMRS) are considered as a secondary outcome because they are pre-defined by a prior power and sample size calculation, see Dalum et al. (2011) and all the other outcomes reported that are of exploratory nature with no prior power calculation.

Illness Management and Recovery Scale

The IMRS comprises the key elements of the IMR program. It is a 15-item rating scale where a higher score on a 5-point scale indicates a better illness-self management, existing in a version for participants (IMRS-P) and for staff members (IMRS-S). It shows good reliability and a sensitivity in detecting change for both versions (participant version Cronbach's $\alpha = 0.73$ and staff version Cronbach's $\alpha = 0.71$) (Färdig et al., 2011; Hasson-Ohayon et al., 2008; Salyers et al., 2007).

Further, we report *post-hoc* results on the three subscales of the IMRS proposed by a recent scale validation study of the IMRS using RASCH analyses (McGuire et al., 2014): a Recovery subscale, a Management subscale, and a Biology subscale for both participants and staff.

Adult State Hope Scale

The Adult State Hope Scale (Snyder et al., 1996) was used to assess hope. It is a self-report scale consisting of 6 items on an 8-point scale where higher numbers indicate greater hope. It is a widely used scale with good reliability (Cronbach's α of 0.93) to asses hope among people with mental illness (Schrank et al., 2012; Snyder et al., 1996).

Mental Health Recovery Measure

The experience of personal recovery was evaluated by the Mental Health Recovery Measure (McCabe et al., 2007; Young et al., 2000). The scale consists of 30 items on a 5-point scale and has been validated in more than 200 people in different settings. Further, the scale has a good reliability with a Cronbach's α of 0.93 (Campbell-Orde et al., 2005).

Clients Satisfaction Questionnaire

The participants' satisfaction with treatment was measured by the Clients Satisfaction Questionnaire which has shown good reliability with a Cronbach's α of 0.93 (Larsen et al., 1979). The scale has 8 items on a 4-point scale and is an estimate of general satisfaction with the services.

IMR Fidelity Scale

The IMR Fidelity Scale (Gingerich & Mueser, 2003) was used for fidelity assessments for all groups to insure the implementation of the IMR program. Unfortunately, information about reliability was not available at the time of the assessments. A total of 10 IMR groups started and 9 of them completed. The one group disbanded after a couple of months because the participants could not come to sessions due to personal reasons (serious hospitalization, got a daytime job, recently had a baby).

The fidelity assessments were made mid-way through the program (after 4 months) and at the end of each IMR group (at 9 months). The first fidelity assessment was a process evaluation, so the IMR group leaders could adjust their practice, if needed. The end fidelity assessment was a final evaluation of the IMR group. IMR practitioners trained in the IMR Fidelity tool from the other CMHCs conducted the assessments. A multiple data approach was used including: interviews, observation of the IMR group, an audit of the service records as well as an audit of the IMR notes of progress.

Statistical analyses

For the outcomes IMRS-P and IMRS-S, a sample size of 200 participants was estimated sufficient to test minimal clinical relevant differences with an alpha of 5% and a power of 80% (Dalum et al., 2011).

The data analyses were based on the intention-to-treat principle. An analysis of missing data in IMRS showed that 44% of all observations for the IMRS-P and 36% of the IMRS-S were incomplete. Therefore, multiple imputations were conducted to enable intention-to-treat analyses. Post-treatment values were imputed for IMRS-P and IMRS-S with the constraints sex, diagnosis, age, CMHC and intervention. The automatic procedure of STATA version 11 (Copenhagen, Denmark) with 100 imputations estimated was used. For the exploratory outcomes and the *post-hoc* analyses of the IMRS subscales, complete case analyses were conducted. Difference in means was analyzed using analysis of covariance and *t*-tests if no baseline means existed. The level of significance was 0.05 for all statistical tests.

Ethical considerations

The trial was approved by the Ethics Committee in the Capital Region of Denmark (H-1-2010-134), reported to the Danish Data Protection Agency (RHP-2011-09), and registered on www.clinicaltrials.gov before recruitment (NCT01361698).

Results

Demography and clinical characteristics

Figure 1 shows a flow diagram of the trial. 202 participants were randomized; four participants were excluded immediately after randomization. Two participants in the control group withdrew informed consent, and one participant in the control group was excluded because the criteria of diagnosis were not fulfilled. Finally, the last participant randomized was assigned to be the only participant in an IMR group and therefore this individual was excluded. Thus, 198 participants entered the trial, 99 participants in each arm.

Baseline characteristics were similar in the two groups (Table 1). A total of 26 participants from the IMR group and

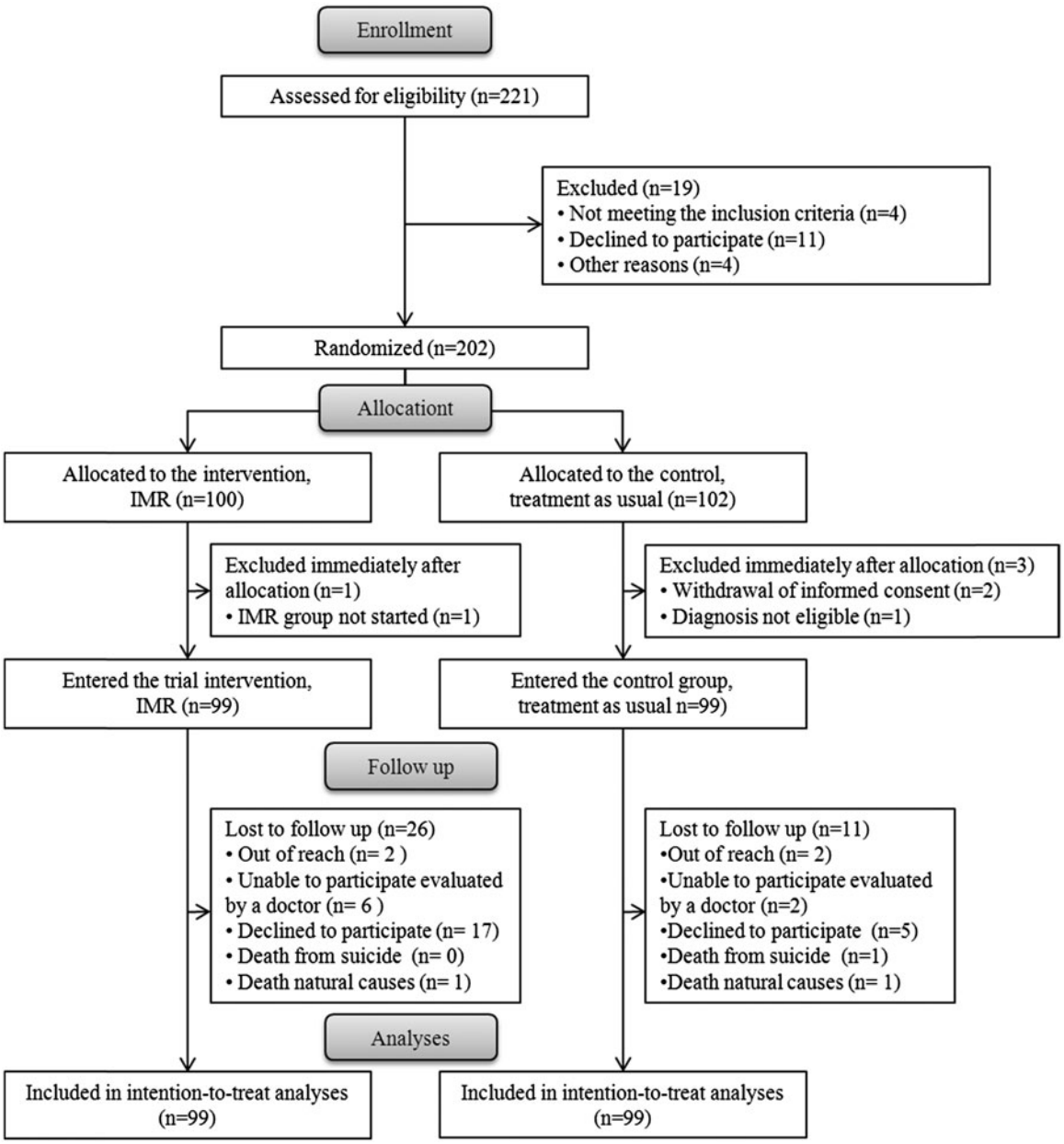

Figure 1 Flow diagram for the Danish IMR trial.

11 participants from the control group did not participate in any of the follow-up assessments. The drop-out rate was not equally distributed across the two groups since the drop-out rate of the intervention group was higher than the drop-out rate of the control group ($\chi^2 = 7.48$, df = 1, $p = 0.006$).

IMR did not have any significant effect on clinical recovery outcomes such as level of functioning or symptoms severity, use of drug/alcohol or hospitalization, and no dose–response effect was detected, which is reported elsewhere (Dalum et al., 2014).

Illness management and recovery outcomes

Table 2 summarizes the differences in the IMR outcomes for both groups. No statistical differences were found between the two groups in the intention-to-treat analyses of IMRS-P, mean difference +1.9 points (95% confidence interval (CI): $-0.6 + 4.5$, $t = 1.49$, df = 1, $p = 0.14$), and IMRS-S, mean difference +0.4 (95% CI: $-2.2 + 3.1$, $t = 0.31$, df = 1, $p = 0.76$). No significant differences were seen in the complete case analyses of the Adult State Hope Scale and the Mental Health Recovery Measure.

Subscales of the Illness Management and Recovery Scale

Table 3 shows the complete case analyses of the IMRS' subscales. A small difference was observed between the two groups in the Recovery subscale rated by the participants (IMR mean: 17.4 ± 3.0 points, control mean: 16.4 ± 3.5, $F = 5.33$, df = 1, $p = 0.02$). No differences were observed in any of the other subscales.

Fidelity and satisfaction with treatment

Overall the fidelity measures show a good implementation (Table 4). However, item number 3 ''*Comprehensiveness of*

Table 1. Baseline characteristics of the participants.

	IMR[a] (N = 99)		TAU[b] (N = 99)	
Variable	N	%	N	%
Site				
CMHC[c] Ballerup	29	30	25	25
CMHC Gladsaxe	30	30	33	32
CMHC Frederiksberg	40	40	41	43
Sex				
Female	45	46	44	44
Age				
Age (mean ± SD)	41 (±11.0)		45 (±11.5)	
Age range	20–68		22–77	
Housing				
Rented housing	75	76	65	66
Cooperative dwelling	14	14	18	18
Owner-occupied housing	8	8	10	10
Homeless	0	0	0	0
Missing data	2	2	6	6
Employment status				
Employed	7	7	12	12
Student	5	5	0	0
Unemployed or retired	84	85	81	82
Missing	3	3	6	6
Education				
Public school	26	26	26	26
High school	17	17	17	17
Vocational training	18	18	18	18
University	27	28	29	30
Missing	11	11	9	9
Living status				
Alone	70	71	69	70
Living with spouse and/or children	19	19	26	26
Other e.g. co-housing scheme	6	6	0	0
Missing	4	4	4	4
Diagnosis				
Schizophrenia	76	77	75	76
Bipolar disorder	23	23	24	24
Recent suicide attempt(s)	2	2	4	4
Alcohol or drug abuse				
Alcohol or drug abuse	15	16	13	14
No abuse	80	80	80	81
Missing	4	4	5	5
Years since first contact (± SD)	14 (±10.3)		16 (±10.2)	
Missing	17	17	14	14

[a]Illness Management and Recovery.
[b]Treatment as usual.
[c]Community Mental Health Center.

the curriculum'' with a mean score of 3.8 ± 1.2 and item number 5 ''*Involvement of significant others*'' with a mean score of 3.3 ± 1.24 across both assessments indicate that these two aspects were probably not fulfilled. Clients Satisfaction Questionnaire (Table 2) did not show any significant differences between the two groups ($F = 0.08$, df = 1, $p = 0.78$).

Treatment as usual

The number of times using treatment as usual in terms of meetings with the case manager or with a psychologist or a psychiatrist, or number of times participating in groups at the CMHC was the same for both groups. IMR participants had a mean of 24.1 ± 23.8 visits and control group participants had a mean of 24.5 ± 20.2 visits, respectively.

Harms and adverse events

No differences were seen between the two groups in adverse events such as drug/alcohol use, suicide or deaths. No harms or life-threatening conditions were reported. Three participants died during the follow-up period, one from suicide in the control group and two died of natural causes, one from each group. According to chief clinicians at the CMHC, this had no relation to participating in the IMR trial.

Discussion

This trial investigated the effects of the IMR program compared with treatment as usual among people with severe mental illness in Denmark. In this paper, we specifically report outcomes related to personal recovery and illness management.

No statistical significant differences were found between the two groups in the outcomes related to IMR: the total scores of the IMRS-P and the IMRS-S in the intention-to-treat analyses using multiple imputation indicates that the participants in the IMR are not better at managing their illness than participants in the control group. Further, no statistical significant differences were seen between the two groups regarding hope, self-perceived recovery or satisfaction with treatment in the complete case analyses. These findings support findings regarding outcomes of clinical recovery in this trial which shows no statistical differences between the two groups (Dalum et al., 2014).

So far, five randomized clinical trials of IMR have been published. Three of these trials find a significant difference in favor of IMR compared with the treatment as usual on the IMRS both rated by the participant and the staff (Färdig et al., 2011; Hasson-Ohayon et al., 2007; Levitt et al., 2009). Two randomized trials find no statistical significant difference on the IMRS between the two intervention groups (Salyers et al., 2010, 2014), which is similar to the findings in this trial. None of the prior trials found effects on self-perceived hope, recovery, coping, social support or quality of life and this trial thereby confirms the other five trials findings.

Earlier trials showing benefits of IMR have all had risks of bias such as inclusion of a broad range of psychiatric diagnoses and no prior power and sample size calculation, and thus their results showing the effects of IMR should be addressed with caution. A potential effect of IMR in terms of IMR needs to be investigated in a systematic review with meta-analyses of the existing trials, consequently a Cochrane Review of IMR is under preparation (Korsbek et al., 2014).

The trial was designed so that both the intervention group and the control group received treatment as usual. IMR did not add any effect on the examined outcomes in this trial and a possible explanation could be that the services provided in Denmark as described in the method section may be more intense, than the services in other countries where IMR has been examined.

Further, the chosen outcome scales are an important topic of the trial design. During the trial it was revealed that ensuring a good Danish version of the recovery-related validated rating scales did not ensure that the scales fitted the Danish culture, e.g. valuing people being visibly different from the majority and aspects of religious beliefs (Zuckerman, 2009). In future studies of the IMR, outcome scales need to better suit the given cultural setting.

Table 2. IMR measures.

	Baseline					Post intervention							
	IMR[a]		TAU[b]			IMR			TAU				
	Mean	SD	Mean	SD	Cronbach's α	N	Mean	SD	N	Mean	SD	Cronbach's α	*p* Value
								Intention-to-treat analyses					
IMRS-P[c]						99	54.7	0.93	99	58.8	0.85		0.14
IMRS-S[d]						99	54.6	0.97	99	54.2	0.92		0.76
								Complete case analyses					
IMRS-P	50.9	6.9	50.9	7.4	0.66	46	54.7	7.6	55	52.8	8.1	0.75	0.04
IMRS-S	50.5	7.3	50.7	6.9	0.69	54	55.3	7.0	62	53.5	8.6	0.78	.14
Mental health	70.9	15.1	69.9	18.7		59	69.5	15.3	57	69.2	18.0		0.90
Recovery measure					0.91							0.92	
Adult State Hope Scale	31.6	8.6	30.9	9.1	0.85	68	32.6	8.3	71	31.8	10.0	0.88	0.53
Clients Satisfaction Questionnaire	24.6	4.5	25.1	4.0	0.91	61	24.6	5.1	58	24.8	4.1	0.92	0.78

[a]IMR: Illness Management and Recovery.
[b]TAU: Treatment as usual.
[c]Illness Management and Recovery Scale – participants' version.
[d]Illness Management and Recovery Scale – staffs' version.

Table 3. Analysis of IMR subscales.

	Baseline				Post treatment						
	IMR[a]		TAU[c]		IMR			TAU			
	Mean	SD[b]	Mean	SD	N	Mean	SD	N	Mean	SD	*p* Value
Recovery scale – participant	15.6	3.5	15.6	3.5	63	17.4	3.0	66	16.4	3.5	0.02
Management scale – participant	15.8	3.9	16.1	4.2	61	17.5	4.4	69	16.9	3.8	0.33
Biology scale – participant	14.0	2.0	14.0	1.5	51	14.1	2.1	60	14.1	1.8	0.76
Recovery scale – staff	15.7	3.1	16.1	3.3	69	17.4	3.2	72	17.1	3.9	0.14
Management scale – staff	15.5	4.1	15.7	4.2	69	17.1	4.2	73	17.5	3.8	0.40
Biology scale – staff	13.9	2.1	14.2	1.5	60	14.3	1.6	69	14.9	6.7	0.55

[a]IMR: Illness Management and Recovery.
[b]SD: standard deviation.
[c]TAU: Treatment as usual.

Table 4. Implementation assessed by IMR Fidelity Scale.

Items	Mean	SD	N
1. No people in a group	5.0	0	19
2. Program length	4.2	0.7	19
3. Comprehensiveness of the curriculum	3.8	1.2	19
4. Provision of educational handouts	4.8	0.9	19
5. Involvement of significant others	3.3	1.2	19
6. IMR goal setting	4.7	0.7	19
7. IMR goal follow-up	4.4	1.1	19
8. Motivation-based strategies	4.9	0.3	19
9. Educational techniques	4.9	0.2	19
10. Cognitive-behavioral techniques	4.9	0.2	19
11. Coping-skills training	5.0	0	9
12. Relapse prevention	5.0	0	9
13. Behavioral tailoring for medication	4.8	0	9
Mid-way assessment of item 1–10	4.2	0.3	10
Final assessment of item 1–13	4.9	0.2	9

Why no effect was detected on the IMRS assessing illness management could be that the IMRS might reflect multiple theoretical dimensions as indicated in the *post-hoc* analyses of the IMRS' subscales (McGuire et al., 2014). Illness management might have been better assessed using a universal illness management scale, for example the self-efficacy scale (Lorig et al., 2001). The overall implementation of IMR in the Danish CHMC was good according to the fidelity scores, but the aspects of ''C*omprehensiveness of the curriculum*'' and ''*Involving family and significant others*'' were not fulfilled in this trial and could explain the lack of effectiveness (Lincoln et al., 2007).

The founders of IMR proposed that effects on illness management should be a proximal outcome of the program detectable shortly after participating in the program (Mueser et al., 2006). This trial did not confirm this assumption and perhaps change in health behavior and illness management is not something that can happen after a 9-months intervention. Matters of recovery are considered to be distal/long-term outcomes. To investigate the long-term effects of the IMR program in Denmark, a follow-up assessment 21 months after baseline is ongoing.

Finally, the IMR program may not be effective in terms of the factors that participants consider as being important. The two factors that most people recognized helped their recovery are knowledge and support according to a Delphi study of 381 people with lived experience of mental illness (Law & Morrison, 2014). These two factors are the essence of rationale of IMR (Mueser et al., 2006), and thus a missing

effect is surprising. Perhaps linking the participant's own goals for recovery and own illness management is possible in the IMR group, but more difficult when adapting to everyday life. Another thought could be that maybe the personal recovery outcomes had been stronger if IMR were available on an individual or individual and group basis rather than just in groups, which other trials must investigate.

Strengths and limitations

This trial has several strengths. It was conducted with adequate generation of allocation sequence; adequate allocation concealment; adequate blinding wherever possible; adequate reporting of all relevant outcomes; intention-to-treat analyses; and no for profit bias (Higgens & Green 2011; Lundh et al., 2012; Savovic et al., 2012; Wood et al., 2008).

A sample size and power calculation was made prior to recruitment and when a high number of missing data occurred, data were analyzed using multiple imputation. Furthermore, only participants with a verified diagnosis of schizophrenia or bipolar disorder entered the trial. The external validity is high because the included participants represent the majority of people with schizophrenia or bipolar disorder receiving treatment in Danish CMCH or CMHCs elsewhere (Thornincroft et al., 2011).

However, this trial has some limitations. It is a limitation that the number of missing data was high due to the high drop-out rate. To address this, intention-to-treat analyses were performed with multiple imputations. None of the included scales were validated in Danish, which could mean that potential cultural aspects of personal recovery are not considered. Further, all outcomes reported in this paper were self-assessed, and it was consequently not possible to blind the outcome assessment, which may increase the risk of bias. However, as the trial results are overall neutral, we assess the actual risk of bias to be minor.

Conclusions and implications for practice

In this trial, IMR did not prove to be more effective than treatment as usual when analyzing illness self-management, hope, perception of recovery, or satisfaction with treatment. Further studies with a longer follow-up, better assessments of IMR and a systematic review of the existing trials are needed to determine if IMR is effective.

Declaration of interest

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