PhD Thesis
Helle Stentoft Dalum

Illness Management and Recovery
Patient outcomes and staff perspectives

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Submitted: 31/10/14
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Titel og undertitel: Illness Management and Recovery
– Patient Outcomes and Staff Perspectives

Title / Subtitle: Illness Management and Recovery
– Patient Outcomes and Staff Perspectives

Subject description: A randomized clinical trial to investigate the effects of the psychosocial intervention Illness Management and Recovery for people with severe mental illness and a qualitative study to explore staff perspectives.

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Submitted: 31 October 2014
 Preface

 Structure of the thesis

This PhD thesis represents the work I have conducted during my employment at the Mental Health Center Frederiksberg and Mental Health Center Ballerup, Capital Region of Denmark from September 2010 till October 2014.

Chapter 1 is an introduction to psychoeducation and the concept of recovery, the Illness Management and Recovery (IMR) program and a review of the literature of the IMR. Chapter 2 outlines the rationale and aims of the thesis. Chapter 3 is the method section of the thesis where the applied quantitative and qualitative methods will be presented. Chapter 4 presents the results by summing results from the papers. Chapter 5 sums up the findings compared to the literature, discusses the potential reasons for the findings and discusses the strengths and limitations. Chapter 6 contains the conclusion. Finally, Chapter 7 provides possible implications and perspectives to further research. This thesis is structured in accordance to the guidelines of the Faculty of Health and Medical Science at the University of Copenhagen and it is based on the papers and manuscripts collected in Appendix A.
Acknowledgements

This PhD thesis is dedicated to all the participating patients and staff at Community Mental Health Center Frederiksberg, Community Mental Health Center Ballerup, and Community Mental Health Center Gladsaxe. I am grateful for your engagement.

A special thanks to Lene Falgard Eplov, my supervisor and mentor. Thank you for always believing in me and for challenging me to making me do what I thought was impossible. I have enjoyed our many discussions over mental health care, recovery, research, politics and life.

Thanks to Inge Kryger Pedersen for your always reflective inputs and valuable knowledge on sociology, article-writing and qualitative research.

Thanks to my research group for helping me complete this PhD thesis and for teaching me about mental illness, mental health service, and clinical research.

Thanks to my colleagues at Competence Center for Rehabilitation and Recovery and colleagues at the Research Unit of Mental Health Center of Copenhagen for your valuable support, motivational feedback and inspiring insights. A special thanks to Lone Hellström for being my friend whom I always can talk to about everything.

Thanks to Harry Cunningham for teaching me what IMR is and introducing me to mental health services in the USA. Thanks to Larry Davidson, Amy Johnson and the people at Yale University Program for Recovery and Community Health for helping me to comprehend what recovery is. I would also like to thank Kim T. Mueser at Center for Psychiatric Rehabilitation, Boston University for inspiring discussion about IMR and psychiatric rehabilitation.

Finally, I will give gratitude to my family - my love.
Financial support

This PhD study was founded by the Danish Health Fund, Mental Health Center Ballerup, Mental Health Center Frederiksberg and the Mental Health Services of Capital Region of Denmark.

List of abbreviations

IMR    Illness Management and Recovery
IMRS   Illness Management and Recovery Scale
GAF-F  Global Assessment of Functioning – function scale
GAF-S  Global Assessment of Functioning – symptoms scale
PSP    Personal and Social Performance scale
MHRM   Mental Health Recovery Measure
HAM    Hamilton Scale of Depression
YMRS   Young’s Mania Rating Scale
NS     Not significant
1. Introduction

This PhD thesis focuses on patient outcomes and staff perspectives of the Illness Management and Recovery (IMR) program, a curriculum-based standardized recovery-oriented intervention to people with severe mental illness. This chapter begins by introducing the conceptual foundations of IMR: psychoeducation and the concept of recovery. Then an outline of why and how the IMR program was invented and the program’s underlying theoretical assumptions will be presented. A presentation of the content of the IMR curriculum will follow to comprehend what the IMR program is. Finally, the last section of this chapter will present the international state-of-the-art research on IMR.

1.1 Theoretical background

Psychoeducation

Patient education is common in the treatment of chronic illnesses such as diabetes and heart diseases [1,2] and also common in psychiatry, where educational approaches are referred to as psychoeducation. Psychoeducational approaches have been developed to increase the patient’s insight and knowledge of his or her mental illness and possible treatment options. Increased knowledge and insight are then supposed to enable the patient to adapt self-management strategies, to cope more effectively with his or her illness, to engage in behavioral changes and to gain an improved prognosis [3].

According to guidelines of psychiatric treatment in Denmark [4,5], European countries and the USA [6-8], psychoeducation should be standard treatment for people with severe mental illness such as schizophrenia and bipolar disorder in acute and post-acute phases.
Psychoeducation consists of systematic, structured information on the mental illness and its treatment. The patients should be provided with information, support and management strategies to promote coping. It is a didactical approach where patients are taught individually or in groups involving interaction between the patient and the information provider, which is often a professional [3,9]. Psychoeducation can be directed to patients alone or patients together with their families [10]. Multidimensional viewpoints are addressed including social, biological and pharmalogical perspectives. The duration of psychoeducation can vary between a brief intervention of four weeks to a longer intervention of up to 25 weeks [6,11]. At the present, it is not known which elements of psychoeducational interventions that are the active ingredient(s), it is proposed that it could be the educational material itself, some non-specific psychotherapeutic effects, being in a group with other people in a similar situation as oneself, or perhaps a combination of the three [11].

A Cochrane review of psychoeducation for people with schizophrenia by Xia et al. identified that psychoeducation seemed to reduce relapses, readmission and encourage medication compliance [3]. The review included 5142 participants (most in-patients) from a total of 44 trials. Interventions were excluded if they contained behavioral training and peer-to-peer support. Peer-to-peer support means that people with lived experience of the illness is an active contributor to the program. The authors argued that the included studies were of limited quality, but that psychoeducation had a promising perspective for mental health service. Lincoln et al. have made a review of 18 studies of psychoeducation of people with schizophrenia with altogether 1532 patients from both in-patient and out-patient settings. This review had other inclusion and exclusion criteria than the Cochrane review and specifically included studies of psychoeducation with and without inclusion of family members [10]. This review found that psychoeducation had a short term effect on relapses and rehospitalization though with a longer follow-up (more than a year) these effects were not significant. A small effect size was seen in the outcome knowledge. No effects on symptoms,
functioning or medication adherence were found. Overall psychoeducation to patients alone was ineffective, but when psychoeducation was directed to patients and their families it proved to be effective. The authors suggested that for psychoeducation to have an impact, the basic messages have to be understood and accepted by the patient, related to his or her own problems as well as remembered and integrated by interactive and behavioral components into everyday life.

According research of psychoeducation to patients with bipolar disorder, group interventions appear to be more effective than both family and individual interventions [11]. For people with schizophrenia it is recommended that psychoeducation should be combined with “obligatory exercises” [6]. These exercises are behavioral approaches such as individual behavioral therapy, problem-solving training, communication training and family therapy.

Psychoeducation is in an on-going development, and a review of the newest trends regarding psychoeducation in schizophrenia argued that pragmatic approaches have influenced the development of new psychoeducational programs [9]. Some of the new initiatives that of psychoeducation combine diagnosis-programs to reach more patients and include peer-to-peer support are promising though the evidence of these new initiatives is not sufficient [12,13].

To sum up, the literature identifies the following points in a psychoeducational program to be effective:

- The program should consist of information, support and self-management strategies to promote coping
- The program should involve the patient with his or her family

The following points are promising with regards to psychoeducation though yet unproven:

- The program should be every-day related and combined with behavioral approaches
- The program should include peer-to-peer support
The Concept of Recovery

The understanding that meaningful recovery can occur to people with severe mental illness like schizophrenia has challenged the former assumption of schizophrenia as a strictly biological disease with an invariable downward prognosis and little hope for improvement [14]. The concept of recovery is conceptualized in a number of ways [15], but recovery can broadly be divided into two aspects: clinical recovery and personal recovery sometimes divided by the notion of ‘recovery from mental illness’ and ‘recovery in mental illness’ [16-18].

Clinical recovery or ‘recovery from mental illness’ implies the ability to function in the community, both socially and vocationally, as well as being relatively free of disease-related psychopathology [19]. Therefore, clinical recovery is conceptualized as a more demanding and longer-term phenomenon than remission. Remission is a necessary but not sufficient step towards clinical recovery. There is consensus about defining symptomatic remission where criteria according to symptoms scales must be fulfilled [20]. There is no consensus in how to conceptualize functional remission. However, there is an agreement that the person has to function well in more than one domain of life, such as independent living, full- or part-time involvement in school or work, and have social relationships [21]. Furthermore, clinical recovery requires both symptomatic and functional remission for a sustained period of time.

Personal recovery or ‘recovery in mental illness’ is a process that is personal and unique to each individual. From the 1980’s mental health treatment changed from long-term hospital treatment to community based treatment and in that period people with mental illness gained more civil rights and supported each other [22]. They protested against the assumption of mental illness like schizophrenia as a chronic disease and argued that many people showed significant functional improvements over time. They wanted to state their own active role in their treatment and argued that their personal experience of gaining hope and developing new meaning in the process of their
illness should be included in the concept of recovery [23,24]. Anthony has captured what personal
recovery in mental illness is, which is a definition broadly accepted: “Recovery is described as a
deeply personal, unique process of changing one’s attitudes, values, feelings, goals, skills, and/or
roles. It is a way of living a satisfying, hopeful, and contributing life even with limitations caused by
illness. Recovery involves the development of new meaning and purpose in one’s life as one grows
beyond the catastrophic effects of mental illness” [25] p. 527. Several studies of and narrative
descriptions by first person accounts of people with lived experience of mental illness are made to
comprehend the meaning of personal recovery. Personal accounts of the experience of personal
recovery capture a “birth of hope” [26] p. 56 where despair and the feeling of giving up is replaced
by having hope for the future and believing in one’s own unique possibilities even though potential
relapses can occur [27-29]. They also point to that the process of personal recovery can provide
ambiguity and anxiety, but also self-efficacy in the individual. Elements that can be reflected in the
process of personal recovery are hope for the future, gaining empowerment and autonomy,
increased quality of life, and participation in meaningful activities [30-32].

To establish consensus about the meaning of personal recovery and what factors enable recovery
among people with an experience of psychosis, a Delphi study with a total of 381 participants was
conducted [33]. The idea was to identify which areas that appear to be the same for a majority of
people. The two factors that most people recognized as factors that enabled their recovery were
knowledge and support. Knowledge included an understanding of the mental illness, how to cope
with the illness and where to seek help. The support factor included social support and relationships
and support of mental health services.
Recovery-oriented mental health care

In mental health service the aspect of personal recovery has proposed new values and standards that are needed to support the patient’s individual recovery process [34-36]. These values are hope, respect for self-determination and being person-oriented rather than illness-oriented [36,37]. Sometimes these values are collected and called the recovery model of mental health care. The recovery model of mental health care has influenced mental health service and given rise to a number of programs to help people with mental illness gain recovery. As described patients want to play an active role in their treatment, and this has provided a new opportunity and obligation for the staff to provide recovery-oriented mental health service. However, mental health care has been, and still is, dominated by the medical model, which values preservation and restoration of mental health and focuses on categorizing and solving problems that result from the illness [17-19].

Recovery-oriented mental service must be flexible and easy to access for the patient instead of having a linear structure where the patient must “enter at point “A” and move through a series of consecutive steps to arrive at point “B”” [26] p. 55. As recovery in mental illness is no linear process and the individual can experience relapses. Mental health services cannot provide recovery, since it is a deeply personal process; but mental health services can aim at providing recovery-oriented service in their treatment and rehabilitation programs. The fundamental basis of recovery-oriented mental health services is to support the patient’s recovery process by facilitating an active collaboration between the patient and the mental health care professional [37]. The professionals should nurture the patients’ hope and the professional should have hope for the patient when he or she has no hope.

A questionnaire study of community mental health nurses’ perspective of recovery-oriented care proposed that there might be a gap between what is taught academically about recovery-oriented care and the perceived ability and confidence in providing recovery-oriented care [38].
To sum up, the literature identifies the following points as needed to be concerned in mental health programs building on the concept of recovery:

- The program should be flexible and easy to access
- The program should draw on social support and encourage relationships
- The program should nurture the patient’s hope and the professional should have hope for the patient when he or she has no hope
- The program should be person-oriented

1.2 The Illness Management and Recovery Program

The Illness Management and Recovery (IMR) program was invented with the aim of gathering different evidence-based psychoeducational and illness self-management strategies to people with severe mental illness of schizophrenia, schizoaffective disorder, bipolar disorder, and major depression into a full-ranged program. In 1997 in USA at a conference of National Institute of Mental Health, it was suggested that the different illness-management strategies already known to people with severe mental illness were incorporated into one full-ranged program [39]. In the years 2002-04 the work of developing the IMR program was led by Professor Kim Mueser and Master of Social Work Susan Gingerich together with a committee of stakeholders including patients, clinicians, researchers, relatives and program leaders. After a profound literature review, five empirically supported strategies were identified and collected into an full-ranged psychoeducational program [40].

The five strategies were:

1. Psychoeducation
2. Cognitive-behavioral approaches to medication adherence
3. Relapse prevention planning
4. Social skills training
5. Coping skills training for managing persistent symptoms
When developing the IMR program the intent was to include recovery in terms of ‘recovery in mental illness’ as the underlying concept to the illness self-management strategies. The founders of IMR argued that illness management and recovery are closely related, and the rationale of the IMR program is that recovery requires that individuals learn how to manage their illness [39,41]. Illness management strategies focus on improving aspects of clinical recovery and recovery strategies focus on improving aspects of personal recovery.

The theoretical assumptions of Illness Management and Recovery

The theoretical assumptions of the Illness Management and Recovery program are The Stress-Vulnerability Model, The Transtheoretical Model, and a Proximal-Distal Understanding of the mechanisms of IMR.

The Stress-Vulnerability Model

The Stress-Vulnerability Model is a theoretical framework of how to understand mental illness [42]. Mental illness is understood as the result of interplay of biological vulnerability, stress, and coping, see figure 1.1. The Stress-Vulnerability Model determines that the cause of mental illness such as schizophrenia is stress in interaction with a psychobiological vulnerability which is determined early in life by genes and environmental factors [14,43]. Stress can for instance be stressful life events, interpersonal conflicts, or poor living conditions. If a person with a biological vulnerability experiences stress this can cause mental illness or trigger relapses.
The Stress-Vulnerability Model proposes that symptom relapses can be prevented by adapting coping skills and getting social support to reduce the stress, and/or by lowering the biological vulnerability for instance by using medication effectively or by avoiding substance/alcohol abuse. In the different modules of the IMR program this model is continuously used to explain mental illness and why strategies and skills for illness are unique to each individual, see figure 1.3.

**The Transtheoretical Model**

The Transtheoretical Model also known as ‘Stages of Change’ is a model of how individuals change their health behavior and habits [44]. It is a general model of health behavioral changes and not specifically attached to mental health. It proposes that behavioral changes happen through a series of stages [45,46], see figure 1.2.

In the first stage of *Precontemplation* the patient does not intend to take action because he or she is resistant, un-informed or un-motivated to make a change. In the second stage of *Contemplation* the
patient is more conscious about the positive aspects and gains of changing behavior, but at the same time the patient can be overwhelmed by the awareness of the potential negative aspects of changing. The difficulty of balancing the pros and cons of changing can produce ambivalence that can keep the patient stuck in this stage. The third stage is Preparation where the patient intends to take action towards a change and has a plan of action like consulting a counselor, talking to the doctor or relying on a self-management approach.

Figure 1.2 The Transtheoretical Model

The fourth stage is Action and here the patient makes a specific evident change in his or her lifestyle or behavior like going for a walk every day or stop drinking alcohol. The fifth stage is Maintenance where the patient strives to maintain the change and prevent relapses. The patient is more confident that he or she can continue the change. Finally, in the sixth stage Termination the patient keeps the new changed behavior or lifestyle and does not capitulate to temptation of returning to old habits. The patient has gained a confidence in him- or herself and will not return to the old habit as a way of coping, if he or she for instance is feeling depressed, anxious or lonely. As illustrated by the
arrow in figure 1.2 relapses often occur. When experiencing relapses the individual return to an earlier stage of changing behavior and then if motivated to make the change start moving forward towards a behavioral change from this stage.

In the IMR program the Transtheoretical Model is a way for the professional to motivate the patients. To facilitate a change in the patient requires an understanding of the patient’s stage and which kind of motivation that might be needed for the patient to progress.

A Proximal-Distal Understanding

In the foundation of IMR the program is assumed to have both proximal and distal outcomes to the participating patients [22]. See figure 1.3 for an illustration.

Figure 1.3 The Proximal-Distal Understanding of the Effects of the IMR program

The figure was originally printed in an article by Mueser et al. in 2006 [39]. It is reprinted with permission from the author and from the publisher.
Proximal outcomes include being able to manage one’s mental illness in different ways for instance by adapting skills to cope with stress, skills to decrease the intake of alcohol and drugs, and skills to use medication effectively. These changes occur in a short term perspective either during the IMR program or immediately after attending the program. The distal outcomes are proposed to be longer-term changes and include outcomes of clinical recovery such as severity of symptoms, level of functioning and remission as well as outcomes of personal recovery such as hope and quality of life. The gains of proximal outcomes are required before gaining the distal outcomes. For instance when the patient learns how to manage his or her illness he or she can move forward and do more meaningful activities which would be assessed as an increase in level of functioning.

The Contents of the Illness Management and Recovery program

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
- 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 participant, and what his or her personal goals are for recovery. During the program these recovery goals are broken down into smaller steps and perhaps changed by the
participant to make them more desirable and/or achievable. The pedagogic approach is to make a connection between the participant’s recovery goals a motivation for self-management of the illness. For instance when the patient learns why and how to cope with stress, he or she gets to reflect over how stress in daily life might be getting in the way for his or her personal recovery goals.

The definition of illness management in the IMR program is “Professional-based interventions designed to help clients and clinicians collaborate in the treatment of their mental illness, reduce susceptibility to relapses, and cope more effectively with their symptoms” [40] p.1273. The IMR program was a part of the National Implementation Evidence-Based Practices project in the USA and therefore made into an implementation resource kit consisting of a curriculum with a manual, hand-outs, information brochures, training videos, a fidelity scale, and outcome measures [39]. The program enables different learning approaches and an involvement of family and significant others. IMR can be provided both one-to-one and in groups. The sessions are intended to last an hour and follow the same structured pattern, and the program with 11 modules is planned to have a duration of approximately nine months.

1.3 Literature review

Randomized clinical trials

A literature search identified three randomized clinical trials of IMR published before this PhD study started and during the course of this PhD study, two additional randomized trials of IMR were published. In addition to the clinical randomized trials of IMR, different evaluations of lower level of evidence such as pre-post evaluations [39,47] as well as cohort study [48,49] have been published and show tendencies towards clinical improvements in patients receiving IMR. In the following is a description of the randomized clinical trials of IMR. Their settings, design, and
findings will be presented in table 1.1.

The first randomized clinical trial was from Israel and was published by Hasson-Ohayon et al. in 2007 [50]. The setting of this trial was in psychiatric rehabilitation centers and a total of 210 patients participated. The participants were evaluated at baseline and post treatment by self-ratings and non-blinded ratings by a staff member. The second randomized trial by Levitt et al. from 2009 included 104 patients from supported housing in the USA [51]. The patients were assessed at 5 and 12 months after baseline by an assessor blinded to allocation. Salyers et al. from 2010 published the third randomized trial which was a cluster designed trial in assertive community teams with a total of 141 participants [52]. The patients were evaluated 12 and 24 months after baseline assessments by self-ratings and non-blinded ratings by a staff member. The fourth randomized trial was conducted in Sweden by Färdig et al. and published in 2011 [53]. A total of 41 patients from community mental health centers participated. They were assessed by an assessor blinded to allocation at 9 and 21 months after baseline. The first four trials all compared IMR to treatment as usual. The fifth randomized trial was made in the USA by Slayers et al. and published in 2014 [54]. A total of 118 patients from veterans’ and a community mental health center were randomized to either IMR or a control-condition of a problem-solving program. Assessments were made by an assessor blinded to allocation at 9 and 18 months after baseline.

In terms of illness management outcomes three of the randomized trials showed a significant difference between the IMR group and the treatment as usual group in favor of IMR on the IMRS (the Illness Management and Recovery Scale developed for the IMR program) both rated by the patient and a staff member [50,51,53]. Contrary, two trials found no statistical significant difference on the IMRS between the two groups of intervention [52,54]. Additionally, two trials have found no effect of IMR on reduced alcohol and drug use [51,52], which was categorized as an aspect of illness management in the distal-proximal understanding described above.
In terms of clinical recovery measures, the findings from the first four trials pointed to a tendency towards IMR being effective. They found that participants in IMR showed significant improvements in assessments of severity of psychiatric symptoms [51,53], psychosocial functioning [51], a reduced hospital use over time [52], and less suicidal ideation [53]. There were also contrasting findings of the effectiveness of IMR, though. The fifth trial found IMR was not significantly different from the control condition when evaluating symptoms, medication adherence, or service utilization [54]. One of the other randomized trials could not detect a significant difference in IMR compared to treatment as usual on suicidal behavior or symptoms [51].

In terms of personal recovery outcomes, no effects on hope, self-perceived recovery, coping, social support or quality of life were found in any of the randomized trials [52-54].

Overall, the literature points to that there might are benefits of IMR but methodological profound trials are needed to prove this.
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Setting</th>
<th>Participants</th>
<th>Diagnoses</th>
<th>Power calculation</th>
<th>Fidelity score</th>
<th>Blinding</th>
<th>Randomization</th>
<th>Interventions</th>
<th>Follow-up</th>
<th>Outcomes and Findings (significant differences by p-value)</th>
<th>Drop-out rate %</th>
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<tbody>
<tr>
<td>Hasson-Ohayon et al. (2007)</td>
<td>Psychiatric rehabilitation centers in Israel</td>
<td>210</td>
<td>Schizophrenia, unspecified psychosis, depression, bipolar disorder, anxiety disorder, eating disorder, personality disorder</td>
<td>No</td>
<td>Yes - average 3.70</td>
<td>No</td>
<td>Randomly assigned by lottery</td>
<td>TAU vs. IMR+TAU</td>
<td>Graduation</td>
<td>IMRS patient version (p&lt;0.01) IMRS staff version (p&lt;0.01) Coping Efficacy Scale (p=ns*) Multidimensional Scale of Perceived Social Support (p=ns)</td>
<td>18</td>
</tr>
<tr>
<td>Levitt et al. (2009)</td>
<td>Supported housing in the USA</td>
<td>104</td>
<td>Schizophrenia, schizoaffective disorder, psychotic or delusional disorder, bipolar disorder or cyclothymia, depression, mood disorder (not otherwise specified), anxiety, cognitive disorder</td>
<td>No</td>
<td>Yes - average 4.38 (±1.19)</td>
<td>Yes</td>
<td>Drawing token, stratified by gender</td>
<td>TAU vs. IMR+TAU</td>
<td>5 and 12 months</td>
<td>IMRS patient version (p=0.002) IMRS staff version (p=0.001) Psychosocial functioning/quality of life (p=0.005) Brief Psychiatric Rating Scale (p=0.488) Modified Colorado Symptom Index (p=0.043) Suicidal Behavior (p=0.501) Alcohol Use Scale rated by case manager (p=0.432) Drug Use Scale rated by case manager (p=0.361) Working self-report (p=0.625) Interested in working self-report (p=1.0) Hospitalization (p=1.0)</td>
<td>&quot;Low exposure rate&quot;</td>
</tr>
<tr>
<td>Salyers et al. (2010)</td>
<td>Assertive community treatment in the USA</td>
<td>141</td>
<td>Affective disorder, psychotic disorder, other (not further specified)</td>
<td>No</td>
<td>Yes - average &gt; 4.0</td>
<td>No</td>
<td>Cluster randomization by team</td>
<td>TAU vs. IMR+TAU</td>
<td>24 months</td>
<td>IMRS patient version (p=ns) IMRS staff version (p=ns) Adult State Hope Scale (p=ns) Satisfaction with service (p&lt;0.05) Hospitalization (p&lt;0.05) Employment (p=ns) Housing (p=ns) Substance abuse (p=ns) Incarceration (p=ns)</td>
<td>26</td>
</tr>
</tbody>
</table>

*ns* = not significant
### Table 1.1 Randomized Clinical Trials of IMR - Continued

<table>
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<th>Diagnoses</th>
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<th>Fidelity score</th>
<th>Blinding</th>
<th>Randomization</th>
<th>Interventions</th>
<th>Outcomes and Findings (significant differences by p-value)</th>
<th>Drop-out rate %</th>
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<td>Färdig et al. (2011)</td>
<td>Community mental health centers in Sweden</td>
<td>41</td>
<td>Schizophrenia, schizoaffective disorder</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Computerized randomization</td>
<td>TAU vs. IMR+TAU</td>
<td>IMRS patient (p=0.001) IMRS staff (p&lt;0.001) Hospitalization (p=ns*) PECC (Psychosis Evaluation tool for Common use by Caregivers) (p=0.001) PECC Suicidality (p=ns) Suicidal Ideation (p=ns) MANSA (Manchester Short Assessment of Quality of Life) (p=0.221) WCQ (Ways of Coping Questionnaire) (p=ns) RAS (Recovery Assessment Scale) (p=0.808) DDD (Defined Daily Dose) (p=ns)</td>
<td>5</td>
</tr>
<tr>
<td>Salyers et al. (2014)</td>
<td>Veterans center and community mental health center</td>
<td>118</td>
<td>Schizophrenia, schizoaffective disorder</td>
<td>Yes, but number of obligatory participants not reached</td>
<td>Yes - average 3.4 (±0.3)</td>
<td>Yes</td>
<td>Randomization</td>
<td>IMR vs. Active control group</td>
<td>9 and 18 months</td>
<td>IMRS patient version (p=ns) IMRS staff version (p=ns) PANSS (Positive and Negative Syndrome Scale) (p=ns) Quality of Life Scale (p=ns) Patient Activation Measure Morisky Scale (assessing medication adherence) (p=ns) Recovery Assessment Scale (p=ns) The Adult State Hope Scale (p=ns) Service utilization from medical records Service utilization (p=ns)</td>
</tr>
</tbody>
</table>

*ns= not significant
2. Rationale and Aims

2.1 A solid contribution to the evidence base

To establish the evidence of the Illness Management and Recovery program on outcomes related to illness self-management, clinical recovery and personal recovery, it is crucial that the methodology which conclusions are made upon is solid. In the prior randomized clinical trials of IMR there are risk of bias in several critical points, see table 1.1. The rationale of this PhD study was to try to fulfill these critical points and contribute to the evidence base by conducting a randomized clinical trial of IMR in Denmark. The critical points were:

- **Power and sample size calculations**: Either no prior power and sample size was conducted or the sample size was smaller than estimated in the prior calculations in the previous trials. This randomized trial would be based on a power and sample size calculation.

- **Several diagnoses included in the same trial**: Only patients with diagnosis of severe mental illness would be included and not patients with several other diagnoses as seen in some of the other trials [50,51].

- **Randomization and stringency**: The description of how the randomization was performed would be transparent, which not all the prior trials’ descriptions were [50,51,54].

- **Fidelity assessment**: To secure the implementation fidelity assessments would be performed, which was lacking in one of the prior trials [53].

- **Blinding**: Blinding of outcome assessment as well as blinding of the statistical analysis would be conducted, not all of the prior trials included blinded assessments [50,52].

- **Drop-outs**: Drop-out rates of 5-26 percent were seen in all of the prior trials [29]. To address potential drop-out strategies for preventing drop-out would be adapted and approaches for handling missing data in the analysis would be performed.
2.2 The perspective of staff providing IMR

Most research about recovery-oriented mental health practice focuses on the effects of different programs and interventions for patients. There is little knowledge of what facilitating recovery-oriented programs mean to staff members and their practice. When providing a recovery-oriented program like the IMR program, it is essential that the staff knows about clinical as well as personal recovery and attempts to provide recovery-oriented service as described in chapter 1. A large part of the IMR program’s curriculum and training material for staff are focused on the concept of recovery and how to have a recovery-oriented approach towards the patients. Therefore a recovery-oriented approach should be reflected in the staff when implementing the IMR program. Nevertheless, when assessing how well IMR is implemented according to the fidelity assessments this important aspect of recovery-orientation is not included. Two American studies have shown when staff is trained in the IMR curriculum they changed their attitude and became more optimistic towards patients’ recovery [55-57]. However, empirical literature regarding staff members’ changes and adoptions of the recovery-oriented approach when conducting IMR is absent. Therefore, to explore how and if staff members experience recovery-oriented changes in their practice when facilitating IMR the staff perspective is included in this PhD study.
2.3 Aims

As described, the evidence of the Illness Management and Recovery program related to patient outcomes is currently incomplete, and the important implementation perspective of recovery-orientation in staff providing IMR is absent in the literature.

As a result the aims of this PhD study were:

1. To evaluate the effects of the Illness Management and Recovery program on outcomes of illness management, clinical recovery, and personal recovery in patients with schizophrenia or bipolar disorder through a randomized clinical trial.
   The primary alternative hypothesis was tested: Patients in the IMR program would improve at least 6 points on the Global Assessment of Function scale (GAF-F) compared to patients receiving treatment as usual at follow-up 9 months after baseline.

2. To analyze what changes mental health professionals have experienced in their attitude towards their own practice when facilitating the IMR program along with their daily work.
3. Methods

This PhD study was originally planned as a mixed method study, where quantitative and qualitative methods were combined. When starting the research process combining the two different methods seemed to be weakening the possibilities of answering the research questions and aims in the best way. Instead it was decided to answer the two research questions separately in a randomized clinical trial and a qualitative study and focus on conducting a solid methodological contribution within in each research discipline. In the following is the method of the randomized clinical trial first described and then follows the method of the qualitative study.

3.1 The randomized clinical trial assessing patient outcomes

Design

This trial was designed as a randomized, assessor-blinded, multi-center, clinical trial of the IMR program compared with treatment as usual. Paper I contains the detailed study protocol of the trial, therefore the following descriptions will be concise and only supplements to the protocol’s information will be elaborated.

In the period from February 2011 to December 2013 the IMR program was implemented and tested in two community mental health centers, Frederiksberg and Ballerup, in the Capital Region of Denmark. To improve the inclusion the community mental health center Gladsaxe was added in October 2011. Baseline assessments were conducted from February 2011 till December 2012 and post treatment assessments from March 2012 till December 2013.
**Ethical considerations**

The study was approved by the Ethics Committee in the Capital Region of Denmark (registration number H-1-2010-134), and it was reported to the Danish Data Protection Agency (registration number RHP-2011-09).

**Participants**

*Participants were included if they:*

- had a diagnosis of schizophrenia or bipolar disorder according to the ICD-10 criteria and verified by the Present State Examination [58] by a psychiatrist or clinical psychologist
- were 18 years or older
- were referred to an included community mental health center
- spoke and understood Danish
- gave informed consent

*Participants were excluded if they:*

- had a guardian or receiving forensic care
- had dementia or mental retardation defined by the ICD-10 criteria
- had a large-scale substance use
- lived in supported housing
- were involved in psychoeducation at the time of inclusion
- did not give informed consent
Randomization

The participants were randomly allocated 1:1 to receive IMR plus treatment as usual or to continue 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 community mental health center. To secure concealment of the allocation sequence and block sizes, the randomization was central and telephone-based by an administrative office outside the research team.

Interventions

Illness Management and Recovery

In the spring of 2010 before the intervention started, the IMR manual version from 2006 with worksheets and hand-outs was translated into Danish. IMR was provided in a group format. Ten patients were assigned to each group and every group was led by two or three staff members. Altogether ten groups were included in the intervention. The IMR program lasted nine months with one weekly session. The attendance was registered to monitor the participation. The group sessions was provided at the local community mental health center during the day.

The staff whom provided IMR was experienced mental health professionals with three or four days of training in facilitating IMR. The two days of training was given prior to the intervention to all staff facilitating IMR, and one day of training again after six months was given all staff facilitating IMR to keep focus on the IMR curriculum. Some of the IMR staff was given an additional day of training one year after the prior training, to brush up their knowledge before they had their own group, as they had not yet facilitated an IMR group. All training was provided by a well-experienced IMR educator from USA. Staff members were not trained in the IMR curriculum if they were not designated to facilitate one of the ten IMR groups.
When IMR was introduced in Denmark special efforts were made to support the community mental health centers and secure a proper implementation. The learning from the research on implementing IMR [55,59-61] was used to secure a good implementation. Members of the research team and the leadership of the community mental health centers met quarterly to facilitate the implementation and coordinate IMR training of staff. The research team and a local IMR coordinator (a member of the staff) had frequently meetings to discuss the implementation, recruitment strategies and fidelity assessments. Besides these initiatives staff facilitating IMR received monthly supervision and met in an IMR network across the three participating community mental health centers to share experiences and help each other implement the program. In each community mental health center supervision was the first half year of implementation provided by the well-experienced IMR educator from USA, who taught the IMR curriculum in the trainings of staff. After the first half year supervision was carried out in the auspices of each community mental health center.

Finally, strategies were made to motivate patients to attend the IMR group since prior trials [52,54] points to that patient’s attendance and participation in the IMR program is crucial. For instance if a patient did not come to the IMR group, one of the IMR group leaders would call and try to motivate him or her to come to IMR group the following week. If a patient was in the hospital, one of the IMR group leaders would get in contact with the patient and provide the missing modules of the IMR program individually, so that the patient would not lack behind when returning to the IMR group.

*Treatment as usual*

 Patients randomized to the control group got ‘treatment as usual’ only. Treatment as usual consisted of a individually adapted interdisciplinary treatment in the community mental health center or in the
patient’s own home. The treatment was individualized for each patient and could contain medication, individual case manager support, individual and group therapy as well as unstandardized psychoeducation. The interdisciplinary treatment approach means collaboration between different professionals in the community mental health center as well as collaboration with the patient’s family members and professionals in other sectors such as the general practitioner or the social worker. The staff of the community mental health centers were trained mental health professionals such as nurses, psychiatrists, psychologists, physiotherapists, occupational therapists, and licensed social workers. Every patient in the community mental health center had a case manager, who together with the patient planned which elements the individualized treatment should consist of. The majority of the staff was nurses, who often had the case manager responsibility and a caseload of approximately 30 patients. On an average basis the case manager saw 4 patients a day. Some contacts were short for instance dispensing medication could take five minutes and some contacts involved a longer meeting with profound dialogue and therapy that could last one hour. The patient could meet with the case manager once a week or more or less depending on the state of patient.

Different recovery-oriented initiatives such as information and education in the concept of recovery was introduced at the community mental health centers prior to and during the randomized trial, though no other systematic recovery-oriented intervention had been implemented prior to or during the trial. All staff members were trained in Motivational Interviewing [62]. Some of the IMR group leaders had the role of being case manager for participants both in the IMR intervention and in the control group. To ensure that the staff members were following the principles of treatment as usual when meeting patients in the control group, they could consult a task force consisting of a well-experienced psychiatrist only performing treatment as usual. To
describe how IMR and the treatment as usual differed from each other see table 3.1, which contains information on how often the patient got treatment, the duration of the contacts, the contents, the variation in the contents, and the approach used. The difference between the two treatments was especially due to the fact that treatment as usual was changeable and that IMR was obligated to a certain approach and followed a curriculum.

**Table 3.1 Treatment as usual compared with IMR**

<table>
<thead>
<tr>
<th></th>
<th>Treatment as usual</th>
<th>IMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often does the patient get</td>
<td>Changeable from once a week to once a month</td>
<td>Always one session a week for nine months</td>
</tr>
<tr>
<td>treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the duration of the</td>
<td>Changeable from 5 minutes till one hour</td>
<td>Always one hour</td>
</tr>
<tr>
<td>treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the content of treatment?</td>
<td>Changeable could be issues like a follow-up on a meeting</td>
<td>The patients’ recovery goals and the other</td>
</tr>
<tr>
<td></td>
<td>with the psychiatrist, an adjustment of medication, a</td>
<td>10 modules from the IMR-curriculum.</td>
</tr>
<tr>
<td></td>
<td>focus on a problem from the past or the present.</td>
<td></td>
</tr>
<tr>
<td>Are there variations in the content?</td>
<td>Changeable if an issue for instance persisting symptoms</td>
<td>During the 9 months of the IMR program the</td>
</tr>
<tr>
<td></td>
<td>or alcohol abuse is concerning the patient for a longer</td>
<td>content will contain all 11 modules of the</td>
</tr>
<tr>
<td></td>
<td>time such as 6 months or longer this issue can be the</td>
<td>curriculum.</td>
</tr>
<tr>
<td></td>
<td>focus of the conversations continuously.</td>
<td></td>
</tr>
<tr>
<td>What type of approach?</td>
<td>Changeable could be individual dialogues, a</td>
<td>The IMR curriculum with the same structure of</td>
</tr>
<tr>
<td></td>
<td>therapeutically approach, psychoeduation, instructions</td>
<td>the sessions every time and focusing on the</td>
</tr>
<tr>
<td></td>
<td>on how to take one’s medication, a walk, and exposure</td>
<td>patient’s recovery goals.</td>
</tr>
<tr>
<td></td>
<td>therapy.</td>
<td></td>
</tr>
</tbody>
</table>

The use of treatment as usual was registered for the intervention group as well as the control group.

**Outcomes**

Assessments of functioning and symptom were obtained through an interview with an assessor blinded to allocation. Information on illness management and recovery was obtained by staff and as self-report by patients and information of personal recovery was obtained by patients’ self-reports.
**Primary outcome: Global Assessment of Functioning**

The primary outcome was Global Assessment of Functioning assessed by GAF-F. The Global Assessment of Functioning scale can be divided into two scales GAF-F and GAF-S, which have been proved useful [63,64]. The GAF-F focuses on the dimension of social and occupational functioning, and the GAF-S focuses on the dimension of severity of symptoms. The scale is a numeric scale where the individual is given a number between 1 and 100.

**Secondary outcomes: PANSS, PSP and the IMRS**

The secondary outcomes were focusing on severity of symptoms and social functioning.

**Positive and Negative Syndrome Scale (PANSS)**

Positive and Negative Syndrome Scale (PANSS) consists of three subscales that capture positive symptoms, negative symptoms and general psychopathology (e.g. depression and anxiety). The scale is a 7-point validated rating scale that consists of 30 items [65]. This scale is developed for people with schizophrenia, but is applicable for people with bipolar disorder as well [66].

**Personal and Social Performance (PSP)**

Personal and Social Performance scale assesses four dimensions of social functioning: 1) socially useful activities, 2) personal functioning and social relationships, 3) self-care, and 4) aggressive behavior. The PSP scale is not validated in Danish, but studies in in-patient settings as well as out-patient settings suggest good reliability and validity [67,68].

**Illness Management and Recovery Scale (IMRS)**

Illness Management was assessed by the Illness Management and Recovery Scale (IMRS). IMRS is
a 15 item rating scale, where a higher score on a 5-point scale indicates a better illness self-management. The scale comprises the key elements of the IMR program and consists of parallel versions for patients (IMRS-P) and for staff members (IMRS-S). In validation studies IMRS show a good internal and test-retest reliability and a sensitivity to detect change over time [69-71]. The IMRS has also proved to be useful in assessing progress in people not participating in the IMR program [72].

A recent study proposes that multiple theoretical dimensions are reflected in the IMRS and that three subscales of the IMRS seem to be more appropriate [73]. The three subscales of the IMRS are a Recovery scale, a Management scale and a Biology scale. The Recovery scale is composed from the items 1, 2, 4, 8, and 12, the Management scale is composed from the items 6, 7, 9, 10, and 11, and the Biology scale is composed from the items 12, 14, and 15. In the analysis of this trial the results of the three subscales of the IMRS are post-hoc reported, see below.

**Explorative outcomes**

Explorative outcomes were symptoms, personal recovery, hope, alcohol/substance use, use of services, satisfaction with service, and adverse effects.

**Hamilton Rating Scale for Depression (HAM-6)**

Symptoms of depression were assessed by the Hamilton Rating Scale for Depression. The original score of the scale consists of 17 items, though in this trial the HAM-6 scale with 6 items is used, since the HAM-6 has shown to be more homogenous and sensitive than the scale with 17 items [74,75].
**Young Mania Rating Scale (YMRS)**

To assess symptoms of mania the Young Mania Rating Scale (YMRS) which consists of 11 items rating was used [76]. The psychometric analyses of YMRS have not been sufficient, but the scale is implemented in the clinical setting and therefore considered appropriate as an explorative outcome [74].

**Mental Health Recovery Measure (MHRM)**

Mental Health Recovery Measure (MHRM) was used to assess personal recovery [77,78]. The scale consists of 30 items on a 5-point scale and has been validated in more than 200 patients in different settings [79].

**Adult State Hope Scale**

To assess hope and optimism the Adult State Hope Scale [80] was used. The theory behind the scale is that hope is viewed as a positive motivational state that is based on an interactively sense of successful capacity and a confidence in having pathways to meet goals [81]. It is a widely used scale to assess hope in patients with mental illness [82]. It consists of 6 items on a rating scale from 1 till 8, where a higher number indicates greater hope.

**Substance use**

Information about substance use was assessed by the patient’s case manager on a simple not validated scale.

**Service utilization**

Information about service utilization was obtained through hospital records.
**Client’s Satisfaction Questionnaire (CSQ)**

Finally the participants’ satisfaction with the services was measured by the Client’s Satisfaction Questionnaire [83]. The scale has 8 items and is one-dimensional, indicating a homogeneous estimate of general satisfaction with the mental health services.

**Harm and adverse effects**

Information on harms and adverse effect was monitored by the patient’s case manager throughout the trial.

**Fidelity assessment of the IMR groups**

To assess how well IMR was implemented the IMR Fidelity Scale was used. The IMR Fidelity Scale consists of 13 items that are rated on a 5 point scale, where a score of 1-3.9 equals the program is not following the IMR curriculum, a score of 4-4.3 equals good fidelity and a score of 4.4-5 equals high fidelity with the IMR curriculum[84].

The IMR Fidelity Scale was used for fidelity assessments for all groups. The fidelity assessments were made mid-way through the nine month program (after four months) assessing items 1-10 and at the end of each IMR group (at nine months) assessing all items. The mid-way fidelity assessment was meant as a process evaluation, so the IMR group leaders could adjust their practice if needed to. The end fidelity assessment was meant as a final evaluation of the IMR group. Staff specially trained in IMR fidelity assessment from one participating community mental health centers was conducting the assessments at the other community mental health centers’ groups and vice versa. A multiple data approach was used including: interviews, observation of the IMR group, an audit of the patient’s service records as well as audit of the IMR notes of progress. The Fidelity assessments resulted in a report as well as a rating on the IMR Fidelity Scale.
**Blinding**

Post treatment assessments regarding level of functioning and symptom severity were conducted by an assessor blinded to treatment allocation. Due to the nature of the intervention neither participants nor staff could be blinded to allocation. Both parties, however, were strongly inculcated not to disclose the allocation status of the participant at the follow up assessment. A new follow-up interview with a new assessor blinded to allocation was arranged for the few participants that accidentally disclosed their allocation. To minimize the risk of random errors in the transformation from the case record form into the database, all data was fed into the computer twice by two independent research assistants. An employee outside the research team fed information about treatment group into the computer and kept the randomization code so the researchers were blinded to allocation while conducting the statistical analysis.

**Figure 3.1 Bland-Altman Plot: Agreement of IMR-raters**

Two people conducted the assessments of all the objective measurements (GAF-F, GAF-S, PSP, PANSS, YMRS, HAM-6) and reached an agreement before rating patients individually. To see how well the two raters agreed, a Bland-Altman plot for the primary outcome GAF-F’s scoring and the PSP’s scoring was conducted, as these measures both assess level of functioning and are somewhat
correlated, see figure 3.1. There did not seem to be a pattern in the mean differences or a large variation in either the GAF or the PSP scoring between the two raters. As seen the figure the majority of the ratings is in the range of plus/minus two points of the scales which was considered acceptable in this trial.

**Sample size**

Prior to recruitment a power and sample size calculation was performed. A total of 200 participants were estimated sufficient for detecting a true difference between the IMR and the control group of at least 6 points on the GAF-F [39,85]. This sample size was based on a power of 80 %, an alpha of 5 % and a standard deviation (SD) of 15 points [86,87]. For the secondary outcome it was determined that the sample size of 200 participants was sufficient to test minimal clinical relevant differences with an alpha of 5 % and a power of 80 %, see table 2 Paper I.

**Statistical analysis**

The data analysis was based on the intention-to-treat principle. The analysis of difference between the two groups was conducted using analysis of covariance. This was done by estimating the dependent post-treatment variable means adjusted from what it would be if all groups were equal on the covariate (the baseline mean of this variable) [88]. If no baseline mean existed, t-tests were conducted.

Missing data was a potential source of bias. An analysis of the missing data was conducted of the following variables GAF-F, PSP, PANSS, IMRS-P, and IMRS-S and it showed that up to 29 % of all observations were incomplete. Multiple imputation was therefore conducted to enable an intention-to-treat analysis. Post-treatment values were imputed for GAF-F, PSP, PANSS, IMRS-P,
and IMRS-S using gender, diagnosis, age, community mental health center and intervention group as constraints. The automatic procedure was used and 100 imputations estimated.

For the exploratory outcomes and the post-hoc analysis of the IMRS subscales, complete case analysis was conducted.

Per-protocol analysis was performed to see, if group attendance would influence the result as proposed in one trial [89]. An analysis using the continuous variable of group attendance for the participants randomized to IMR was made as well as an analysis using a dichotomous variable categorizing attendance into 0-10 sessions or ≥11 sessions.

Subgroup analysis tested whether diagnosis or gender interfered with the primary and secondary outcomes.

The level of significance for all statistical tests was 0.05. The IBM SPSS Statistics version 19 for Windows was used for statistical analysis and STATA version 11.2 was used for multiple imputation.

### 3.2 The qualitative study exploring staff perspectives

**Pre-understanding**

The pre-understanding for the qualitative study was partly founded in the literature of IMR and recovery-oriented mental health care as described in the introduction and partly founded on a pilot study. To get into the field of mental health services in Denmark a pilot study was carried out. Observations in Danish community mental health centers of what nurses’, psychologists’, and psychiatrists’ work consisted of and how they approached their patients were conducted. Interviews with nurses and psychologists working in the community mental health centers were carried out to get additional information on the regular practice of the professionals. For instance the pilot study
revealed the importance of the relation between the patient and the professional to make sure that the patient gets the help needed as well as provided information about the content of the usual treatment described earlier in this chapter in table 3.1.

The experiences of implementation studies from Israel and the USA suggested that by integrating IMR the concept of recovery was influencing the mental care professionals [61]. One of the studies argued that “practitioners implementing IMR must learn new skills and adopt, or at least integrate, a new or modified professional identity” [59] p. 144. So it was hypothesized that IMR might influence the professionals’ skills and their regular practice.

**Design**

A qualitative design provided an insight into staff members’ reflections and attitudes about IMR and working in a recovery-oriented manner. Further, this design enabled the possibility to explore variation and differences between staff members. The methodological framework was Situational Analysis by Clarke which builds upon Grounded Theory. Situational Analysis provided a method with mapping and diagramming which was beneficial when looking into specific situations and varieties in mental health professionals’ positions to certain themes [90]. This approach was used when generating data as described below as well as analyzing data.

**Participants**

To get information from staff members who had been providing IMR for a longer time as well as from staff members with a new experience of IMR, a selective sampling approach was used [91]. As participants were defined before the start of the interviews and not chosen along with the data collection. The participants were mental health care professionals from the community mental health centers in New Hampshire, USA, where the IMR program was well-established and
professionals from community mental health centers in Capital Region of Denmark, where the IMR had just been introduced in connection with the randomized trial of this PhD study. In both countries IMR was implemented as a new practice within existing practices. The American staff members were selected to participate, if they had been formally trained in IMR and had been practicing IMR for at least two years at the community mental health center. For the American practitioners no relationship with the interviewer (Helle Stentoft Dalum) was established prior to the study commencement. Member of the research group Harry Cunningham from the Mental Health Center of Greater Manchester in New Hampshire, USA contacted the local manager at the included community mental health centers and then the manager asked the potential member if he or she wanted to participate.

In Denmark the professionals were selected as they were the first to practice IMR in Denmark. A relationship was for some of the Danish practitioners established with the interviewer (Helle Stentoft Dalum) before the time of the interview. As information meetings about the PhD study and thereby the randomized clinical trial to staff of the Danish community mental health center had taken place. The interviewees were asked to participate by an email request and verbally.

A total of eight professionals from USA and eight professionals from Denmark participated. The American professionals were interviewed in the fall of 2011 and the Danish professionals were interviewed in spring of 2012. For background characteristics of the interviewees, see Table 1, Article IV.

**Data collection**

To obtain rich information on how the professionals experienced facilitating a recovery-oriented program as a part of their practice, qualitative in-depth semi-structured interviews were conducted. These interviews provided an opportunity to look into specific pre-defined aspects and thereby have
a similar starting point for every interview. But semi-structured interviews also made it possible to explore one particular aspect if the interviewee had many reflections on this aspect.

The data was collected in two stages;

- In Stage 1, the American professionals were individually interviewed in an effort to explore which themes appeared from their experiences. An interview guide inspired by proposed values for recovery-oriented service [92] was used to gain a broad insight. A memo was written after each interview summarizing impressions of the interviewees’ values to be used in the analysis [93].

- In Stage 2, a new interview guide was developed from the pre-analysis of the American interviews (see below) and used for the interviews conducted with the Danish professionals. These interviews were carried out using the same methods as in the USA only to get more detailed and profound knowledge about the themes developed in Stage 1.

Interviews both in the US and in Denmark took place in an office or meeting room at the local community mental health center and lasted approximately one hour. The interviews were audio-recorded and transcribed verbatim on the basis of a transcription guideline. Illustrative quotations were extracted from the transcriptions when coded and analyzed. ID numbers and nationality were used for interviewees’ names when linked to quotes, for instance ‘USA1’.

**Ethical considerations**

The New Hampshire Department of Health and Human Services had given ethical approval to the American interviews (IRB reference # 199). Participation was voluntary and the participating professionals’ confidentiality was maintained. The professionals participating in this study should fill out a written informed consent. In Denmark an ethical approval is not mandatory in non-
experimental studies. Nevertheless, the same level of ethical standards as in the American interviews was fulfilled. It was emphasized that participating was voluntary. It was important to stress that participation in this interview would not influence the professional’s job and what he or she said would only be used for research purposes. The professionals were also informed that quotes from the interviews would be anonymous in research publication, so the interviewee would not be identifiable.

**Analysis**

The interviews were analyzed in two stages as well using the techniques of Situational Analysis.

- In Stage 1 an inductively pre-analysis of the American interviews was carried out immediately after the American interviews were conducted. This was done to analyze which themes that would be interesting to get more information on the following Danish interviews. The interviewees’ accounts on specific topics were given an initial code [94]. Figure 1 in Paper IV is an example of the coding process used during the two analytical stages. The initial codes were combined into condensed meaning units, then into subcategories, then into categories in the pre-analysis. The categories were then combined and three main themes were identified:
  1) changes in attitude towards mental illness
  2) changes in focus of the dialogue with the patients
  3) changes in role assumption

- In Stage 2, the interview transcripts from Stage 2 were analyzed deductively to enrich the whole analysis and to get further insights into the variation and complexity of the defined themes.

NVivo8.0 qualitative software was used to manage data.
Situational Analysis includes three overall mapping methods, each one having its own purpose and approach [90,95]: ‘Situational mapping’, ‘Social worlds and arena mapping’, and ‘Positional mapping’. Since the focus of the study was professionals’ experiences of recovery-oriented changes in attitude and practice and not their specific discourse or how they experienced changes related to non-human elements ‘Social worlds and arena mapping’ was not performed.

**Situational mapping**

Situational mapping was used as a technique to focus on key elements and their relation other elements within the specific area of investigation[96]. Situational maps were drawn to get an overview of the different initial codes’ relation. This mapping method was applied in Stage 1 as well as in Stage 2 of the analysis. In Stage 2, all interviews were included to get an overview of the themes and the relation to other themes and subthemes.

Figure 3.2 is an example of the situational mapping showing the initial codes’ relation to the overall theme ‘attitude’.

**Figure 3.2: Situational mapping: Focus on Professionals’ Attitude**
Positional mapping

Positional mapping includes mapping different positions on issues of controversy in the situation of concern [96]. To visualize the major positions taken in the data on the certain defined themes and to analyze the complexity and differences within each theme positional maps were drawn. Figure 2 in Paper IV is an example of a positional map, where the quotes concerning what professionals considered important in mental health services are mapped on a continuum of extremes.
4. Results

In Paper II and Paper III the results from the randomized trial are presented. Paper II focuses on patient outcomes related to clinical recovery and Paper III focuses on patient outcomes related to illness management and personal recovery. In this chapter the results from Paper II and Paper III of the randomized trial are presented as a whole. Paper IV comprised the results from Paper IV of the qualitative study. The result section presented in Paper IV is reproduced in the following, since an extraction would limit the opportunity to show the qualitative variations and therefore be an inexpedient simplification of the results. In the end of the chapter, the findings of both studies are summed up.

4.1 Patient outcomes

Demography and clinical characteristics

A flow diagram of the participants through the trial can be found in figure 1 in Paper II. A total of 202 participants were randomized. Four participants were excluded immediately after randomization: Two participants in the control group withdrew informed consent, one participant in the control group was excluded because the criteria of diagnosis was not fulfilled. Finally, the last participant randomized was assigned to be the only participant in an IMR group and therefore it was decided to exclude this individual. 198 participants entered the trial, hence, 99 participants in each intervention group.

The baseline characteristics of the 198 participants are listed in table 1 in Paper II. Baseline characteristics were similar and prognostic factors were equally distributed in the two intervention groups. A total of 26 participants from the IMR group and 11 participants from the control group did not participate in any of the follow-up assessment.
**Primary outcome**

IMR was not significantly different from treatment as usual regarding level of functioning assessed by GAF-F (p=0.27). Mean difference was +2.1 points and the 95% confidence interval (CI) was -1.6 points to +5.8 points in the intention-to-treat analysis. When analyzing as complete cases the same result was found, see table 2 in Paper II.

**Secondary outcomes**

In the intention-to-treat analysis of the secondary outcomes, no group differences were found; see table 2 in Paper II and table 2 in Paper III.

**Illness management**

In the intention-to-treat analysis illness management assessed by the Illness Management and Recovery Scale showed no effects in the patient version IMRS-P, mean difference +1.9 points (95% confidence interval (CI): -0.6 points to +4.5 points, p=0.14), or in the staff version IMRS-S, mean difference +0.4 (95% CI: -2.2 points to 3.1 points, p=0.76). In the complete case analysis of the IMRS-P there was a significant difference between the two groups with a p-value of 0.04. However, due to large amount of missing data in the follow-up assessments for the IMRS-P, the non-significant result from the intention-to-treat analysis with multiple imputation was more accurate. No difference between the two groups was seen in the complete case analysis of IMR-S.

**Clinical recovery**

In regards to social functioning assessed by PSP the mean difference was +2.5 points (95% CI: -1.5 points to +6.7 points, p=0.21), and in regards to positive and negative symptoms assessed by PANSS the mean difference was -1.1 points (95% CI: -6.0 points to 3.8 points, p=0.66). When
analyzing data as complete cases, similar results were found for PSP and PANSS as in the intention-to-treat analysis.

**Explorative outcomes**

In the complete case analysis of the exploratory outcomes, no group differences were found; see table 2 in Paper II and table 2 in Paper III.

**Illness management**

Participants in IMR did not differ from people in the control group in terms of use of alcohol or drugs (p=0.57).

**Clinical recovery**

No differences between the two intervention groups were seen in any of the explorative clinical recovery assessments of GAF-S (p=0.96), HAM-D (p=0.50), and Young Mania Rating Scale (p=0.63).

**Personal recovery**

No significant differences were seen in the Adult State Hope Scale (p=0.53) or the Mental Health Recovery Measure (p=0.90).

**Service utilization**

In table 2 in Paper II the service utilization is listed. The number of visit to the community mental health center (use of treatment as usual) in terms of meetings with the case manager, meetings with a psychologist or a psychiatrist, or times participating in group activities was the same for both
groups. IMR participants had a mean of 24.1 visits (SD=23.8) and control group participants had a mean of 24.5 visits (SD=20.2). Participants in the IMR group had a mean number of 13.5 days (SD=71.1) in the psychiatric hospital whereas participants in the control group had a mean number of 12.5 days (SD=46.3), no statistical significant difference (p=0.28) was seen. There were no significant differences in the number of times the psychiatric emergency service was used (p=0.83) or in number of hospital admissions (p=0.92) between the two groups.

**Harms and adverse effects**

There were no significant differences between the two groups in suicide or deaths. Three people died in the period of follow-up, one from the control group of suicide and two died of natural causes, one from each group. No relation between participating in the IMR trial and the deaths was detected. No further harms or life-threatening conditions were reported during the trial.

**Per-protocol subgroup analyses**

The results of the three per-protocol subgroup analyses are listed in table 3 in Paper II.

**IMR attendance**

No association between a higher number of sessions attended and the GAF-F score was seen (p=0.49). There were no significant differences between the two groups of IMR attendance in any of the secondary outcomes: PSP (p=0.11), PANSS (p=0.19), or IMR-P (p=0.51). For the IMR-S the p-value was 0.00, indicating a difference between the two groups. However, there is a statistical uncertainty to this estimation due to the fact that each group consisted only of 14 and 40 patients.
**Diagnosis**

No statistical significant difference in GAF-F due to differences diagnosis was seen, the p-value for schizophrenia was p=0.11 and the p-value for bipolar disorder was p=0.79. The secondary outcomes did not show any significant difference either with regards to schizophrenia: PSP (p=0.16), PANSS (p=0.71), IMR-P (p=0.07), and IMR-S (p=0.06) and with regards to bipolar disorder: PSP (p=0.24), PANSS (p=0.57), IMR-P (p=0.09), and IMR-S (p=0.89).

**Gender**

Subgroup analysis showed no differences in the effect of IMR due to gender differences regarding the outcomes. With regards to the males GAF-F (p=0.10), PSP (p=0.06), PANSS (p=0.43), IMR-P (p=0.13), and IMR-S (p=0.18) and with regards to the females GAF-F (p=0.80), PSP (p=0.69), PANSS (p=0.81), IMR-P (p=0.17), and IMR-S (p=0.68).

**Post-hoc analysis**

Table 3 in Paper III shows the complete case analysis of the IMRS’ subscales. A small difference was seen between the two groups in the Recovery subscale rated by the participants IMR mean: 17.4 points, standard deviation (SD=3.0), control mean: 16.4, (SD=3.5) and a p-value of 0.02. No differences were observed in any of the other subscales.

**Implementation**

Overall the IMR fidelity assessments showed a good implementation of the IMR program in the Danish community mental health centers, see table 4 in Paper III. A total of ten IMR groups started and nine of them completed. One group ended before time because the participants could not come to sessions due to personal reasons (for instance serious hospitalization, got a job in the day hours,
recently had a baby).

The IMR Fidelity mean score across the three participating community mental health centers assessed mid-way at four months was 4.2 (SD 0.3) equaling good fidelity and the mean score for the end assessment was 4.9 (0.2) equaling high fidelity. However, item number 5 ‘Involvement of significant others’ with a mean score of 3.3 (SD 1.24) across both assessments indicated that involvement of family and significant others was not fulfilled.

Table 2 in Paper III shows that no significant different between the two groups was found on the Clients Satisfaction Scale at the end of intervention (p=0.78).

4.2 Staff perspectives

Three themes in staff members’ reflections on changes in attitudes and practices emerged in the qualitative study: “Hopeful attitude”, “New focus in the dialogue with patients” and “Person-centered role”.

A hopeful attitude

The theme ‘A Hopeful Attitude’ captures some of the professionals’ experiences and examples of how they tend to have a new attitude towards the field of mental illness. They express how they have experienced a shift in their attitude, for example a more optimistic attitude towards their patients’ opportunities in life instead of dampen the patients’ chances in life. The following quote captures this:

“I have a whole new optimism: I now dare to say without worrying about the accuracy that people do recover and get well!” (DK3)
Introduced to the concept of recovery by practicing IMR this professional has gained a new optimism towards the opportunities the patients have in their lives. Another IMR professional experiences a “whole new attitude” because of the focus on recovery.

“Today we have a whole new attitude towards having a mental illness. A lot of people with mental illness manage very well. And then we talk about the success stories”

(DK4)

Some of the professionals have experienced a change towards a more hopeful attitude, an attitude which is now accepted among colleagues this professional expresses by saying “we”. Supporting the patients by having hope for them and believing in them, even when the patients do not believe in themselves, has for many professionals become a part of their working approach. In contrast, a few of the interviewed staff members seemed more pessimistic. One interviewee says:

“I don’t know the final result. I don’t purport the patients that it can be fantastic, if I don’t think so.” (DK2)

This quote exemplifies how some professionals avoid talking about hope for recovery.

A new focus in the dialogue with patients

This theme captures how the professionals experience different attitudes towards what should be the focus of dialogue with the patients compared to their earlier approach. An essential part of the IMR program is the patients’ own goal-setting, and the professional and the patient frequently talking about the patient’s goals, dreams and hopes. This focus has become an integrated part of the overall practice for many of the interviewed staff members. They find that recovery goals in the dialogue with the patients have become a new focus outside the IMR framework, for example when they talk to patients individually as their case manager. One professional exemplifies how the patient’s own goal-setting is an integrated focus on all of his work with groups of patients:
“I probably, more so than other people, overemphasize the goal aspect of IMR. I’m all about the goals. And it’s come out in terms of my own practice, especially with the groups.” (USA1)

Another professional is aware of how she has changed her focus in the dialogue with patients:

“It is very much about thinking that you are just a wave sloshing about in all directions. A lot of psychiatric patients feel like that. So we tell them that this is about setting goals. Because people who have set goals, the more concrete these goals are, [the individual experiences that] you are not a wave just sloshing about in the water. Then you start to gain foothold and get a hold of it, so you can decide for yourself.” (DK7)

This professional draws attention to her belief that through individual goal-setting patients get an opportunity to gain control over their own lives even though the life may seem chaotic. A majority of the staff members mention that in their dialogue with patients, the focus on the patients’ individual recovery goals has become more common than addressing disease induced goals. An individual recovery-goal can be something quite simple like “get out of their bed every day” (DK3), but also something complex like “travel to France” (DK3). Examples of disease induced goals reflecting the medical model are “to take my medication every day” (USA5) or “verbalizing an understanding of my symptoms” (USA5). These goals do not motivate the patient as they do not contain anything he/she wants to happen. Goals like these are seen as linked to the mental illness and are not individualized into what the patient prefers. However, not all the interviewed professionals express a focus on recovery goals in the conversations with their patients. One of the professionals says:
“During the individual conversation we don’t discuss it as goals as such. Instead we talk about which problems, which aspects of her [the patient’s] life she has problems with or could improve. How she can work with that.” (DK6)

This quote illustrates the staff member is valuing the concepts from the medical model in her work by focusing on problems and barriers for recovery, for example by using terms like “problems” to “improve”.

**A person-centered role**

This theme comprises the staff members’ experiences of gaining a new role within the recovery model. While facilitating IMR some of the staff members experienced their professional role changing. For example they describe a stronger person-centered approach in their work. This approach balances the dual importance of the patient’s own values along with their professional values. One of the staff members reflects on her role shift:

“Before, I was very insisting and kept the patients longer, and I brought up 10,000 ideas and threw them at the patient. I so much wanted the patient to get better. Now I am more relaxed, keeping in mind that it is the patient who has problems, which we look at together. I can guide the patient from my theoretical knowledge. Then the patient can see whether it works for him and we continue the work together.” (DK5)

This quote illustrates how the professional in her former practice proposed many ideas to help the patient solve his problems without possibly listening to what the patient really wanted. After facilitating IMR the staff member evolved to a different approach with a starting point in the goals of the individual patient to use her professional knowledge to support the patient.

In the medical model, certain role definitions exist. For example the role of the patient is referred to as the “help-seeker” and the role of the professional is referred to as the “helper” (DK3). This
professional-patient relation suggests an imbalance in power; the helper has the power to help/decide what is best for the help-seeker. So in this case the helper decides what interventions would be best for the help-seeking individual. The helper role is problem-centered and implies a paternalistic approach to patients. The professional role in the medical model is to help the patient to do what the professional mental health “expert” considers best for him or her. One of the interviewees labels himself and the professionals in general as “fix-it people”.

“I think one of the things about therapists is that we are “fix-it people”. Give us a problem, we will start thinking of solutions and trying to change things.” (USA3)

He notes that the approach on how to work with patients is not only ingrained in how he views his job (“we are”), but also how he performs (“thinking of solutions and trying to change things”). Developing a recovery-oriented mindset is clearly different from being a helper or a problem-solver. It is something that demands a new approach in the work with patients.

Another interviewee points to why a recovery-oriented role is experienced as very different from the former role as a professional:

“So as a clinician you had to change your way of thinking, and to change the way you are thinking, you had to re-strategize. Nobody fits a traditional mold.” (USA4)

This interviewee uses the phrase “re-strategize” to describe a belief that all aspects of the role of the professional have to be changed. The professionals need new strategies from the very first meeting with a patient to figure out how to work with the patient. To “change your way of thinking” is not something that one can do over night. One staff member explains how it is difficult to keep focusing on providing service according to the recovery model:

“I know that you can always get sucked back into that old maintenance [medical] model or wanting to set goals for the patient. Rather than really letting them set their own goals.” (USA1)
This interviewee addresses the difficulties in taking a new role in the dialogue with the patient, as it can be difficult not to return to old habits like “wanting to set goals for the patient”.

4.3 Summaries of findings

IMR was profoundly implemented into the community mental health centers according to the fidelity assessments. The randomized trial showed that IMR had no significant effect on the primary outcome GAF-F at the end of intervention. No significant differences were seen in the secondary outcomes, explorative outcomes, per-protocol analysis or post-hoc analysis.

Three themes in staff members’ reflections on changes in attitudes and practices emerged in the qualitative study: “Hopeful attitude”, captures a change in the professionals’ attitude towards a more positive view on the future for patients living with mental illness. “New focus in the dialogue with patients” thematizes how the professionals focus more on the individuals own goal for recovery rather than disease induced goals in dialogue with patients. “Person-centered role” comprises a shift in the professional role where the professional values the patient’s own ideas in addition to the professional’s standards.
5. Discussion

The following presents a discussion of the findings of illness management (Paper III), clinical recovery (Paper II), personal recovery (Paper III), and the findings related to implementation and staff perspective (Paper IV). This is followed by a discussion of the strengths and limitations of the randomized clinical trial and the qualitative study, respectively.

5.1 Discussion of findings

The randomized clinical trial was designed so that both groups – experimental and control – received treatment as usual. Therefore the potential influence of treatment as usual was equivalent in both groups and the potential difference between the two groups could only be caused by IMR. According to the theoretical framework IMR has proximal patient outcomes as well as proximal patient outcomes. The gains of proximal outcomes are required before gaining distal outcomes. Illness management (a proximal outcome) is expected to be assessable during or shortly after attending the IMR program whereas clinical recovery and personal recovery (distal outcomes) are expected to happen and be assessable later on.

Illness management

Paper III showed no statistical differences between the two groups in illness management and recovery assessed by the IMRS-P or the IMRS-S. This result indicated that the patients in the IMR were not better at managing their illness than patients in the control group as hypothesized. Three of the prior randomized trials have shown a significant difference on the IMRS between the two groups of intervention in favor of IMR [50,51,53]. Whereas two randomized trials not have found a statistical significant difference on the IMRS between the two groups of intervention [52,54] which
is similar to the findings of this trial. So at this point no consensus in the findings of IMR’s effectiveness on illness management assessed by IMRS is found.

A recent psychometric study proposed that the IMRS has some limitations and that the scale might reflects multiple underlying dimensions [73]. The post-hoc analysis of the proposed subscales of the IMRS in Paper III could support the assumption that IMRS assesses different dimensions and not illness management alone. However, a psychometric analysis of the IMRS subscale was not performed in this trial. To assess patients’ illness management it could perhaps have been beneficial to include a validated scale with a more specific focus on illness management such as a self-efficacy scale [97].

In relation to illness management in terms of reduced substance and alcohol use no difference between the two groups of intervention was found. Despite the fact that alcohol and drug use is a specific module in the IMR program, the findings of this trial therefore confirms the other trials’ findings of no significant difference in substance use [51,52]. The founders of the IMR program proposed that effects on outcomes of illness management should be a proximal outcome of the program, something detectable shortly after receiving the program [39]. This is an assumption the findings from this trial did not confirm.

That the reason IMR did not prove to be effective in terms of illness management might be that the program builds on a too simplified assumption of human change, and the rationale that psychoeducation is required to create a change in human behavior is not true.

In the Transtheoretical Model which IMR builds on health related changes are viewed as rational and deterministic processes, where a linear relationship exists between psychosocial predictors and behavioral changes. In the IMR program it is assumed that the patient learns skills to manage the illness, and then applies these skills into his or her own life leading to clinical and personal
recovery. On the other hand it is argued that when addressing treatment and rehabilitation to people with severe mental illness flexibility is crucial, since not all patients can go strictly from A to B, relapses happen while the patient experiences being in a process of recovery [26]. Perhaps mental health interventions like IMR could learn from the field of public health. Here it is suggested that changes in health behavior should be viewed as a complex adaptive system, where factors like timing of interventions, relevant initial condition, mood, and feelings play an important role [46]. When planning interventions, the interventions should be informed by the knowledge that change can happen by “a wave of inspiration” and without prior planning [98] p. 1382, which are perspectives that are probably also relevant in mental health.

It could also be discussed whether the assumption of the Stress-Vulnerability Model might is an obstacle to help the patient to manage his or her illness. The model proposes that mental illness is a result of interplay of biological vulnerability, stress, and coping and if the patient learns about his own biological and stress thresholds, he or she can better manage his mental illness. However, this view of mental illness may implicate that patients stay status quo to prevent the risk of stress that might occur when trying new meaningful activities or changing routines. The patient might not progress towards clinical and personal recovery when focusing on maintenance and stabilization and avoiding stress. On the other hand the Stress-Vulnerability Model provides an understanding of mental illness in the IMR program and the continuous focus on the patients’ goals for recovery in the IMR program ensures a focus towards progress and not maintenance.

**Clinical recovery**

Paper II found that participants in the IMR program were not significantly different from participants in the treatment as usual group in relation to the primary outcome GAF-F, the secondary outcomes social functioning, and positive and negative symptoms or explorative
outcomes of symptoms severity. Findings were consistent in intention-to-treat analysis using multiple imputation, in the complete case analysis, and in the per-protocol analysis.

This result is consistent with the latest trial of IMR showing no difference in symptoms [54]. Two of the five earlier published trials found that IMR was effective towards decrease in severity of symptoms [51,53] and better psychosocial functioning [51], which is inconsistent with the results in this trial. However, the earlier trials showing benefits of IMR on the clinical outcomes have all had a high risk of bias and therefore their results showing positive effects of IMR should be addressed with caution. In relation to hospitalization one of the earlier trials found that patients had a reduced hospital use over time [52] and another trial could similar to this trial not detect a significant difference in hospitalization [54].

This randomized trial was the first to investigate clinical recovery outcomes specifically in relation to IMR attendance, diagnosis, and gender. These subgroup analyses showed no significant differences of IMR compared to treatment as usual. So of this trial could not be explained by gender differences or differences between the diagnoses of schizophrenia and bipolar disorder. Neither was it shown that attending IMR sessions was different from not attending the sessions, as would have been an intuitive expectation.

Maybe IMR did not prove to be effective because the rationale that psychoeducation is required to gain clinical recovery is not true, as already mentioned.

Another explanation could be that psychoeducation is required for patients to gain clinical recovery as the literature proposes but maybe the IMR program is not effective as a psychoeducational intervention. According to the literature a psychoeducational program should provide knowledge of the illness, give support and provide self-management strategies to promote coping, and to be effective the program should involve the patient and his or her family. These aspects are contained
in the IMR program. Alternatively, the IMR program may need an update to include the newest knowledge. Programs containing elements of peer-to-peer support show promising potential according to a Danish Health Technology Assessment of illness management programs towards people with chronic illness as well as mental health research [12,13,99]. Peer-to-peer support is indirectly a part of IMR, when IMR is facilitated in groups as in the Danish randomized trial. In the group the participant can be a role model to the other participants and use the other participants as role models, thereby the participants support and help each other. On the other hand IMR is provided by mental health care professionals and not by people with lived experience of mental illness, perhaps it would be beneficial if people with lived experiences could be IMR group leaders. This has been tested in one study which showed participants’ knowledge and perceptions of recovery was improved, but also that it was difficult to implement peer-provided IMR [100].

Finally, the design of this trial can be the reason why no effect on clinical recovery is seen. According to the theory of the IMR program clinical recovery outcomes such as functioning and symptom remission are considered to be distal outcomes, therefore a longer follow-up period might be needed to test the effectiveness of the IMR program on these outcomes properly. Improvements in functioning are supposed to happen after the participant has adapted the new illness management skills into his/her life. Without setting an exact time frame for when the effect will occur according to the IMR theory, this trial perhaps assessed distal clinical outcomes in a proximal short-time perspective. To confirm this, a 21-months follow-up for patients in this trial is currently on-going.

**Personal recovery**

Paper III showed that patients in the IMR group did not differ significantly from patients receiving treatment as usual in the outcomes of hope and self-perceived recovery. These findings are similar
to the findings of other randomized trials assessing hope and personal recovery [52-54]. It is surprising that IMR does not seem to have an effect on personal recovery outcomes in any of these trials, as personal recovery in terms of participant’s own recovery goals is a profound part of the IMR program.

The reason IMR might not be beneficial regarding aspects of personal recovery could be the already mentioned namely that 1) IMR’s rationale that personal recovery requires the individuals learn how to manage their illness is not true, 2) the rationale is true but IMR is not a suitable program, or 3) maybe IMR is effective, but the time frame for this trial is assessing the outcomes of personal recovery to soon.

Finally, the reason why no effects on personal recovery outcomes were seen could be that there is a limitation in the scales used to assess personal recovery in this trial. When this trial was planned in 2011 no measures of personal recovery existed in Denmark which is why measurements from the USA was used. An effort was made to ensure a proper translation of the scales but no scales of personal recovery were validated in Danish. This is a weakness of the study, since it was not ensured that the scales fitted the Danish culture. For instance in the USA, where the Mental Health Recovery Measure was developed, religion is considered an important aspect of people’s lives. This is reflected in item 25 “When I am feeling low, my religious faith or spirituality helps me feel better”. In Denmark religion does not influence peoples’ lives in the same way and according to research Danish people are considered “irreligious” [101], so questions about religion in relation to personal recovery might seem irrelevant.

The Adult State Hope Scale might also have some limitations, even though it has been used in several studies in mental health research [82] and in two IMR trials [52,54]. The Adult State Hope Scale includes items for pathways to achieve goals such as having the ability to think of routes to
reach one’s goal as well as items for perceived capacity to use one’s pathways to reach desired goals. By linking hope and goals this scale seemed to match the IMR program, which also links personal recovery (and thereby hope) to recovery goals. However, the cultural aspect of the scale showed to be a weakness. Talking about one’s own perceived success such as item 4 “Right now, I see myself as being pretty successful”, is most likely not what Danish people strive to. In Denmark talking about one’s own success is considered out of the norm, the norm is to conform [102]. So to link increased hope to being successful might blur the result of the scale, as this scale might is unable to detect changes in a Danish population of patients. Another possible explanation could be that the Adult State Hope Scale is unable to capture the underlying construct of hope and that the link between goals and hope is false.

**Implementation and staff perspective**

The overall implementation of IMR in the Danish community mental health centers was good according to the fidelity assessments on the IMR Fidelity Scale, both when rated mid-way and at the end of the groups. However, the aspect of involving family and significant others was not fulfilled in this trial and could maybe explain the lack of effectiveness in relation to clinical recovery, personal recovery and illness management [10]. As a review comparing psychoeducation for patients alone to psychoeducation for patients and their family concluded psychoeducation proved only to be effective when including the family [10].

Paper IV’s findings support the findings from mental health research investigating changes in professionals’ attitude when trained in a recovery-oriented program. These studies have similar to this qualitative study shown that professionals get more optimistic towards patients’ potentials of
recovery and have found that the professionals implement the recovery-oriented approach in their daily practice for instance change their focus in care plans [103,104].

The assessments from the Clients Satisfaction Scale showed that the patients in this trial were not more or less satisfied with their treatment when receiving IMR compared to treatment as usual. So the recovery-oriented changes in attitude and practice that the professionals experienced in Paper IV were not reflected in the patients’ assessments of their satisfaction with service, which is critical.

The previous literature of IMR has not explicitly examined professionals’ practice or attitude when providing IMR, though to work recovery-oriented is a necessary part of the IMR program. It is a lack in the IMR program that recovery-orientation in the staff providing IMR is not assessed as a part of the implementation assessments in the IMR Fidelity Scale. Subsequently this important dimension of the implementation was examined in the qualitative study of professionals’ recovery-orientation in Paper IV. The results from Paper IV indicated that not all professionals facilitating IMR experienced recovery-oriented changes in their attitude and practice. Because of the time frame for this PhD study it was not possible to interview all the Danish IMR providers about their experienced changes. So it is unknown how the recovery-orientation was in general in the staff that practiced IMR. A potential reason for the result of this trial with regards to patient outcomes could be that the professionals in general did not comprehend to work recovery-oriented when they began facilitating IMR and therefore did not follow the intentions of the IMR curriculum.

After this PhD study started a new scale for IMR was developed by the founders of IMR: the IMR Treatment Integrity Scale [105]. This scale was developed to assess the professionals competencies in providing IMR related to the IMR Fidelity Scale as well as the professionals’ competencies in general. It seems like this new scale approaches the current lack in the IMR Fidelity scale by assessing staff members’ recovery-orientation.
Before starting the randomized clinical trial it could perhaps have been appropriate to make sure that the staff members providing IMR were working recovery-oriented. Therefore it could perhaps have been useful with a pilot phase, where the professionals provided IMR and adapted a recovery-oriented approach before the beginning of this trial.

5.2 Strengths and limitations

Overall it is a limitation that the mixed method approach was not used in the PhD study as planned, but the randomized clinical trial and the qualitative study was treated as complementary parts. On the other hand it is a strength that the results from the two studies can be mixed. As discussed above an investigation of the recovery-oriented changes in the staff could potentially inform and contribute to an explanation of the results of the patient outcomes. In the following the two methods’ strengths and limitations are discussed separately.

The randomized clinical trial (Paper I, II & III)

Strengths

The randomized clinical trial has several strengths. The trial was conducted according to the best methods in order to reduce the risk of systematic errors (bias), random errors and design errors. The trial was conducted with adequate generation of allocation sequence, adequate allocation concealment, adequate blinding wherever possible, adequate reporting of all relevant outcomes, intention-to-treat analysis, and no for-profit bias [106-109]. Prior to recruitment of participants a sample size calculation was made and furthermore only patients with a validated diagnosis of schizophrenia or bipolar disorder were included. The external validity was high because the included patients were representative of the majority of patients with severe mental illness getting
treatment in a community mental health center in Denmark and elsewhere [110].

Limitations

However, this trial has some limitations. It is a limitation that many of the observed data were incomplete due to a high rate of drop-out. To address this issue a data set with multiple imputation was estimated to improve the statistical test values. It is also a limitation that some of the secondary and explorative outcomes were not validated in Danish. The prior strategies to motivate patients to attend the IMR sessions did not prove to be sufficient and it is a weakness that not all IMR groups graduated.

The qualitative study (Paper IV)

To discuss the strengths and limitations of the qualitative study on staff perspectives (Paper IV) the focus will be on relevance, validity and reflexivity, which are the core aspects to be addressed in qualitative inquiry in health research [111].

Relevance

Relevance of the study considers whether the applied methods used are relevant to answer the research question. As empirical research concerning IMR providers’’ recovery orientation was limited prior to this study, the explorative approach was considered appropriate in the interviews with the well-experienced American IMR professionals. This inductive approach helped to explore the potential possibilities of changes instead of having a narrow focus to begin with. Whereas the deductive approach was considered appropriate in the Danish interviews when investigating more aspects of the specific defined themes evolved from the pre-analysis of the American interviews. Using this inductive-deductive approach together with Situational Analysis’’ mapping provided an
opportunity to analyze the variations in the interviewed professionals’ reflections of practicing IMR such as differences in attitude. The method of Situational Analysis was chosen to be a proper method to get new perspectives on the three defined themes. The transformation and interpretation of the interviewees’ quotes into categories and themes was tried to be transparent by presenting the different maps from the analytical process. Transparency has also been aimed at in the analysis where illustrative quotations were extracted from the interview transcriptions to exemplify how empirical data was analyzed and interpreted.

**Reflexivity**

Reflexivity concerns the effects the researcher has on collecting data, interpreting findings and drawing conclusions [111]. It could be a limitation that the Danish staff members knew the PhD study as well as the researcher conducting the interviews beforehand, as they were providing IMR and thereby stakeholders in the randomized clinical trial. Potentially they might have been biased in being more positive towards the IMR program and towards the researcher, whom they already knew. For that reason interviews with the well-experienced American staff members - where no prior relation between interviewer and interviewee was established - was conducted to begin with. Interviewing both the American and the Danish professionals provided the opportunity to get insights from experienced as well as novice IMR providers. To interview the American IMR providers before the Danish IMR providers also helped to scrutinize the potential variations and contrary opinions among the interviewees.

The method of Situational Analysis also provided strategies to be reflexive and create a distance from the data material [112]. For instance instead of starting out by analyzing conversations of recovery goals, which was a theme that appeared in the pre-analysis, the positional mapping revealed different positions in the content of the dialogues. The theme was therefore called “A new
focus in the dialogue with patients” to address that some professionals talked about recovery goals and some professionals talked about patients’ problems. Situational Analysis also enabled an adaption of metapositions to the Danish interview transcripts and thereby to analyze if potential preconceptions were supported by the empirical data.

Transferability

Transferability concerns the degree to which the results can be generalized or transferred into other settings or contexts. The interviewees in this study volunteered to participate and therefore they might have been more positive towards IMR and the recovery model or more negative. The selective sampling with both American and Danish professionals was used to provide insights of the well-experienced and the novice IMR providers, because the time frame of this PhD study did not make it possible to wait for the Danish professionals to become well-experienced in IMR. Different positions in the positional maps could indicate that the data material was saturated. However, it is not certain that the data material was saturated, since it is unknown whether all possible positions were found. The analysis showed that there are different positions for instance towards what should be valued in one’s attitude towards the patients, but the analysis did not determine whether all possible positions were described. Had there been more time to conduct the study it would probably have been suitable to conduct more interviews with the aim of creating saturation.

The interviewed professionals all worked with community mental health treatment and case management, which are common treatment and rehabilitation approaches towards people with severe mental illness internationally [113]. The findings on how the recovery-orientation affects the professionals’ attitude and practice might therefore be transferable and useful when implementing IMR and comparable programs in other similar settings in Denmark and elsewhere.
6. Conclusion

1. The randomized clinical trial showed that IMR had no significant effect on the primary outcome GAF-F at the end of intervention. Moreover, no effects were found on patient outcomes related to illness management, clinical recovery or personal recovery.

This conclusion may be due to:

- The theoretical assumptions of the IMR program are wrong
- The IMR is lacking the “active” ingredient of a psychoeducational program
- Aspects of clinical and personal recovery were assessed too soon to show an effect
- Insufficient scales were used to measure illness management and personal recovery

2. When providing IMR the staff experienced recovery-oriented changes by becoming

- more hopeful in their attitude towards the patients
- more person-centered instead of adopting the expert role
- more focused on the patients’ recovery goals than on disease induced goals
7. Implications and further research

7.1 Implications

IMR was not found to be effective in this trial. However, the following is needed to confirm these results:

- A longer follow-up is needed to investigate the long-term effects on illness management, clinical recovery and personal recovery therefore an additional longer follow-up (21 months after baseline) is ongoing.

- A meta-analysis of the existing IMR trials is needed to confirm the results of this trial and consequently a Cochrane Review of IMR is under preparation [114].

- More focus on the IMR practitioners’ recovery-orientation to make sure that they follow the intentions of the IMR curriculum.
7.2 Perspectives for further research

The conclusions of this PhD thesis offer several possible perspectives for further research.

- **IMR’s rationale of psychoeducation’s effectiveness is perhaps not true.** It is a misassumption that gaining personal recovery as well as clinical recovery requires that the patients learn how to manage their illness. Therefore there is a need for more research on behavioral changes in people with mental illness and maybe to include complex aspects such as mood stage, initial condition and how motivation is individual.

- **The rationale of psychoeducation is true but the IMR program is perhaps not effective.** IMR comprehends many aspects of what the literature proposes to be effective in psychoeducation, however there is a need for more research in order to understand what the possible “active” ingredient in psychoeducation is and perhaps more research on peer-support.

- **The IMR is effective but perhaps not assessed properly.** In potential future studies of the effectiveness of recovery-oriented programs like the IMR program there is a need for developing scales that are universal to grasp the underlying construct of illness management and personal recovery and fit into different cultural settings.
8. Summaries

8.1 English summary

Background and objective: Illness Management and Recovery (IMR) is a curriculum-based psychosocial intervention with a recovery-oriented approach. The IMR program is facilitated by staff for groups of patients with severe mental illness and the program duration is nine months. The program has been evaluated in different settings, however evidence of the effects of IMR is still lacking. To establish the evidence of the IMR program with regards to outcomes related to illness management, clinical recovery and personal recovery a randomized clinical trial based on a solid methodology was conducted. The intent of the IMR program is that staff providing IMR have a recovery-oriented approach towards the patient, though when assessing how well IMR is implemented according to the curriculum’s fidelity scale this important aspect is not included. To explore how and if staff members experience recovery-oriented changes in their practice when facilitating IMR, the staff perspective was investigated in a qualitative study as a part of this PhD study.

Methods: The randomized clinical trial was an assessor-blinded, multi-center trial investigating the IMR program compared with treatment as usual. 198 people diagnosed with schizophrenia or bipolar disorder participated, 99 in each group. The primary outcome was level of functioning assessed with the Global Assessment of Functioning (GAF-F) at the end of intervention, 9 months after randomization. Secondary and explorative outcomes included severity of symptoms, use of alcohol/drugs, illness management, personal recovery, hope, and hospitalization at the end of treatment. Implementation was assessed by the IMR fidelity Scale. The qualitative study of staff perspective was based on semi-structured in-depth qualitative interviews conducted with 16 staff members experienced in facilitating IMR in either the USA or Denmark.

Results: IMR had no significant effect on the primary outcome GAF-F at the end of intervention
(mean difference of +2.1 points in favor of IMR, p=0.27). The 95% confidence interval (-1.64 point to +5.6 points) indicates that the hypothesized difference of 6 points favoring IMR is unlikely. Neither symptom severity, use of alcohol/drugs, illness management, personal recovery or hospitalization differed significantly between the two groups. IMR was implemented with high fidelity according to the IMR Fidelity Scale.

In the qualitative study three themes emerged from the majority of the staff members’ reflections on changes in attitudes and practices when facilitating IMR: 1) the staff changed their attitude towards a more positive and hopeful view on the future for patients living with mental illness 2) the staff focused more on the patient’s own goal for recovery rather than on disease-induced goals in the dialogues with patients and 3) the staff experienced a shift in their professional role where they valued the patient’s own ideas in addition to their professional’s standards. A few of the interviewed staff did not express a recovery-oriented change in their attitude and did not experience a change in their practice, though.

**Conclusion:** The majority of the interviewed staff members experienced that values from the recovery model were reflected in their attitude and practice when they had facilitated IMR. IMR was not effective compared to the control group. No effects of IMR were seen among patients with schizophrenia or bipolar disorder on level of functioning, symptom severity, use of alcohol/drugs, illness management, personal recovery, hope or hospitalization.

The conclusion of the trial may be due to:

- The theoretical assumptions of the IMR program are wrong
- The IMR is lacking the “active” ingredient of a psychoeducational program
- Aspects of clinical and personal recovery were assessed too soon to show an effect
- Insufficient scales were used to measure illness management and personal recovery
8.2 Dansk resumé

Baggrund og formål: Illness Management and Recovery (IMR) er en manualiseret psykosocial undervisningsintervention målrettet patienter med svære sindslidelse. Undervisningen foregår i grupper, der ledes af uddannet personale. IMR programmet er evalueret i forskellige lande; dog mangler der fortsat viden om IMR er effektiv. Dette randomiserede kliniske forsøg blev gennemført på et metodologisk solidt grundlag for at undersøge evidensen af IMR programmet i forhold til patienters sygdomsmestring, samt deres kliniske og personlige recovery.

Intentionen med IMR-programmet er, at personalet som varetager undervisningen har en recovery-orienteret tilgang til patienter. Personalets recovery-orientering bliver dog ikke inkluderet, når implementeringen af IMR-programmet måles ved den såkaldte trofasthedsmåling med IMR Fidelity Scale. For at undersøge hvordan og om personalet oplever ændringer i forhold til en recovery-orientering i deres praksis, når de underviser i IMR, blev et kvalitativt studie med dette formål gennemført som en del af denne Ph.d.

Metode: Det randomiserede kliniske forsøg undersøgte IMR sammenlignet med sædvanlig behandling i tre distriktspsykiatrier i Region Hovedstaden. 198 patienter med henholdsvis skizofreni og bipolar affektiv sindslidelse deltog i forsøget, 99 i hver gruppe. Det primære mål var funktionsniveau målt ved Global Assessment of Functioning, GAF-F, efter interventionen, det vil sige ni måneder efter baseline målingerne. Sekundære og eksplorative mål var symptomer, stof- eller alkoholmisbrug, sygdomsmestring, personlig recovery, håb samt indlæggelser. Implementeringen blev målt ved trofasthedsmålinger med IMR Fidelity Scale. Det kvalitative studie af personaleperspektivet byggede på semi-strukturede dybdegående interviews med 16 personer med erfaring i at undervise i IMR i enten USA eller Danmark.

Resultater: IMR havde ingen signifikant effekt på GAF-F (p=0.27), forskellen var 2,1 points i IMRs favør. Den forventede forskel mellem IMR og kontrol gruppen på 6 point var ikke til stede,
da 95%-konfidensintervallet var på -1,64 til +5,6 point. Der viste sig ikke nogen effekt af IMR på symptomer, stof- og alkoholmisbrug, sygdomsmestring, personlig recovery, håb eller indlæggelser. Implementeringen af IMR var vellykket ifølge målinger på IMR Fidelity Scale.

Det kvalitative studie viste, at størstedelen af de interviewede IMR undervisere oplevede ændringer i deres holdning og generelle praksis, når de havde fået erfaring med at undervise i IMR. De oplevede at de 1) fik en mere håbefuld og optimistisk tilgang, 2) fokuserede mere på patienternes egne mål for recovery end på sygdomsspecifikke mål i samtalerne med patienterne, samt 3) de ændrede deres professionelle rolle og lagde mere vægt på patienternes egne værdier og ønsker i forhold til deres egne professionelle værdier. Det var dog ikke alle de interviewede, der oplevede recovery-orienteerde ændringer efter at have undervist i IMR.

Konklusion: IMR underviserne oplevede recovery-orienteerde ændringer i deres holdning og generelle praksis ved at have undervist i IMR. Hos patienter med skizofreni og bipolar affektiv sindslidelse havde IMR ingen effekt på funktionsniveau, symptomer, misbrug af alkohol og stoffer, sygdomsmestring og recovery, håb og indlæggelser i sammenligning med vanlig behandling. Dette kan skyldes, at:

- de teoretiske antagelser IMR bygger på ikke holder
- IMR ikke er et effektivt psykoedukativt program
- klinisk og personlig recovery blev målt for tidligt til at kunne vise en effekt
- måleskalaerne til sygdomsmestring og personlig recovery var mangelfulde
9. References


Ref Type: Report

Ref Type: Online Source


Ref Type: Report


Appendix A

Paper I: Illness Management and Recovery (IMR) in Danish community mental health centres
Illness management and recovery (IMR) in Danish community mental health centres

Helle Stentoft Dalum1, Lisa Korsbek1, John Hagel Mikkelsen2, Karin Thomsen3, Kristen Kistrup4, Mette Olander1, Jane Lindschou Hansen5, Merete Nordentoft6 and Lene Falgaard Eplov1

Abstract

Background: Schizophrenia and bipolar disorder are severe mental illnesses that can have a significant disabling impact on the lives of people. Psychosocial interventions that stress hope and recovery as a part of a multi-dimensional approach are possibly indicated to support people with severe mental illness in facilitating recovery. Illness Management and Recovery (IMR) is a curriculum-based psychosocial intervention designed as a structured program with a recovery-oriented approach. The aim of IMR is to rehabilitate people with severe mental illnesses by helping them acquire knowledge and skills in managing their illness and achieve personal recovery goals. Previous randomised clinical trials indicate that IMR can be implemented with a good effect and a high fidelity though further trials are crucial to demonstrate the potential effectiveness of IMR.

Methods/Design: The trial design is a randomised, assessor-blinded, multi-centre, clinical trial of the IMR program compared with treatment as usual for 200 participants diagnosed with schizophrenia or bipolar disorder under the care of two community mental health centres in the Capital Region of Denmark. The primary outcome is level of functioning at the end of treatment. The secondary outcomes are disease symptoms; use of alcohol/drugs; individual meaning of recovery; hope; hospital admissions and out-patient psychiatric treatment at the end of treatment and the abovementioned and level of functioning at follow-up 21 months after baseline.

Discussion: If the results of this trial show IMR to be effective these positive results will strengthen the evidence of IMR as an effective comprehensive psychosocial intervention with a recovery-oriented approach for people with severe mental illness. This will have significant implications for the treatment and recovery of people with severe mental illness.

Trial registration: Registration number NCT01361698.

Background

Schizophrenia and bipolar disorder are severe mental illnesses that impact people’s lives in many disabling aspects. Research indicates that medication alone is not sufficient to help people with these diagnoses but has to be a part of a multi-dimensional approach complemented with evidence-based psychosocial interventions in a more comprehensive rehabilitation model [1,2]. Psychosocial interventions that stress coping and personal goals may contribute to facilitating recovery from the profound functional and social deficits characterising people with schizophrenia and bipolar disorder [3-5].

A recovery-oriented approach to these severe mental illnesses holds that individuals are more than the sum of their symptoms and that recovery involves a redefinition of one’s illness as only one aspect of a multi-dimensional sense of self [6].

Illness Management and Recovery (IMR) is a curriculum-based, standardized program based on a recovery-oriented approach to rehabilitation for people with severe mental illnesses. The program is designed by Kim Mueser et al. as an evidence-based practice based on the principles of recovery to help people with severe mental illnesses to set individual meaningful goals for their lives and gain illness self-management skills and thereby contribute to their individual recovery process [7]. By collecting the evidence of different empirically supported practices including psycho-education, relapse...
prevention, behaviour training to improve medication adherence, coping skills training and social training. IMR was developed as a full-ranged rehabilitation program and consolidated into a single standardised program for study and dissemination.

The theoretical foundation for the IMR program is the trans-theoretical model and the stress-vulnerability model. The trans-theoretical model assumes that human change developed over a series of stages and by motivating people in the stage they are in through the IMR program they can easier succeed in achieving their own personal recovery goals [8,9]. The stress-vulnerability model builds on the assumption that the course of severe mental illness is determined by an interaction of biological vulnerability, stress and coping. The aim of IMR is to interrupt the circle of stress and vulnerability that leads to poor functioning and relapse [10,11], see Figure 1.

The core values of IMR are hope, personal choice, collaboration, respect, and recognizing people as experts in their own experience of mental illness. First and foremost, the process of teaching Illness Management and Recovery involves conveying a message of hope and optimism, so that people with mental illness believe that they can reach their own goals and begin a progress of recovery. Non-controlled studies of IMR have provided some support for the effectiveness and feasibility of the program [12-14]. The effectiveness has been tested in a few randomised trials with various settings [15-18] and these trials indicate that IMR in group level can be implemented with a good effect and a high fidelity to the program curriculum [19,20]. Due to methodological limitations in the previous trials regarding the blinding process, follow-up assessments and the power of the sample size further trials are crucial to prove the effect.

In the present IMR trial, the following alternative hypotheses will be tested: Patients in the IMR program will have improved at least 6 points on the Global Assessment of Function scale (GAF-F) compared with patients receiving treatment as usual at follow-up 9 months after baseline. Furthermore, the participants in the IMR program will show a greater improvement after 9 months in relation to symptoms, drug/alcohol addiction, relapse, rehospitalisation and treatment, knowledge about their mental disease, coping strategies, recovery and hope. Moreover the difference between the intervention groups will be sustained 21 months after baseline.

**Methods/Design**

The trial design is a randomised, assessor-blinded, multi-centre, clinical trial of the IMR program compared with treatment as usual in 200 participants diagnosed with schizophrenia or bipolar disorder under the care of two community mental health centres in the Capital Region of Denmark.

From January 2011 to December 2013 IMR will be tested in two community mental health centres with the participation of 200 patients. The duration of the trial will be four years. Recruitment to the trial has begun in January 2011 and is due for completion in February 2012. The intervention will start March 2011 and the follow-up assessments in November 2011. The participants will take part in the trial for the baseline interview, and for the follow-up interviews by 9 and at 21 months (one year after the intervention is ended). Moreover a naturalistic follow-up is planned in a period of ten years to evaluate any long-term effects. After the 21 months of follow-up the patients allocated to the control group will be offered IMR, if the program is shown to be effective.

The experimental intervention

Patients randomised to the experimental intervention will be offered IMR plus ‘treatment as usual’. The details of the IMR program has been described elsewhere [21], but will be briefly outlined below. The program is organised into 11 curriculum topic areas: 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 getting your needs met in the mental health system. The first topic area is an explanation of the concept of recovery followed by an identification of personal recovery goals related to the individuals' own meaning of recovery. While the first 10 modules have been part of the IMR manual [22] from the start, the 11th module on healthy lifestyle is added later and has not been tested previously. We include this module in the IMR program on the recommendation of the founders of the program (personal communication with Professor Kim Mueser, Dartmouth University, USA).

IMR can be provided in an individual or group format, and generally lasts between four and ten months with a series of weekly sessions where mental health practitioners help the participants to develop personalized strategies for managing their mental illness and moving forward in their lives. Every session has the same routine, which means that the whole program is following a structured pattern. The curriculum topic areas are taught by IMR facilitators using a combination of educational, motivational, and cognitive-behavioral teaching strategies and homework assignments developed collaboratively with the participant. With the participants' consent, significant others (e.g. family, friends) are encouraged to be involved in helping participants learn self-management strategies and pursue their personal goals. In the program the participant's individual goals are often broken down into smaller steps to facilitate a continuously progress towards achieving the goals.

In this Danish trial IMR will be implemented in group format with 10 patients assigned to each group and two IMR facilitators, and the IMR program will require nine months of weekly sessions to complete. The curriculum of IMR has been translated into Danish prior to the intervention.

To ensure the fidelity of the intervention at the community mental health centres the IMR facilitators will:

- Be experienced mental health clinicians with all together at least four days course in teaching IMR. The teaching will be given prior to the intervention, and again after six months and if need again after one year by a well-experienced IMR educator from USA (The Mental Health Center of Greater Manchester, New Hampshire).
- Receive supervision from the well-experienced IMR educator via an Internet connection to begin with every second week and later on once a month.
- Be involved in a network group for all IMR facilitators, formed to support the implementation of IMR in the two community mental health centres.
- Be evaluated by a trained IMR facilitator from the other community mental health centre halfway through each IMR course using the IMR Fidelity Scale. The IMR Fidelity Scale consists of 13 items that are rated on a 5 point scale [22].

The control group
Patients randomised to the control group will get treatment as usual only. This means individual adapted interdisciplinary treatment including medication, individual support, occupational therapy, psycho-education and group therapy. Some of the staff members that also are IMR facilitators have the role of being primary care provider both for participants in the IMR intervention and in the control group. To ensure that the staff members are following the principles of treatment as usual when meeting patients in the control group, they can consult a task force consisting of a well-experienced psychiatrist only performing treatment as usual.

Inclusion and exclusion criteria
Eligible participants will be adults (age 18+) of both sexes who are: 1) associated with one of the two participating community mental health centres; 2) diagnosed following the ICD-10 criteria of schizophrenia or bipolar disorder; 3) able to speak and understand Danish; 4) giving informed consent verbally and in writing.

Patients will be excluded if they have: 1) a guardian or a forensic psychiatric arrangement; 2) comorbidity with the ICD-10 criteria of the diagnoses of dementia or mental retardation; 3) a large-scale substance abuse - if later on the abuse is under control, inclusion in the trial will be possible; 4) a current home of supported housing - since the treatment as usual given to this group of patients is significant different from patients living independently; 5) a current involvement in a psycho-educational course - patients are eligible for participation in the trial after the psycho-educational course has ended if they meet the inclusion criteria at this point; 6) not given informed consent.

Recruitment and randomisation
Patients will be recruited from two community mental health centres in the Capital Region of Denmark: Frederiksberg-Vanløse and Ballerup-Egedal-Herlev, respectively. Each potential participant is interviewed with the diagnostic tool Present State Examination by a psychiatrist or a trained psychologist to evaluate whether the patient meets the criteria of diagnosis. After informed consent is obtained for each eligible patient the baseline
assessments will be conducted. After baseline assessments the participants will be randomly allocated to either IMR or continue with treatment as usual. To secure concealment of the allocation sequence the randomisation will be central and telephone-based through The Copenhagen Trial Unit. The allocation sequence will be computer-generated, using permuted blocks of a varying block size with equal allocation to the two arms. The allocation sequence is stratified by diagnosis and community mental health centre.

Participant withdrawal
If the participant decides to withdraw from the trial they can 1) participate in the baseline interview and then withdrawal from the treatment but participate in the follow-up interviews; 2) participate in the baseline interview and then withdrawal from the treatment and not participate in the follow-up interviews 3) withdraw from the whole trial so that all data about them are deleted.

Assessments
At baseline, the participants' socio-demographic information on education, employment, marital status, clinical diagnosis, suicide attempts, and earliest contract with psychiatric services will be collected.

Primary and secondary outcome measures
The primary outcome of the trial is overall functioning measured by Global Assessment of Function (GAF-F) post-intervention - after nine months. The GAF scale [23] can be divided into two scales GAF-F and GAF-S (one that focuses on functioning and one that focuses on symptoms) [24]. In this trial the focus of the primary outcome is functioning which is why the GAF-F scale is used. Information about the participant's level of functioning will be obtained from interviews with participants at baseline and follow-up.

The secondary outcomes include level of symptoms, social functioning, personal recovery experience and hope, substance abuse, use of services and suicide attempts. This information is obtained through an interview with an assessor blind to the allocation. The participant fill in questionnaires about their personal recovery and hope, the primary care provider (not blinded to the allocation) fill in a questionnaire about substance abuse, adverse events, and suicide attempts. Information about service use is obtained through the hospital records. The measurements are chosen according to a well-known distinction between clinical recovery and personal recovery [25,26]. Clinical recovery refers to the absence of symptoms, an improvement in functioning and prolonged remission. Personal recovery refers to living a fulfilling and hopeful life even with limitations caused by illness. In this trial we have divided the assessments of recovery in accordance with these two perspectives.

Clinical recovery
All outcome measures to assess clinical recovery are continuous scales. The overall level of symptoms is assessed by the subscale of symptoms of the global measurement Global Assessment of Function - Symptoms (GAF-S) [24]. The Positive and Negative Syndrome Scale (PANSS) [27] assesses the level of an severity of positive and negative symptoms as well as the general psychopathology. This scale is primary developed to measure symptoms of people diagnosed with schizophrenia but can be useful to people diagnosed with bipolar disorder as well [28]. The scale is a 7-point rating instrument that consists of 30 items.

Hamilton Rating Scale for Depression scale assesses the level of symptoms of depression. In this trial we use the version of the scale that includes 6 items referred to as Ham D0 [29] which is covering the core symptoms of depression.

Young Mania Rating Scale (YMRS) [29,30] is an instrument developed to rate severity of manic episodes. The YMRS consists of 11 items and a severity rating is assigned to each rating.

Personal and Social Performance (PSP) [31] is a scale developed from the Social and Occupational Functional Assessment Scale (SOFAS) to assess psychiatric patients level of functioning [32]. The scale assesses four domains of social functioning: socially useful activities, personal and social relationships, self-care and disturbing and aggressive behaviour. Besides giving more detailed and varied information about the participants' level of function, the PSP scale is used to secure the reliability of the GAF score.

Personal recovery
Participants are answering questionnaires to assess aspects of their personal recovery this includes continuous scales of recovery, illness management, hope and satisfaction with psychiatric services.

Illness Management and Recovery Scale (IMR Scale) is a scale especially developed to the IMR program [33]. It summarizes different areas in 14 items relevant to the recovery process including personal goals, knowledge about the illness, admissions, use of alcohol or drugs, functioning, symptoms, stress and coping. The IMR Scale exists in two separate versions: one for the patient and one for the primary care provider.

Mental Health Recovery Measure (MHRM) [34] is a measurement of recovery in a general level and not specific attached to the IMR program. MHRM includes different aspects related to the process of personal recovery. It is a 30-item self-report scale designed to
assess the recovery process for people with severe mental illnesses e.g. schizophrenia and bipolar disorder.

The Adult State Hope Scale [35] is a self-report scale of hope and optimism. It consists of 6 items and is rated on a scale from 1 to 8. The scale was psychometrically tested in college students and in a community sample, but has also been shown to be appropriate for people with severe mental illnesses as well [36].

Clients Satisfaction Questionnaire [37] assesses the participants’ satisfaction with the psychiatric services. This information is relevant from both groups point of views since satisfaction with services can explain eventual drop out and the level of effect on the other measures. The satisfaction of the clients also gives indications of how the mental health community should look like in the future according to its users.

Blinding
Assessments regarding clinical recovery will be conducted by an assessor blind to treatment allocation. The assessor will go through a profound assessment training program. Issues concerning inter-rater reliability will have no bearing on this trial since only one person will be conducting the assessments. Due to the nature of the intervention neither participants nor staff can be blinded to allocation, but are strongly inculcated not to disclose the allocation status of the participant at the follow up assessments. An employee outside the research team will feed data into the computer in separate datasheets so that the researchers can analyse data without having access to information about the allocation.

Monitoring for participant compliance
The use of treatment is registered for both the experimental intervention group and the control group. This is done to ensure the similarity of the treatment as usual that both groups are offered. The attendance at the IMR sessions is registered to monitor the participation compliance. All information regarding covariates, primary outcome, secondary measures, use of psychiatric service and attendance at the IMR sessions is recorded in a case record form. A view of the data collection is listed in table 1.

Analysis
Power and sample size
We are planning a trial of the continuous response variable, GAF-F, from independent control and experimental participants with one control per experimental participant. A previous study involving psycho-education in a Danish community mental health centre showed that response within each participant group was normally distributed with a standard deviation of 15 [38]. In the few previous studies using IMR or elements of IMR the effectiveness has been assessed by using the total GAF score showing a difference of 6-10 points [21,39]. Based on this knowledge we will conservatively estimate the true difference in the experimental and control group means to be 6 points on the GAF-F score. Using this estimation will require a total of 200 participants to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The type I error probability associated with this test of the null hypothesis is 0.05. The power and sample size calculations have been made using the PS Power and Sample Size Calculations program version 3.0.34 [40].

The power of some the secondary measures has also been estimated with a total number of 200 participants. This showed that a sample size of 200 participants is sufficient to show a relevant effect size in PSP, PANSS and the IMR Scale corresponding to similar studies, see table 2. The remaining secondary measures have not been tested due to the fact that similar trials with these outcomes could not be obtained. Thus, the results of these analyses should be interpreted with caution, and the analyses should be considered as exploratory.

Data analysis
The analysis will be performed by using the IBM SPSS Statistics version 19 for Windows. The data analysis will be based on the principle of intention-to-treat. The significance level for the analysis of the primary outcome and the secondary outcome will be 0.05.

Demographic variables will be listed in a table. The primary outcome measure is the continuous measurement GAF-F. The primary analysis of effectiveness will compare GAF-F at 9 months. The secondary analysis will compare effectiveness of the secondary outcome measures at 9 months and GAF-F and the secondary outcomes at 21 months. The analysis of differences between groups will be conducted using t-tests and analysis of the variances will be conducted using ANOVA. Repeated measures techniques may also be applied. Dichotomous outcome assessments will be analysed using logistic regression and paired dichotomous outcomes will be analysed using McNemar tests, or using logistic regression with random effects. Missing data is a potential source of bias and therefore the operation of multiple imputations will be used to address the issue of missing values. An analysis of the drop-out will be conducted to validate the complete case analyses.

Ethical considerations
All participants are offered treatment as usual, i.e. treatment according to best practice and adapted to the individual needs of the patient. The trial will follow the international ethical guidelines of informed consent in
Table 1 Data collection

<table>
<thead>
<tr>
<th>Source of collection</th>
<th>Assessments</th>
<th>Time of recording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtained through interview</td>
<td>Global Assessment of Functioning (GAF-F and GAF-S)</td>
<td>Baseline X 9 months (post intervention) X 21 months (one year follow up) X</td>
</tr>
<tr>
<td></td>
<td>Personal and Social Performance (PSP)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Positive and Negative Syndrome Scale (PANSS)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Hamilton Rating Scale for Depression (HAM-D6)</td>
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</tr>
<tr>
<td></td>
<td>Young Mania Rating Scale (YMRS)</td>
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<tr>
<td>Primary treatment provider fill out questionnaires</td>
<td>Alcohol and drug consumption</td>
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</tr>
<tr>
<td></td>
<td>Diagnose</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>First contact with psychiatric service</td>
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<tr>
<td></td>
<td>Suicide attempts</td>
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</tr>
<tr>
<td></td>
<td>Marital status</td>
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</tr>
<tr>
<td></td>
<td>Housing condition</td>
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</tr>
<tr>
<td></td>
<td>Education</td>
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</tr>
<tr>
<td></td>
<td>Employment</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Use of treatment as usual</td>
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</tr>
<tr>
<td></td>
<td>IMR attendance - only for intervention group</td>
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</tr>
<tr>
<td></td>
<td>Life-threatening conditions (other than suicide)</td>
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<tr>
<td></td>
<td>Illness Management and Recovery Scale - staff version</td>
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</tr>
<tr>
<td>Patient fill out questionnaires</td>
<td>Illness Management and Recovery Scale - patient version</td>
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<td></td>
<td>Mental Health Recovery Measure</td>
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<td></td>
<td>Adult State Hope Scale</td>
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<td></td>
<td>Clients Satisfaction Questionnaire</td>
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</tr>
<tr>
<td>Hospital records</td>
<td>Suicide</td>
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</tr>
<tr>
<td></td>
<td>Death (all causes)</td>
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</tr>
<tr>
<td></td>
<td>Number of hospital admissions</td>
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</tr>
<tr>
<td></td>
<td>Length of hospital admissions</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Use of out-patient services</td>
<td>X</td>
</tr>
</tbody>
</table>

clinical trials. Consent will be voluntary, informed and given both verbally and in writing. The participants will be informed about their rights to decline participation or to withdraw with no consequences to their future care or treatment. The participants will not receive a fee for their participation. Signed consent forms will be dated, with a copy being given to the participant, and the original form kept with

Table 2 Power calculations of PSP, PANSS and IMR Scale

<table>
<thead>
<tr>
<th>Measure</th>
<th>The level of significance</th>
<th>Power</th>
<th>St. deviation in a similar study</th>
<th>Effect size in a similar study</th>
<th>Minimum sample size</th>
<th>Reference</th>
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</thead>
<tbody>
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<td>0.8</td>
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<td>7</td>
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<td>Nasrallah et al. 2008 [40]</td>
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<td>PANSS</td>
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<td>0.8</td>
<td>11</td>
<td>5</td>
<td>154</td>
<td>Fowler et al. 2009[41]</td>
</tr>
<tr>
<td>IMR scale</td>
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<td>0.8</td>
<td>0.5</td>
<td>0.41</td>
<td>48</td>
<td>Hasson-Ohayon et al. 2007[17]</td>
</tr>
</tbody>
</table>

Note: PSP: Personal and Social Performance; PANSS: Positive and Negative Syndrome Scale; IMR Scale: Illness Management and Recovery Scale.
the research data in a locked filing cabinet. The trial has been reviewed and approved by The Ethics Committee in the Capital Region of Denmark (registration number H-1-2010-134), it is reported to the Danish Data Protection Agency and it is registered at http://www.clinicaltrials.gov (number NCT01361698).

Previous research does not indicate that IMR induces risk to the participating patients. All adverse events e.g. increase in symptoms, decrease in functioning, changes in alcohol/drug consumption and incidents of suicide, and also all beneficial events e.g. increase in level of function, hope or progress in recovery will be registered and reported. Participating in the Present State Examination, baseline and follow up interviews may cause some disturbance to the participants, but will be planned flexibly with possible breaks when needed. The results from this trial will contribute with evidence to improve treatment and rehabilitation of people diagnosed with schizophrenia and bipolar disorder. The results will also contribute to future evidence in relation to the IMR program. In the opinion of the research team the pros greatly counterbalance the cons in this trial.

Discussion
The IMR trial is a randomised clinical trial to evaluate the effectiveness of the IMR-program for people diagnosed with schizophrenia and bipolar disorder in according to their level of functioning.

In this design of testing the IMR program an important factor is to insure the fidelity to the IMR program curriculum, so that the IMR program is the taught the same way, using the same slides and same topic areas across the participating community mental health centres. A strength of this trial is therefore that all IMR facilitators go through a specific course of education prior to the intervention, have profound supervision during the intervention and that we test the fidelity using the IMR fidelity scale throughout the course of each IMR group.

Another strength in the design of this trial is that a solid sample size calculation has been made, so we will be able to perform a data analysis with good strength according to the primary outcome, GAF-F. Besides this we have estimated the power of some the secondary measures with a total number of 200 participants. This showed that a sample size of 200 participants is sufficient to show a relevant effect size in the secondary outcome measurements PSP, PANSS and the IMR Scale which will strengthen the results in these aspects. Furthermore, the risk of selection bias related to allocation sequence generation and concealment is low, as the randomisation is performed centrally according to a computer-generated allocation sequence generation. The fact that the assessor of the primary outcome is blinded and that intention-to-treat analysis are going to be used as a statistically approach in the data analyses are also strengthening the design of this trial.

Some would argue that that there is a difference between the level of functioning of the two diagnoses, which is seen in studies comparing level of functioning for in-patients, though literature about this issue is inconsistent in their conclusions [41-43]. A recent study from Norway comparing Global Assessment of Function for the diagnoses schizophrenia and bipolar disorder in a mixed study population of in-patients and out-patients conclude that schizophrenia and bipolar disorder cannot be viewed as categorically different [44]. In the design of this trial we have carefully considered this aspect and have chosen to mix patients with two the diagnosis, since there some support of an equal level of functioning on the GAF score (it ranges from 51.79 to 53.00) [24,38,45] for this trial population and since patients included in the trial are admitted to the same treatment unit reflected same level of functioning. However, to secure that the compared groups are similar the allocation sequence is stratified by diagnosis and community mental health centre. This way potential difference in prognostics features between the two diagnoses and community mental health centres are accounted for, which increase the validity of comparison between the intervention and control group.

A limitation in the design of this trial is that some of the staff members both are IMR facilitators and at the same time maybe have patients that get treatment as usual. We have chosen not to force the patients to change their primary care provider after the result randomisation. This demands that the staff members have a stringent separation of what is the treatment as usual and what is treatment methods according to the IMR concept. To handle situation where staff might be confused of they are mixing the IMR concept with treatment as usual they can consult a task force consisting of a well-experienced psychiatrist only performing treatment as usual.

A limitation to the trial design is that only the assessor rating the factors associated to the aspects of clinical recovery is blind to allocation. When investigating a rehabilitation program like IMR it is not possible to blind the participant or the staff, so this might increase bias. The risk of bias could be seen according to the assessments related to personal recovery which is rated both by the primary care provider and by the participating patient since the awareness of the currently treatment might bias the outcome. On the other hand we think it is strength of this trial that we both get a subjective view of recovery when the person in recovery are to evaluate his/her own process and a more objective
view with the clinical assessment from the primary care provider which have fulfilling knowledge of the patient though close contact.

Acknowledgements and funding
This trial is founded by the Danish Health Fund, Psychiatric University Centre Ballerup, Psychiatric University Centre Frederiksberg and the Mental Health Services of Capital Region of Denmark. We are grateful for the participation of the patients and the assistance of the clinical staff in each community mental health centre.

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Authors’ contributions
All authors participated in the conception and design of the trial. ISD has drafted the manuscript and has along with LK been involved in revising it critically and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Received: 28 June 2011 Accepted: 17 August 2011 Published: 17 August 2011

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doi:10.1186/1745-6215-12-195

Cite this article as: Dalum et al: Illness management and recovery (IMR) in Danish community mental health centres. Trials 2011 12:195.
Paper II: Illness Management and Recovery: Clinical Outcomes of a Randomized Clinical Trial in Community Mental Health Centers
Illness Management and Recovery: Clinical Outcomes of a Randomized Clinical Trial in Community Mental Health Centers


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Abstract

Objective Illness Management and Recovery (IMR) is a curriculum-based psychosocial intervention designed as a structured program with a recovery-oriented approach. The program has been evaluated in different settings, however evidence for the effects of IMR is still lacking. The aim of this randomized trial was to investigate the benefits and harms of the Illness Management and Recovery program compared with treatment as usual in Danish patients with schizophrenia or bipolar disorder. Methods Randomized, assessor-blinded, multi-center, clinical trial investigating the IMR program compared with usual treatment. 198 people diagnosed with schizophrenia or bipolar disorder participated. The primary outcome was level of functioning assessed with the Global Assessment of Functioning (GAF-F) at the end of intervention, 9 months after randomization. Secondary and explorative outcomes included severity of symptoms, abuse of alcohol/drugs, and hospitalization at the end of treatment. Results IMR had no significant effect on the primary outcome GAF-F at the end of intervention (difference of 2.1 points in favor of IMR, P=0.27). The 95% confidence interval (-1.64 point to +5.6 points) makes the possibility of the hypothesized difference of 6 points favoring IMR unlikely. Neither symptom severity, abuse of alcohol/drugs, or hospitalization differed significantly between the two groups. Conclusion Among Danish patients with schizophrenia or bipolar disorder level of functioning, symptom severity, abuse of alcohol/drugs, and hospitalization were similar among those assigned to IMR and those assigned to treatment as usual. Clinical trial registration information number NCT01361698 at www.clinicaltrials.gov

Introduction

Illness Management and Recovery (IMR) is a curriculum-based rehabilitation program developed to help people with severe mental illness bettering their illness self-management and to obtain a decrease in severity of symptoms, an increase in level of functioning, and a prolonged remission (1). Previous, five randomized trials investigating IMR have been conducted with varying sizes and design (2-6). The findings from four of these trials indicate that IMR is effective in terms of clinical recovery measures. Participants receiving IMR show significant improvements in psychiatric symptoms (2;4), positive symptoms, negative symptoms, symptoms of depression and anxiety, coping with symptoms (3), psychosocial functioning (4), as well as a reduced hospital use over time (5), and less suicidal ideation (2) compared with participants who receive treatment as usual. The latest published trial investigating IMR versus an active control group finds that IMR is not significantly different from control group when assessing symptoms, medication adherence, or service utilization (6). The results from these trials should, however, be interpreted with caution. All trials lack one or more several important aspects such as power and sample size calculation, outcome assessment by blinded assessors, or an approach for handling missing data resulting in high risk of bias. Consequently, the intention with this trial was to add knowledge to the existing evidence of the IMR program by meeting the highest standards of methods in a randomized clinical trial. The aim of this randomized trial was to investigate the benefits and harms of the IMR program compared with treatment as usual in Danish patients with schizophrenia or bipolar disorder. The following alternative hypothesis was tested: Participants in the IMR program would score at least 6 points more than participants receiving treatment as usual on the Global Assessment of Function scale...
(GAF-F) at the end of the 9 month intervention period. In this paper, the results on the clinical outcomes: functioning, symptom severity, social functioning, drug/alcohol abuse, and service utilization will be presented. Results regarding self-perceived recovery will be presented elsewhere.

METHODS

Design
The IMR trial was designed as randomized, assessor-blinded, multi-center, clinical trial of the IMR program compared with usual as treatment in community mental health centers in the Capital Region of Denmark; see the trial protocol (7).

Recruitment
Participants were recruited from three community mental health centers in the Capital Region of Denmark. Participants completed baseline assessments from March 2011 till December 2012 and follow-up assessments from March 2012 till December 2013. To improve the inclusion rate an additional community mental health center was added to the original two.

Participants
Eligible participants were at least 18 years old, associated with a participating community mental health center, diagnosed according to the ICD-10 criteria of schizophrenia or bipolar disorder, able to speak and understand Danish, and providing verbal and written informed consent. To verify the diagnosis prior entering the trial, the Present State Examination (8) was used. Patients were excluded if they had a guardian or a forensic arrangement, had comorbidity with the ICD-10 criteria of dementia or mental retardation, had a large-scale and dominating substance abuse, lived in supported housing, were involved in psychoeducation at the time of inclusion, or had not provided informed consent.

Randomization
After the baseline assessment, participants were randomly allocated 1:1 to IMR plus treatment as usual or treatment as usual alone. To secure the concealment of the allocation sequence, the randomization was central and telephone-based through an administrative office unrelated to the research team. The allocation sequence was stratified by diagnosis and community mental health center. The allocation sequence was computer-generated using permuted blocks varying in sizes of 6, 8 and 10.

Interventions
The Illness Management and Recovery
Patients randomized to the experimental intervention were offered IMR plus ‘treatment as usual’ (see below). Illness Management and Recovery is a curriculum-based program organized in 11 modules which consist of: 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 getting your needs met in the mental health system. IMR was provided in a group format with weekly one-hour sessions during a period of nine months. Ten patients were assigned to each group which was facilitated by two or three practitioners. Prior trials (5;6) point to that participants’ attendance and participation in the IMR program are
essential, therefore strategies such as motivational phone calls and in-hospital-sessions were made to motivate participants to come and to be engaged in the IMR program, if necessary. A further description of the IMR program can be found elsewhere (7;9;10).

_Treatment as usual_
Participants randomized to the control group received ‘treatment as usual’ only. The treatment as usual consists of individually adapted interdisciplinary treatment in the community mental health center or in the patient’s own home. The treatment was individualized for each patient and could contain medication, individual case manager support, individual and group therapy for example cognitive behavioral therapy as well as unstandardized psycho-education. Every patient had a case manager which together with the patient planned the individualized treatment. The patient met with case manager or attended other activities at the community mental health center once a week or more or less often depending on the state of the patient. Some meetings were brief, e.g., when dispensing medication and some meetings were longer with a profound dialogue.

_Measures_

_Clinical Outcomes_
The primary outcome was global functioning post intervention – after nine months – assessed by the Global Assessment of Functioning (GAF-F) (11-13). The secondary outcomes were the Danish validated Positive and Negative Syndrome Scale (PANSS) which focus on severity of symptoms (14) and the Personal and Social Performance (PSP) which focused on social functioning and was not yet validated in Danish (15). Explorative outcomes were Hamilton Rating Scale for Depression (HAM-6) (16;17), Young Mania Rating Scale (YMRS) (18-20), information about substance abuse assessed by the case manager, and service utilization obtained through hospital records.

_Assessment of implementation_
The IMR Fidelity Scale (21) was used for fidelity assessments for all groups to secure and assess the implementation of the program. A multiple data approach was used including interviews, observation of the IMR group, an audit of the patient service records as well as audits of the IMR notes of progress. The fidelity assessments were made half-way through the program (after 4 months) and at the end of the intervention for each IMR group (9 months).

_Procedures_

_Power and sample size_
Prior recruitment a sample size of 200 participants was estimated sufficient for detecting a true difference in the IMR and control group of at least 6 points on the GAF-F (1;22). This sample size was based on a power of 80%, an alpha of 5% and a standard deviation (SD) of 15 points (23;24). For the secondary outcomes it was determined that the sample size of 200 participants was sufficient to test minimal clinical relevant differences with an alpha of 5% and a power of 80% (7).

_Blinding_
Due to the nature of the intervention, it was not possible to blind trial participants or treatment providers. However, blinding was employed in all other aspects of the trial. Post intervention assessments regarding level of functioning and symptom severity were
conducted by an assessor blind to treatment allocation. Two different assessors performed the assessments and a proper inter-rater reliability was ensured, see appendix A for Bland-Altman plot of inter-rater reliability. Participants as well as the staff were strongly inculcated not to disclose the allocation status of the participant at the follow up assessment. The statistical analyses were conducted with the two intervention groups coded as A and B, and the Steering Committee drew the conclusions with the blind still intact.

**Statistical analysis**

The data analysis was based on the intention-to-treat principle. The analysis of difference between the two groups was conducted using analysis of covariance. This was done by estimating the dependent post-treatment variable means adjusted from what it would be if all groups were equal on the covariate (the baseline mean of this variable) (25). If no baseline mean existed t-tests were conducted. Missing data was a potential source of bias. An analysis of missing data was conducted in the primary and secondary variables GAF-F, PSP, and PANSS and it showed that up to 23% of all observations were incomplete. Therefore multiple imputation was conducted to enable intention-to-treat analyses. Post-treatment values were imputed for GAF-F, PSP, and PANSS, using sex, diagnosis, age, community mental health center and intervention group as constraints. The automatic procedure was used and 100 imputations estimated.

Per-protocol analysis was performed to see if group attendance would influence the result as proposed in one trial (26). An analysis using the continuous variable of group attendance for the participants randomized to IMR was made as well as an analysis using a dichotomous variable categorizing attendance into 0-10 sessions or ≥11 sessions. Subgroup analyses tested whether diagnosis or sex interfered with the primary and secondary outcomes. The level of significance for all statistical tests was 0.05. The IBM SPSS Statistics version 19 for Windows was used for statistical analysis and STATA version 11.2 was used for multiple imputations.

**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 inclusion of the first participant (NCT01361698).

**RESULTS**

Figure 1 shows the flow diagram for the participants through the trial. 202 participants were included and randomized but four of them were excluded immediately after randomization: Two participants from the control group withdrew their informed consent, one participant from the control group did not meet the criteria for diagnosis after all, and one participant was assigned as the only participant in an IMR group, therefore the research group decided to exclude this individual of the trial instead. Therefore, 198 participants entered the trial, 99 participants in each intervention group. The baseline characteristics of the 198 participants are listed in table 1. Prognostic factors were equally distributed in the two intervention groups. A total of 26 participants from the IMR group and 11 from the control group did not participate in the follow-up assessments. The
drop-out rate was not equally distributed across the two groups and there was a statistically significant association between drop-out and intervention arm ($\chi^2=7.48$, df=1, $p=0.006$).

**Intention-to-treat analyses**

Multiple imputations were used to analyze data according to intention-to-treat principle (table 2). IMR was not significantly different from treatment as usual regarding level of functioning assessed by GAF-F, mean difference: +2.1 points (95% confidence interval (CI): -1.6 points to +5.8 points, $t=1.10$, df=1, $p=0.27$). For the secondary outcomes, there were no group differences regarding PSP, mean difference: +2.5 points (95% CI: -1.5 points to +6.7 points, $t=1.25$, df=1, $p=0.21$), or PANSS, mean difference: -1.1 points (95% CI: -6.0 points to 3.8 points, $t=-0.44$, df=1, $p=0.66$).

**Complete case analyses**

When analyzing data as complete cases, similar results were found for GAF-F, PSP, and PANSS as in the intention-to-treat analyses. No differences between the two intervention groups were seen in any of the explorative assessments of GAF-S, HAM-D, and Young Mania Rating Scale.

**Service utilization**

The number of visit at the community mental health center (use of treatment as usual) in terms of meetings with the case manager, meetings with a psychologist or a psychiatrist, or times participating in group activities at the community mental health center was the same for both groups. IMR participants had a mean of 24.1 visits (SD=23.8) and control group participants had a mean of 24.5 visits (SD=20.2), respectively. This number covered a wide range where some participants in both groups had no visits and some had more than 130 visits during the follow period. Participants in the IMR group had a mean number of days in the psychiatric hospital of 13.5 (SD=71.1) whereas participants in the control group had a mean number of 12.5 days (SD=46.3), there was no statistical significant difference ($\chi^2=1.18$, df=1, $p=0.28$). There were no significant differences in the number of times the psychiatric emergency service was used or in number of hospital admissions between the two groups.

**Per-protocol subgroup analysis**

The results of the three per-protocol subgroup analyses are listed in table 3. There was no association between a higher number of sessions attended and the end of intervention GAF-F score ($F=5.7$, df=1, $p=0.49$). Subgroup analyses showed no differences in the effect of IMR according to diagnosis or sex regarding the outcomes GAF-F, PSP or PANSS.

**Harms and adverse events**

There were no significant differences between the two groups in drug/alcohol use, suicide or deaths. Participants in IMR did not differ from people in the control group in terms of misuse of alcohol or drugs ($F=1.46$, df=1, $p=0.57$). Three people died in the period of follow-up, one of suicide from the control group and two died of natural causes, one from each group. No relation between participating in the IMR trial and the deaths was detected. No further harms or life-threatening conditions were reported during the trial.

**Implementation**

The IMR Fidelity mean score across the three
participating community mental health centers assessed half-way at 4 months was 4.2 (SD 0.3) equaling good fidelity and the mean score for the end assessment was 4.9 (0.2) equaling high fidelity. A total of 10 IMR groups started and 9 of them completed. One group ended before time because the participants could not come to sessions because of personal reasons (e.g., serious hospitalization, got a job in the day hours, recently had a baby).

Discussion
This trial investigated the benefits and harms of the IMR program compared with treatment as usual. This trial showed no significant difference in relation to the primary outcome, GAF-F, or the secondary outcomes social functioning, and positive and negative symptoms. Exploratory analyses of symptom severity, drug/alcohol use, or service utilization also showed no differences between the groups. Findings were consistent in intention-to-treat analyses using multiple imputations and in the complete case analyses. The subgroup analyses showed no significant differences of IMR according to rate of participation in the IMR sessions, diagnosis, or sex. This trial thereby supports the recent findings that IMR is not significantly effective towards clinical recovery assessments (6). There is a need for collecting the evidence of the randomized trials of IMR in a systematic review with a meta-analysis and this is under preparation (27). Earlier trials showing benefits of IMR have all had a high risk of bias and therefore their results showing positive effects of IMR should be addressed with caution.

Strengths and limitations
This trial has several strengths. The trial 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 (28-31). The Illness Management and Recovery Fidelity Score indicated that the implementation of the program was satisfactory. A strength of this trial is that prior beginning recruitment a sample size calculation was made. Furthermore, only patients with a validated diagnosis of schizophrenia or bipolar disorder were included in the trial. In the randomization process an external partner conducted the randomization and assured the concealment of sequence and allocation. It is also strength of the trial that most outcome assessments were conducted blinded, so that the knowledge of group status did not influenced the process. The external validity is high because the included participants represent the majority of patients with severe mental illnesses getting treatment in a community.

However, this trial also has some limitations. It is a limitation that 23 percent of the observed data were incomplete because they rate of drop-out was high. To address this issue, intention-to-treat analyses was done with multiple imputation. This is the least biased way to deal with missing data (32). It is also a limitation that the secondary outcome Personal and Social Performance scale was not validated in Danish. However, the scale has been validated in a number of other countries and seems reliable and valid.

Overall IMR did not differ from treatment as usual in any of the analyzed outcomes. This means that IMR added to treatment as usual
in a Danish context does not result in better or worse outcomes for the participants. A possible explanation is that the participants already received a sufficient high quality treatment as part of the usual treatment, and that IMR in that context does not add anything further.

Another possible explanation can be found in the theoretic framework for IMR. According to the theory of the IMR program clinical recovery outcomes such as functioning and symptoms remission are considered to be distal outcomes, therefore a longer follow-up period is needed to address the effectiveness of the IMR program properly. Improvements in functioning is supposed to be found after the participant has adapted the new illness management skills into his/hers life. Perhaps the reason why this trial did not find any difference between IMR and the treatment as usual is that the period of follow-up was too brief. Without setting an exact time frame for the IMR theory maybe this trial assessed a distal outcome in a proximal short-time perspective (post treatment). A longer follow-up assessment could perhaps show if IMR is effective according to global assessment of functioning and the other distal clinical recovery outcomes. The trial is therefore also designed to have a longer follow-up, as a 12-month after treatment follow-up is completed currently.

**Conclusion**
IMR had no significant effect on the primary outcome GAF-F at the end of intervention (difference of 2.1 points in favor of IMR, P=0.27). The 95% confidence interval (-1.64 point to +5.6 points) makes the possibility of the hypothesized difference of 6 points favoring IMR unlikely. IMR was not significantly different from treatment as usual at end of intervention in terms of clinical outcomes such as level of functioning, symptoms severity, or hospitalization. This randomized trial contributes to the evidence base of IMR by providing a methodological solid base for its conclusions. A perspective for the future is to design randomized trials with a longer follow-up and collect the evidence of the randomized trials of IMR in a systematic review with meta-analysis.

**Patients’ perspective**
Participants in this trial were very positive and even though they were not paid for their contribution they reported a will to contribute to further psychiatric research. The feedback from the IMR practitioners attending the group was they profited from the IMR program and being in group with other participants.

**Acknowledgements and Funding** We are very grateful for the patients’ participation and the clinicians’ engagement. This trial was founded by the Danish Health Fund, Mental Health Centre Ballerup, Mental Health Centre Frederiksberg and the Mental Health Services of Capital Region of Denmark.
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<td>40.7 (8.3)</td>
</tr>
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<td><strong>PSP¶ (mean ± SD)</strong></td>
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<td></td>
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<tr>
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<td>48.9 (11.3)</td>
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<td></td>
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<td>PANSS† (mean ± SD)</td>
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<td>64.9 (14.3)</td>
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<tr>
<td>GAF-S** (mean ± SD)</td>
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<td>43.6 (9.4)</td>
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<td>7.5 (14.3)</td>
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</table>

* Community Mental Health Center, † Illness management and recovery, ‡ Treatment as usual
§ Global Assessment of Functioning - Functions scale, ¶ Personal and Social Performance § Positive and Negative Syndrome Scale
** Global Assessment of Functioning – Symptoms scale, ‼ Hamilton Rating Scale for Depression ‱ Young Mania Rating Scale
Table 2 Analysis of primary, secondary and exploratory outcomes

<table>
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<tr>
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<td>99</td>
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<td>18.9</td>
<td>99</td>
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<td>63</td>
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<td>YMRVS§§</td>
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<tr>
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<td>n</td>
<td>%</td>
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<tr>
<td>Participants using alcohol/drugs</td>
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<td>Death (all causes)</td>
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*Illness management and recovery  
† Treatment as usual  
‡ Standard deviation  
§ Global Assessment of Functioning  
|| Personal and Social Performance  
¶ Positive and Negative Syndrome Scale  
** GAF-S Global Assessment of Functioning – Symptoms scale  
†† Hamilton Rating Scale for Depression, 6 items  
§§ Young Mania Rating Scale
Table 3 Subgroup analysis: IMR attendance, diagnosis and sex, end of intervention results

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<th>11+ sessions</th>
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<td>18</td>
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<table>
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<th>SD</th>
<th>N</th>
<th>TAU Mean</th>
<th>SD</th>
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<td></td>
<td></td>
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<tr>
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* Illness management and recovery
† Standard deviation
‡ Treatment as usual
§ Global Assessment of Functioning
‖ Personal and Social Performance
¶ Positive and Negative Syndrome Scale
Appendix

Bland-Altman Plot: Agreement of IMR-raters
Paper III: Patients' and Staffs' Evaluation of the Illness Management and Recovery Program: A Randomized Clinical Trial
Submitted

Patients’ and Staffs’ Evaluation of the Illness Management and Recovery Program: A Randomized Clinical Trial

Helle Stentoft Dalum, Anna Kristine Waldemar Madsen, Carsten Rygaard Hjorthøj, Lisa Korsbek, John Hagel Mikkelsen, Karin Thomsen, Jane Lindschou, Kristen Kistrup, Mette Olander, Merete Nordentoft & Lene Falgaard Eplov
Abstract

Objective: The aim of this randomized trial was to investigate the benefits and harms of the curriculum-based psychosocial intervention Illness Management and Recovery (IMR) program in patients with severe mental illness in three community mental health centers in the Capital Region of Denmark.

Methods: Randomized, assessor-blinded, multi-center, clinical trial of the IMR program compared with treatment as usual in 198 participants diagnosed with schizophrenia or bipolar disorder. In this report, we focused on outcomes related to illness self-management and self-perceived recovery assessed at the end of the 9 months intervention period.

Results: There were no statistical differences between the two groups in the IMR scale for participants (IMRS-P), mean difference +1.9 points (95% confidence interval (CI): -0.6 points to +4.5 points, t=1.49, df=1, p=0.14), or in the IMR scale for staff (IMRS-S), mean difference +0.4 (95% CI: -2.2 points to 3.1 points, t=0.31, df=1, p=0.76) in the intention-to-treat analyses using multiple imputation. There were no differences between IMR and treatment as usual regarding hope, recovery, or satisfaction with service.

Conclusions: IMR appears not to be better than treatment as usual in this population of Danish patients with schizophrenia or bipolar disorder. 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.

Introduction

Psychoeducational programs for patients 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 [1]. The Illness Management and Recovery (IMR) program combines psychoeducational, self-management and behavioral approaches and is every-day life focused with the option of including the patient’s family [2]. IMR is hypothesized to improve recovery as a result of the patient learning illness management skills. Recovery is defined in numerous ways. 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 [3-7]. IMR may have a positive effect on aspects of personal recovery and self-management skills [8-10], however, this is still disputed [11-13]. Thus, there is a need for a large randomized clinical trial with a solid methodological approach to investigate the effects of IMR. The current trial aimed to investigate the benefits and harms of IMR versus treatment as usual. In this paper, we report results regarding on the illness self-management and personal recovery outcomes. Results regarding clinical recovery outcomes will be presented elsewhere [14].

Methods

Design

The IMR trial was designed as a randomized, assessor-blinded, multi-center, clinical trial investigating the IMR program compared with treatment as usual. The design has previously been reported in detail [15]. The trial was conducted from February 2011 to December 2013 in three community mental health centers (CMHC) in the Capital Region of Denmark. To improve recruitment, an additional community mental health center was added to the original two.

Participants

Included participants were diagnosed with schizophrenia or bipolar disorder according to the ICD-10 criteria and verified by the Present State Examination[16] by a psychiatrist or
clinical psychologist; 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 plus treatment as usual or to continue 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 were blinded to allocation during the intervention. Outcomes reported in this paper were subjective and self-assessed and thus 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)
The IMR program is composed of psychoeducation, cognitive-behavioral approaches to medication adherence, relapse prevention planning, social skills training, and coping skills training [17] and made into a curriculum-based program consisting of 11 modules [18]. IMR was provided in a group format with ten participants in each group and was led by mental health practitioners from the CHMC, who were trained in the curriculum of IMR. The IMR program lasted nine months with one weekly session of one hour and took place at the CMHC during the day. A more detailed description of the IMR program and the implementation in the CMHC can be found elsewhere [15].

Treatment as usual
The treatment as usual consisted of individually adapted interdisciplinary treatment in the CMHC or at the patient’s own home. The treatment included medication, individual case-manager support with an average caseload of 30 patients, individual and group therapy, unstandardized psychoeducation, and psychiatric or psychological counseling. Every patient had a case manager who in cooperation with the patient planned which elements the individualized treatment should consist of. The patient met with the case manager or attended other activities at the CMHC once a week on average depending on the present state of the patient.

Outcomes
All outcomes were assessed at baseline and at the end of intervention, 9 months after randomization. Research in the area of recovery is relatively new in Denmark and no well-founded scales existed in Danish. 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 secondary outcomes of Illness Management and Recovery Scale total score for participants and staff are reported (see below) and all other outcomes reported in this paper are of exploratory nature.

Illness Management and Recovery Scale
The Illness Management and Recovery Scale (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 indicate 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 to detect change [19-21].

Further, we post-hoc report results on the three subscales of the IMRS: a Recovery subscale, a Management subscale, and a Biology subscale for both participants and staff [22].

**Adult State Hope Scale**
The Adult State Hope Scale [23] 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 to assess hope in patients with mental illness [24].

**Mental Health Recovery Measure**
The experience of personal recovery was evaluated by the Mental Health Recovery Measure [25,26]. The scale consists of 30 items on a 5-point scale and has been validated in more than 200 patients in different settings [27].

**Clients Satisfaction Questionnaire**
The participants’ satisfaction with services was measured by the Clients Satisfaction Questionnaire [28]. The scale has 8 items on a 4-point scale and is an estimate of general satisfaction with the mental health services.

**Illness Management and Recovery Fidelity Scale**
IMR Fidelity Scale was used to secure and assess the implementation of the IMR program in each group [29]. The scale consists of 13 items on a 5-point scale and a multiple data approach was used including: interviews, observation of the IMR group, an audit of the patient service records as well as audit of the IMR notes of progress. External assessors conducted the fidelity assessments, which were conducted mid-way through the program (after 4 months) assessing items 1-10 and conducted at the end of each group (9 months) assessing all 13 items.

**Statistical analysis**
Prior recruitment a sample size estimation showed that 200 participants was sufficient for the primary outcome Global Assessment of Function (GAF-F) that will be reported elsewhere [14]. For the secondary outcomes IMRS-P and IMRS-S, it was estimated that the sample size of 200 participants was sufficient to test minimal clinical relevant differences with an alpha of 5% and a power of 80% [15]. 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 imputation was 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 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 for all statistical tests was 0.05.

**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 is a flow diagram of the participants through the trial. 202 participants were randomized, four participants were excluded immediately after randomization: Two participants in the control group withdrew informed consent, one participant in the control group was excluded because the criteria of diagnosis was not fulfilled. Finally,
the last participant randomized was assigned to be the only participant in an IMR group and therefore it was decided to exclude this individual. Thus 198 participants entered the trial, 99 participants in each arm. Baseline characteristic were similar in the two groups (Table 1). A total of 26 participants from the IMR group and 11 participants from the control group did not participate in any of the follow-up assessment. The drop-out rate was not equally distributed across the two groups ($\chi^2=7.48, \text{df}=1, p=0.006$).

**Illness Management and Recovery outcomes**

Table 2 summarizes the differences in the illness management and recovery outcomes for both groups. There were no statistical differences between the two groups in the intention-to-treat analyses of IMRS-P, mean difference $+1.9$ points (95% confidence interval (CI): $-0.6$ points to $+4.5$ points, $t=1.49$, df=1, p=0.14), and IMRS-S, mean difference $+0.4$ (95% CI: $-2.2$ points to $3.1$ points, $t=0.31$, 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: $17.4$ points, standard deviation (SD) $3.0$, control mean: $16.4$, SD=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, see table 4. However, item number 5 ‘Involvement of significant others’ with a mean score of $3.3$ (SD $1.24$) across both assessment indicate involvement of family and friends was not fulfilled. Clients Satisfaction Scale (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 times participating in groups at the community mental health center was the same for both groups. IMR participants had a mean of $24.1$ visits (SD=$23.8$) and control group participants had a mean of $24.5$ visits (SD=$20.2$), respectively.

**Harms and adverse events**

There were no differences between the two groups in adverse events such as drug/alcohol use, suicide or deaths. No harms or life-threatening conditions were reported during the trial. Three participants died in the period of follow-up, one of suicide from the control group and two died of natural cause 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 in patients with severe mental illness in Denmark. In this paper, we specifically report outcomes related to personal recovery and illness management.

There were no statistical significant differences between the two groups in the outcomes related to IMR: total scores of the IMRS-P and the IMRS-S in the intention-to-treat analyses using multiple imputation, indicating that the patients in the IMR are not better at managing their illness than patients in the control group. Further, participants in the IMR group did not differ statistically significantly from participants receiving treatment as usual regarding hope, self-perceived recovery or satisfaction with service in the complete case analyses. The findings therefore supports findings regarding outcomes of clinical recovery of this trial.

5
which also shows no statistical differences between the two groups [14,30].

So far five randomized clinical trials of IMR have been published. Three of these find a significant difference between the IMR group and the treatment as usual group in favor of IMR on the IMRS both rated by the participant and the staff [8-10]. Whereas two randomized trials find no statistical significant difference on the IMRS between the two intervention groups [12,13] which is similar to the finding 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 and therefore their results showing effects of IMR should be addressed with caution. A potential effect of IMR in terms of illness management and recovery need to be investigated in a systematic review with meta-analyses of the existing trials, consequently a Cochrane Review of IMR is under preparations [31].

This trial did not find an effect of IMR. The reason may be the design of the trial or the fact that IMR is not better or worse than treatment as usual. 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 [2]. This trial did not confirm this assumption. Matters of recovery are considered to be distal outcomes that can be assessed after a while. To investigate the long-term effects on both illness management and recovery measures of the IMR program in Denmark a follow-up assessment 21 months after baseline is ongoing.

Another explanation why no effect was detected on the IMRS assessing illness management is that the IMRS might reflect multiple theoretical dimensions as indicated in the post-hoc analyses of the IMRS’ subscales [22]. Illness management might have been assessed better by using more universal illness management scale, for example the self-efficacy scale [32].

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., aspects of religious beliefs [33]. In future studies of the IMR program there is a need for developing scales that suit the given cultural setting.

Finally, the IMR program may is not be effective in terms of the factors that patients consider as being important. The two factors that most people recognized helped in their recovery were knowledge and support according to a recent Delphi study of 381 people with lived experience of mental illness [34]. The two factors are the essence of rationale of IMR [2] and therefore a missing effect is surprising. The overall implementation of IMR in the Danish CHMC was good according to the fidelity scorings, but the aspect of involving family and significant others was not fulfilled in this trial and could maybe also explain the lack of effectiveness [35].

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 [36-39]. A sample size and power calculation was made prior recruitment and when a high number of missing data occurred, data was analyzed using multiple imputation. Furthermore only patients 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 patient with schizophrenia or bipolar disorder receiving treatment in Danish community.
mental health centers or community mental health service elsewhere [40].

However, this trial also has some limitations. 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 can increase the risk of bias. However, as the trial results are overall neutral, we assess the actual risk of bias to be minor.

Conclusion
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 service. Further studies with a longer follow-up, better assessments of illness management and recovery and a systematic review of the existing trials are needed to determine if IMR is effective.

Disclosure and acknowledgements: We are very grateful for the patients’ participation and the clinicians’ engagement. This trial was founded by the Danish Health Fund, Mental Health Centre Ballerup, Mental Health Centre Frederiksborg and the Mental Health Services of Capital Region of Denmark.

References
3. Anthony WA: Recovery from mental illness: The guiding vision of the mental health service system in the 1990s.


Abuse and Mentak Health Services Administration, Center for Mental Health Services, 2004.


Figure 1 Flow Diagram for the Danish Illness Management and Recovery trial

Enrollmen

Assessed for eligibility (n=231)
- Excluded (n=19)
  - Not meeting the inclusion criteria (n=4)
  - Declined to participate (n=11)
  - Other reasons (n=4)

Randomized (n=202)

Allocated to the intervention.
IMR (n=100)
- Excluded immediately after allocation (n=1)
  - IMR group not started (n=1)

Allocated to the control treatment as usual (n=102)
- Excluded immediately after allocation (n=3)
  - Withdrawal of informed consent (n=2)
  - Diagnosis not eligible (n=1)

Entered the trial intervention.
IMR (n=99)

Follow up
- Lost to follow up (n=26)
  - Out of reach (n=2)
  - Unable to participate evaluated by a doctor (n=6)
  - Declined to participate (n=7)
  - Death from suicide (n=9)
  - Death natural causes (n=1)

Entered the control group, treatment as usual (n=95)
- Lost to follow up (n=11)
  - Out of reach (n=2)
  - Unable to participate evaluated by a doctor (n=2)
  - Declined to participate (n=5)
  - Death from suicide (n=3)
  - Death natural causes (n=1)

Analyses
- Included in intention-to-treat analyses (n=99)
- Included in intention-to-treat analyses (n=99)
Table 1 Baseline Characteristics of the Participants

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<th>TAU† (N=99)</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
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<tr>
<td>Years since first contact (± SD)</td>
<td>14 (±10.3)</td>
<td>16 (±10.2)</td>
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<tr>
<td>Missing</td>
<td>17</td>
<td>17.2</td>
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<td>14.1</td>
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</table>

* Illness Management and Recovery
† Treatment as usual
‡ Community Mental Health Center
Table 2 Illness management and recovery measures

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<tr>
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<th>Post intervention</th>
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<tr>
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<td>IMR</td>
</tr>
<tr>
<td></td>
<td>Mean  SD</td>
<td>Mean  SD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intention-to-treat analysis</td>
</tr>
<tr>
<td>IMRS-P‡</td>
<td>54.7 .93</td>
<td>99 58.8 .85</td>
</tr>
<tr>
<td>IMRS-S§</td>
<td>54.6 .97</td>
<td>99 54.2 .92</td>
</tr>
<tr>
<td>IMRS-P</td>
<td>50.9 6.9</td>
<td>50.9 7.4</td>
</tr>
<tr>
<td>IMRS-S</td>
<td>50.5 7.3</td>
<td>50.7 6.9</td>
</tr>
<tr>
<td>Mental Health</td>
<td>70.9 15.1</td>
<td>69.9 18.7</td>
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<tr>
<td>Recovery Measure</td>
<td></td>
<td></td>
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<tr>
<td>Adult State Hope Scale</td>
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<td>30.9 9.1</td>
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<tr>
<td>Clients Satisfaction</td>
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<td>25.1 4.0</td>
</tr>
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<td>Questionnaire</td>
<td></td>
<td></td>
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</tbody>
</table>

*IMR: Illness Management and Recovery  
†TAU: Treatment as usual  
‡Illness Management and Recovery Scale – participants’ version  
§****Illness Management and Recovery Scale – staffs’ version
Table 3 Analysis of Illness Management and Recovery subscales

|                                | Baseline |            | Post treatment |            |            |            |            |            |  |
|--------------------------------|----------|------------|----------------|------------|------------|------------|------------|------------|  |
|                                | IMR*     | TAU‡       | IMR            | TAU       | N          | N          | P-value     |            |  |
|                                | Mean     | SD†        | Mean           | SD         |            |            |            |            |  |
| Recovery Scale – Participant   | 15.6     | 3.5        | 15.6           | 3.5        | 63         | 16.4       | 3.5         | 66         | 0.02      |
| Management scale – Participant | 15.8     | 3.9        | 16.1           | 4.2        | 61         | 16.9       | 3.8         | 69         | 0.33      |
| Biology scale - Participant    | 14.0     | 2.0        | 14.1           | 1.5        | 51         | 14.1       | 1.8         | 60         | 0.76      |
| Recovery Scale –Staff          | 15.7     | 3.1        | 16.1           | 3.3        | 69         | 17.1       | 3.9         | 72         | 0.14      |
| Management scale – Staff       | 15.5     | 4.1        | 15.7           | 4.2        | 69         | 17.5       | 3.8         | 73         | 0.40      |
| Biology scale – Staff          | 13.9     | 2.1        | 14.2           | 1.5        | 60         | 14.9       | 6.7         | 69         | 0.55      |

*IMR: Illness Management and Recovery
† SD: standard deviation
‡ TAU: Treatment as usual
# Table 4 Implementation assessed by Illness Management and Recovery Fidelity Scale

<table>
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<th>Items</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>1. No people in a group</td>
<td>5.0</td>
<td>0.0</td>
<td>19</td>
</tr>
<tr>
<td>2. Program length</td>
<td>4.2</td>
<td>0.7</td>
<td>19</td>
</tr>
<tr>
<td>3. Comprehensiveness of the curriculum</td>
<td>3.8</td>
<td>1.2</td>
<td>19</td>
</tr>
<tr>
<td>4. Provision of educational handouts</td>
<td>4.8</td>
<td>0.9</td>
<td>19</td>
</tr>
<tr>
<td>5. Involvement of significant others</td>
<td>3.3</td>
<td>1.2</td>
<td>19</td>
</tr>
<tr>
<td>6. IMR goal setting</td>
<td>4.7</td>
<td>0.7</td>
<td>19</td>
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<tr>
<td>7. IMR goal follow-up</td>
<td>4.4</td>
<td>1.1</td>
<td>19</td>
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<tr>
<td>8. Motivation-based strategies</td>
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<td>0.3</td>
<td>19</td>
</tr>
<tr>
<td>9. Educational techniques</td>
<td>4.9</td>
<td>0.2</td>
<td>19</td>
</tr>
<tr>
<td>10. Cognitive-behavioral techniques</td>
<td>4.9</td>
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<td>19</td>
</tr>
<tr>
<td>11. Coping-skills training</td>
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</tr>
<tr>
<td>12. Relapse prevention</td>
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</tr>
<tr>
<td>13. Behavioral Tailoring for Medication</td>
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<table>
<thead>
<tr>
<th>Mean</th>
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</thead>
<tbody>
<tr>
<td>Mid-way assessment of item 1-10</td>
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<tr>
<td>Final assessment of item 1-13</td>
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Paper IV: From Recovery Values to Recovery-Oriented Practice? A Qualitative Study of Health Professionals’ Experiences When Facilitating a Recovery-Oriented Rehabilitation Program
From Recovery Values to Recovery-Oriented Practice?

A Qualitative Study of Health Professionals’ Experiences When Facilitating a Recovery-Oriented Rehabilitation Program

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ABSTRACT
Introduction: The recovery model has influenced mental health services and fostered new standards for best practice. However, knowledge about how mental healthcare professionals (HCPs) experience recovery-oriented programs is missing. Aim/Question: This paper explores HCPs’ experiences when facilitating a recovery-oriented rehabilitation program. The research question is how do HCPs experience a change in their attitude and practice when applying recovery-oriented programs? Methods: This paper draws on semi-structured in-depth qualitative interviews conducted with 16 HCPs experienced in facilitating a recovery-oriented rehabilitation program in either the USA or Denmark. Results: Three themes in HCPs’ reflections on changes in attitudes and practices emerged in the qualitative study: “Hopeful attitude” captures a change in the HCPs’ attitude towards a more positive view on the future for clients living with mental illness; “New focus in the dialogue with clients” thematizes how the HCPs focus more on the individuals own goal for recovery rather than disease induced goals in dialogue with clients; “Person-centered role” comprises a shift in the professional role where the HCPs value the client’s own ideas in addition to the professional’s standards. Conclusion: This study shows that values from the recovery model are reflected by HPCs as having implications for their attitude and practice when providing recovery-oriented service.

INTRODUCTION
Theories and models of recovery have influenced mental health services and fostered new standards for best practice. But how do HCPs experience their professional practice when implementing recovery-oriented services? The values of the recovery model are: promoting hope, well-being, self-management and improving social inclusion (Anthony, 1993; Davidson, Tondora, O’Connell, Kirk, Jr., Rockholz & Evans, 2007; Slade, 2009). The fundamental basis of recovery-oriented services is to support the person’s recovery process by facilitating an active collaboration between the person with mental illness and the mental health care professional (Farkas, 2007). However, mental health care has been, and still is, dominated by the medical model, which values preservation and restoration of mental health and focuses on categorizing and solving problems that result from the illness (Davidson & Roe, 2007; Slade, Amering & Oades, 2008; Warner, 2009).

In 2006 the American Substance Abuse and Mental Health Services launched a plan to transform the mental health care in terms of the values of recovery (O’Connor & Delaney, 2007; Substance Abuse and Mental Health Services Administration (SAMHSA), 2006). In this transformation a distinct strategy was promoting recovery-oriented practice to enable the professionals to be recovery-oriented and the initiative Recovery to Practice from 2010 has been a part of this strategy (Delaney, 2012). Action plans and strategies for mental health care to promote recovery-oriented practice are also proposed by mental health authorities around the world and is not only an American phenomenon (Le, Leamy, Bird, Davidson, Williams & Slade, 2011).

The literature about recovery-oriented changes in mental health care delivery is spare though. Studies in relation to recovery-oriented training programs for professionals have shown that professionals’ attitude towards clients’ recovery improved when evaluated in a repeated-measures design (Wilrycx, Croon, van den Broek & van, 2012) and in a cross-sectorial study (Gudjonsson, Webster & Green, 2010).

Three other studies have addressed how this new knowledge and attitude towards recovery has been transferred into the practice of the professionals. One of the studies suggests that if the recovery training is provided jointly by both clients and staff, it might be profitable for the relationships (Salkeld, Wagstaff & Tew, 2013). Another study finds that recovery training gives the professionals new knowledge and leads to changes in care plans. By analyzing audit data from care plans by logistic regression it has found quantifiable changes in outcomes such as change in care plan focus.
and change in responsibility of action (Gilburt, Slade, Bird, Oduola & Craig, 2013). Finally a cross-sectorial study has investigated how training of professionals in the elements of a recovery-oriented rehabilitation program has influenced their attitudes as evaluated by questionnaires. The authors find that HCPs’ training correlates with their higher client optimism and greater orientation towards the client’s goals (Tsai, Salyers & McGuire, 2011).

Nevertheless, there might be a gap between what is taught academically about recovery-oriented care and the perceived ability and confidence by the professionals in delivering recovery-oriented practice. A questionnaire study of community mental health nurses’ perspective of recovery-oriented care argues that such a gap exists and that there is little knowledge of the mental health professionals’ experiences and perceptions of applying the recovery-oriented approaches (Gale & Marshall-Lucette, 2012). All together the few studies in this field indicate that formal training in the recovery philosophy influences the mental health care professionals’ knowledge and attitude; but there is little information of how the professionals experience working by the recovery philosophy, and how they apply this new kind of care in their daily practice.

Thus, the aim of this study is to investigate: What changes have mental health professionals experienced in their attitude towards their own practice when facilitating a recovery-oriented program along with their daily work?

We will use the Illness Management and Recovery (IMR) program as an example of a recovery-oriented program implemented into common practice, since it is a well-defined program founded on recovery. The IMR program is developed as an evidence-based curriculum program facilitated by professionals to promote recovery for people with severe mental illnesses (Mueser, Meyer, Penn, Clancy, Clancy & Salyers, 2006). The program consists of 11 modules within 6-12 months with 1-2 weekly sessions. Previous research of the IMR program has focused on either clients’ outcome measures or on the organizational implementation of the program (McGuire, Kukla, Green, Gilbride, Mueser & Salyers, 2014) and not on the mental health care professionals actual practicing the IMR along with their daily clinical practice.

**METHODS**

**Prior understanding of recovery-oriented mental health care**

This article’s understanding of the concept of recovery from mental illness is based on the conceptualization by Dr. William Anthony, the former director of the Boston Center for Psychiatric Rehabilitation. He defines recovery as a “deeply personal, unique process of changing one’s attitude, values, feelings, goals, skills and/or roles. It is a way of living a satisfying, hopeful, and contributing life even with limitations caused by illness. Recovery involves the development of new meaning and purpose in one’s life as one grows beyond the catastrophic effects of mental illness” (Anthony, 1993). Recovery is thereby regarded as the individual’s personal process that includes living a satisfying, meaningful and hopeful life.

As a pilot study, observations and background interviews with nurses and psychologists working in the community mental health centers in Denmark were carried out to get knowledge about their work, their attitude towards their job, and how it was performed. The literature about recovery-oriented service says that the fundamental basis of this healthcare service is to support the person’s recovery process by facilitating an active collaboration between the person with mental illness and the mental health care professional. The professionals’ competencies that give rise to a recovery-oriented practice include an attitude which infuses hope, development and quality of life by respecting the individual’s own choice and by involving the individual in their own recovery and treatment (Barker & Buchanan-Barker, 2011a; Barker & Buchanan-Barker, 2011b; Camann, 2010; Davidson, O’Connell, Tondora, Styron & Kangas, 2006; Davidson, Schmutte, Dinzeo & Andres-Hyman, 2008; Farkas, 2007; Farkas, Gagne, Anthony & Chamberlin, 2005; Slade, 2009).
Design and data collection
To obtain rich information of how the professionals experienced facilitating a recovery-oriented program as a part of their practice qualitative in-depth semi-structured interviews were conducted. The data was collected and analyzed in two stages. In Stage 1 (September 2011), the American HCPs were individually interviewed in an effort to determine which themes appeared from their experiences. An interview guide inspired by Farkas et al.’s proposed values for recovery-oriented service was used to gain a broad insight, with questions such as: “How do you consider the relationship between the client and you?” (Farkas et al., 2005). All interviews took place at the interviewee’s office and lasted approximately one hour. The interviews were audio-recorded and transcribed verbatim on the basis of a transcription guideline. A memo was written after each interview summarizing impressions of the interviewees’ values to be used in the analysis (Lempert, 2007). An inductively pre-analysis of the American interviews was then carried out, see below. In the next stage of the study (Stage 2), a new interview guide was developed from the pre-analysis and used for the interviews conducted with the Danish HCPs in the spring of 2012. These interviews were carried out using the same methods as in the USA only to get more detailed and profound knowledge about the themes developed in Stage 1.

Participants
In sum, we recruited 16 mental health care professionals (HCPs) from the USA and Denmark. To get information both from HCPs who have been providing IMR for a longer time and from HCPs with a new experience of IMR a selective sampling approach was used (Coyne, 1997). The participants were both HCPs from the community mental health centers in New Hampshire USA where the IMR program was well-established and HCPs from community mental health centers in Capital Region of Denmark where the IMR had just been introduced. The American HCPs were selected to participate if they that had been formally trained in IMR and had been practicing IMR for at least two years at the community mental health center. Eight HCPs from three community mental health centers (named site A, B, and C) in New Hampshire USA were participated. A person from the research team contacted the local manager who asked HCPs if they wanted to participate. In Denmark eight HCPs were selected as they were the first to practice IMR in Denmark. They worked in two community mental health centers in the Copenhagen-area (named site D and E) and at the time of the interview they had less than one year’s experience with practicing IMR. All the interviewees varied in educational background. Table 1 includes a list of all the 16 HCPs with more details of their characteristics. Many of them were nurses, but also psychiatrists, case managers and occupational therapist were represented among the interviewees. Their work were similar, and it was common for all HCPs to have case manager responsibilities besides providing IMR. The IMR program was an “added” program along with a similar range of traditional community mental health practices both countries. To keep the anonymity of the HCPs in the accounts quoted, they are identified by their country and study ID number, i.e. ‘USA1’.

Analysis
The interviews were analyzed using the techniques of Situational Analysis (Clarke, 2005; Mathar, 2008). This analytical approach builds on grounded theory and provides a method with mapping and diagramming to look into specific situations and varieties in positions that the different HCPs hold (Clarke, 2005) . Situational Analysis includes three overall mapping methods, each one having its own purpose and approach: 1) Situational mapping is a technique that focuses on key elements within the specific area of investigation such as major human, nonhuman, discursive and other
elements and their relationship; 2) Social worlds and arena mapping is a way to organize the key elements into categories that operate in the situation of concern; 3) Positional mapping includes mapping different positions on issues of controversy in the situation of concern. In the study, we have used all the three different mapping techniques. However, in this article we focus on the results from the positional mapping, because this mapping technique provides us a tool to visualize and analyze the complexity in the professionals’ experiences of their attitude towards their own practice facilitating a recovery-oriented program.

In Stage 1 of the analytical process the American interviewees’ accounts on specific topics were given an initial code. The initial codes were then combined into subcategories that captured an expanded greater meaning of the text. In the process of mapping subcategories into categories, three main themes were identified: changes in attitude towards mental illness; changes in focus of the dialogues with the clients; and changes in role assumption. The interview transcripts from Stage 2 were analyzed deductively to enrich the whole analysis and qualify the three themes. Figure 1 is an example of the coding process used during the two analytical stages. To visualize the major positions taken in the data on a certain theme and to analyze the differences within each theme in depth, we drew positional maps from situational analysis (Clarke, 2005), see figure 2. NVivo8.0 qualitative software was used to manage data.

Ethical considerations
The New Hampshire Department of Health and Human Services Institutional Review Board approved the American part of the study (IRB reference # 199). In Denmark an ethical approval is not mandatory in non-experimental studies. Nonetheless, the same level of ethical standards was applied in both countries: participation was voluntary, HCPs’ confidentiality was maintained and the gathered information was only used for research purposes.

FINDINGS
A hopeful attitude
The theme ‘A Hopeful Attitude’ captures some of the HCPs’ experiences and examples of how they tend to have a new attitude towards the field of mental illness. They express how they have experienced a shift in their attitude, for example a more optimistic attitude towards their clients’ opportunities in life instead of dampen the clients’ chances in life. The quote as follows captures this:

“I have a whole new optimism: I now dare to say without worrying about the accuracy that people do recover and get well!” (DK3).

Introduced to the concept of recovery by practicing IMR this HCP has gained a new optimism to the opportunities the clients have in their lives. Another HCP experiences a “whole new attitude” because of the focus on recovery.

“Today we have a whole new attitude towards having a mental illness. A lot of people with mental illness manage very well. And then we talk about the success stories” (DK4).

Some of the HCPs have experienced a change toward a more hopeful attitude, an attitude which is now accepted among colleagues which she express by saying “we”. Supporting the clients by having hope for them and believing in them, even when the clients do not believe in themselves, have for many HCPs become a part of their working approach. In contrast, a few of the interviewed HCPs seemed more pessimistic. One HCP says:

“I don’t know the final result. I don’t purport the clients that it can be fantastic, if I don’t think so” (DK2).

This quote exemplifies how some HCPs avoid talking about hope for recovery.
A new focus in the dialogue with the clients

This theme captures how the HCPs experience different attitude towards what should be the focus of dialogue with the clients compared to their earlier approach. An essential part of the IMR program is the clients’ own goal-setting, and the HCP’s and the client’s frequently talking about the client’s goals, dreams, and hopes. This focus has become an integrated part of their overall practice for many of the interviewed HCPs. They find that recovery goals in the dialogue with the clients also have become a new focus outside of the IMR framework, for example when they talk to clients individually as their case manager. One HCP exemplifies how the client’s own goal-setting is an integrated focus on all of his work with groups of clients:

“I probably, more so than other people, overemphasize the goal aspect of IMR. I’m all about the goals. And it’s come out in terms of my own practice, especially with the groups” (USA1).

Another HCP is aware of how she has changed her focus in the dialogue with clients:

“It is very much about thinking that you are just a wave sloshing about in all directions. A lot of psychiatric clients feel like that. So we tell them that this is about setting goals. Because people who have set goals, the more concrete these goals are, [the individual experiences that] you are not a wave just sloshing about in the water. Then you start to gain foothold and get a hold of it, so you can decide for yourself” (DK7).

This HCP draws attention to her belief that through individual goal-setting clients get an opportunity to gain control over their own lives even though the life may seem chaotic. A majority of the HCPs mention that in their dialogue with clients, the focus on the clients’ individual recovery goals instead has become more common than addressing disease induced goals. An individual recovery-goal can be something quite simple like “get out of their bed every day” (DK3), but also something complex like “travel to France” (DK3). Examples of disease induced goals reflecting the medical model are “to take my medication every day” (USA5), or “verbalizing an understanding of my symptoms” (USA5). These goals do not motivate the client as they do not contain something he/she wants to happen. Goals like these are seen as linked to the mental illness and are not individualized into what the client prefers. However, not all the interviewed HCPs express a focus on recovery goals in the conversations with their clients. One of the HCPs says:

“During the individual conversation we don’t discuss it as goals as such. Instead we talk about which problems, which aspects of her [the client’s] life she has problems with or could improve. How she can work with that” (DK6).

This quote illustrates the HCP’s valuing the concepts from the medical model in her work by focusing on problems and barriers for recovery, for example by using terms like “problems” to “improve”.

A person-centered role

This theme comprises the HCPs’ experience of gaining a new role assumed within the recovery model. While facilitating IMR, some of the HCPs experienced their professional role as changing. For example they describe a stronger person-centered approach to their work. This approach balances the dual importance of the client’s own values along with their professional values. One HCP reflects on her role shift:

“Before, I was very insisting and kept the clients longer, and I brought up 10,000 ideas and threw them at the client. I so much wanted the client to get better. Now I am more relaxed, keeping in mind that it is the client who has problems, which we look at together. I can guide the client from my theoretical knowledge. Then the client can see whether it works for him and we continue the work together” (DK5).
This quote illustrates how the HCP in her former practice proposed many ideas to help the client solving his problems without possibly listening to what the client really wanted. After facilitating IMR, the HCP evolved to a different approach with a starting point in the goals of the individual client to use her professional knowledge in supporting the client.

In the medical model, certain role definitions exist. For example the role of the client is referred to as the “help-seeker” and the role of the HCP is referred to as the “helper” (DK3). This HCP-client relation suggests an imbalance in power; the helper has the power to help/decide what is best for the help-seeker. So in this case the helper decides what interventions would be best for the help-seeking individual. The helper role is problem-centered and implies a paternalistic approach to clients. The HCP’s role dominating in the medical model is to help the client to do what the professional mental health “expert” considers is best for them. One of the HCPs labels himself and the HCPs in general as “fix-it people”.

“I think one of the things about therapists is that we are “fix-it people”. Give us a problem, we will start thinking of solutions and trying to change things” (USA3).

This HCP notes that the approach on how to work with clients is not only ingrained in how he views his job (“we are”) but also how he performs (“thinking of solutions and trying to change things”). Developing a recovery-oriented mindset is clearly different from being a helper or a problem solver. It is something that demands a new approach in the work with clients.

Another HCP points to why a recovery-oriented role is experienced as very different from the former role as a HCP.

“So as a clinician you had to change your way of thinking, and to change the way you are thinking, you had to re-strategize. Nobody fits a traditional mold.” (USA4).

This HCP uses the phrase “re-strategize” to describe a belief that all aspects of the role of a HCP have to be changed. The professionals need new strategies from the very first meeting with a client to figure out how to work with the client. To “change your way of thinking” is not something that one can do over night. One HCP explains how it is difficult to keep focusing on delivering service according to the recovery model:

“I know that you can always get sucked back into that old maintenance [medical] model or wanting to set goals for the client. Rather than really letting them set their own goals.” (USA1)

This HCP addresses the difficulties in taking a new role in the dialogue with the client, as it can be difficult not to return to old habits like “wanting to set goals for the client”.

**DISCUSSION**

In this study we have provided examples of how HCPs experience the transition from recovery values into recovery-oriented practice. When practicing IMR, most of the interviewed HCPs find that they have gained a more hopeful attitude towards their clients’ living with a mental illness. They focus more on the clients’ own goals for recovery instead of disease induced goals in the dialogues with clients. Moreover, most of the HCPs strive to become more person-centered instead of assuming the expert role. Not all of the interviewed HCPs have expressed a recovery-oriented change in their attitude or experienced a change in their practice. This could be due to the professionals’ resistance to the IMR program as proposed in an implementation study of IMR by Whitley et al. They find that some professionals did not want to implement IMR because it was “that the current emphasis on recovery-oriented service is a passing fad” (Whitley, Gingerich, Lutz & Mueser, 2009) p. 208). This paper is addressing the initial initiatives towards a recovery-oriented service in a setting dominated by the medical model. Thus, some of the professionals might be
skeptical towards IMR and the recovery-oriented values it builds on and prefer the values of the medical model. The medical model of mental health care has dominated the field of mental health care for many years and to change attitude and practice of a whole group of professionals might not be possible with implementing one single recovery-oriented program.

In our analysis we have examples of how recovery values are experienced and adapted into the practice of HCPs. Farkas and colleagues propose four key recovery values reflecting a recovery-oriented mental health program: person-orientation, person-involvement, self-determination/choice and growth potential (Farkas et al., 2005). Those values are all reflected in our findings. The value of person-orientation means that the service focuses on the person as an individual rather than focusing on the person as a patient. Person-involvement means focusing on the individual’s right to full partnership in all aspects of his/her recovery. These values are reflected in the characteristics of the new role that is captured in our study’s theme “A Person-Centered Role”. The HCPs found that they had to “re-strategize” what they are suppose to do as professionals, when they are working with a person having a illness and not with the illness itself.

The practical use of the clients’ own goals as the dominating focus in every conversation and therapy session, described in this study’s theme “A new focus in the dialogue with clients”, is a way of integrating the values of self-determination and self-choice in practice. According to Farkas et al. (2005) self-determination means that the service provider focuses on the individual’s right to make his/her own decision about all aspects of the recovery process including desired goals. Finally, the message and awareness of hope, captured in our study’s theme “A Hopeful Attitude”, is pervading the HCPs’ attitude towards life with a mental illness. This change in attitude reflects the value of growth potential that implies a commitment to maintain hope in the inherent capacity of an individual to recover.

This study is one of the first addressing how the shift from the medical model to the recovery model is experienced by HCPs when facilitating a recovery-oriented rehabilitation program. Using the inductive-deductive approach together with Situational Analysis’ mapping have provided an opportunity to analyze the variations in professionals’ reflections of practicing IMR. The method of Situational Analysis was chosen to be an appropriate method to get new perspectives on the three themes which seemed useful in accordance to the aim of the study. The findings provide illustrations of what changes the professional experience and the findings might be useful for implementations of recovery-oriented mental health service, in other settings as well. Selective sampling was used which could be a limitation in creating possible variation in the data material and thereby influence the external validity. Nevertheless, a varied range of different positions in the positional maps (see Paper IV) indicated that the data material was saturated. However, it is not certain that the data material was saturated since it was not investigated whether all possible positions were found. More studies about how changes in attitude also reflect as changes in practice are needed. Future observational studies could contribute with insights in the process of transforming changed attitudes into practice.

CONCLUSION
This study illustrated a spectrum of changed attitudes and values that are indentified in mental health care professionals’ reflections on their practice. Three themes evolved from qualitative in-depth interviews with American and Danish health care professionals: 1) becoming more hopeful in their attitude towards their clients’ living with mental illness; 2) striving to become more person-centered instead of assuming the expert role; 3) focusing more on the clients’ own goals for recovery than on disease induced goals in their dialogues with clients. These aspects of mental health professionals’ reflections on providing a recovery-oriented rehabilitation program should be further studied to show how practice in mental health care settings might be changed over time in providing recovery-oriented service.
Authors’ Contributions
#1 conducted the interviews and analysis and drafted the manuscript. #2 and #3 provided critical edits to the analysis, the discussion and the manuscript. #4 helped with data collection in the USA and provided constructive feedback on the manuscript. All authors have read and approved the final paper.

Disclosures and acknowledgments
Thanks to all interviewees in the USA and in Denmark for sharing your experiences and insights. The authors declare no conflicts of interest. This study was founded by the Danish Health Fund, Mental Health Centre Ballerup, Mental Health Centre Frederiksberg and the Mental Health Services of Capital Region of Denmark.

REFERENCES
Gudjonsson, G.H., Webster, G., & Green, T. (2010). The recovery approach to care in psychiatric services: staff attitudes before and after training. The Psychiatrist, 34(8), 326-329.


Table 1 Characteristics of the mental health care professionals

<table>
<thead>
<tr>
<th>Country</th>
<th>Gender</th>
<th>Site</th>
<th>Education</th>
<th>Years of experience</th>
<th>Title</th>
<th>IMR experience</th>
<th>Years with IMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Man A</td>
<td>Licensed social worker</td>
<td>15</td>
<td>Manager</td>
<td>Facilitates an IMR-group, IMR supervision</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman B</td>
<td>Licensed social worker</td>
<td>12</td>
<td>Manager</td>
<td>IMR-supervision, IMR-training</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman B</td>
<td>Case manager with degree in sociology</td>
<td>6</td>
<td>Case manager</td>
<td>Currently ran an IMR-group</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman B</td>
<td>Trained case manager</td>
<td>8</td>
<td>Case manager</td>
<td>Staff trainer, IMR-supervisor</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman B</td>
<td>Trained case manager</td>
<td>17</td>
<td>Case manager</td>
<td>Facilitates IMR one-by-one</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman C</td>
<td>BA in psychology and MA in education in counseling</td>
<td>8</td>
<td>Manager</td>
<td>IMR supervision</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Woman C</td>
<td>Trained case manager</td>
<td>6</td>
<td>Case manager</td>
<td>Facilitates IMR one-by-one</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>Man C</td>
<td>Bachelor in social work</td>
<td>5</td>
<td>Case manager</td>
<td>Facilitates IMR one-by-one</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman D</td>
<td>Psychiatrist</td>
<td>17</td>
<td>Manager</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman D</td>
<td>Nurse specially trained in mental health</td>
<td>9</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman D</td>
<td>Nurse</td>
<td>23</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman E</td>
<td>Nurse</td>
<td>17</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman E</td>
<td>Nurse specially trained in mental health and a cognitive education</td>
<td>22</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman E</td>
<td>Nurse specially trained in mental health</td>
<td>13</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman E</td>
<td>Nurse specially trained in mental health</td>
<td>10</td>
<td>Nurse with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Denmark (DK)</td>
<td>Woman E</td>
<td>Occupational therapist</td>
<td>2</td>
<td>Occupational therapist with case manager responsibility</td>
<td>Facilitates an IMR-group</td>
<td>&lt;1</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1 Coding process an inductive and deductive approach

<table>
<thead>
<tr>
<th>Unit of meaning</th>
<th>Condensed meaning unit</th>
<th>Subcategories</th>
<th>Category</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;I think one of the things about therapists, is that we are &quot;fix-it people&quot;. If there is a problem, we will start thinking of solutions and trying to change things.&quot;</td>
<td>Practitioners are traditional &quot;fix-it people&quot; that want to fix the patients problems</td>
<td>Experience that practitioners are traditional trained to be &quot;fix-it people&quot;</td>
<td>Traditional role for the practitioner</td>
<td>A Person-centered Role</td>
</tr>
</tbody>
</table>

Stage 1: From empirical data (American interviews) to theoretical themes

Stage 2: From theoretical themes to empirical data (Danish interviews)

"Before, I was very insisting and kept the patients longer, and I brought up 10,000 ideas and threw them at the patient. I so much wanted them to get better. Now I am more relaxed, keeping in mind that it is the patient who has problems, which we look at together, and I can guide the patient from my theoretical knowledge. Then the patient can see whether it works for him/her and we continue the work together."

A shift from wanting to fix the patients’ problems to taking starting point in what the patient wants

Experiencing that she has changed her own approach to the patients and now let them set the agenda

Changing professional role towards letting the patient set the agenda

A Person-centered Role
"Giving hope to patients is most important"

"Both giving hope and correcting false fixed reality assumptions of the course of the illness are important."

"What is most important depends on the patient and the situation"

"Missing position in data"

"Giving accurate facts about the course of the illness is most important"
Appendix B

Co-authorships