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## Early Recognition Method – Amplifying relapse management in community mental health care; a comprehensive study of the effects on relapse and readmission

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### ABSTRACT

This naturalistic multicenter study explored the relationship between participating in the Early Recognition Method (ERM) intervention and relapse, defined as spending at least one night at a psychiatric ward. The intervention was tailored to adult patients with schizophrenia or bipolar disorder in an outpatient mental health care setting.

Before the intervention, the staff received training in application of the strategy. The ERM strategy is protocolized and includes identification and monitoring of individual early warning signs and development of a personal plan of action. The study showed a reduction in mean number and duration of readmissions during the period the patients participated in the intervention, compared to an equal pre-intervention period. For patients with bipolar disorder the reduction was statistical significant. The difference in outcome between the two diagnostic groups suggests that further tailoring of the application of the ERM strategy might improve the relapse prevention outcome.

### Introduction

Relapse prevention is essential in treatment programs for people with severe mental illness (SMI) (Johansen, Hounsgaard, Frandsen, Fluttert, & Hansen, 2021; Emsley et al., 2013). One reason is that SMI, such as schizophrenia or bipolar disorder with the associated cyclical pattern of relapse and remission, is associated with great costs for the affected person and his or her relatives (Morris et al., 2013; Oud et al., 2016). Society also experiences great costs due to the frequent increase in treatment needs, either in the community setting or in hospital setting (Miziou et al., 2015; Okpokoro et al., 2014). Evidence shows that a history of hospitalization predicts future hospitalizations, in both schizophrenia and bipolar disorder (Daniels et al., 1998). According to a 2018 report from the Danish National Board of Health, 23.000 patients

were hospitalized in psychiatric wards in 2017. The average number of hospitalizations was 1.9, and the average duration was 19.2 days. Of the discharged patients, 11% were readmitted after 1–7 days, and 23.8% were re-admitted between 8 and 30 days. One percent of the patients experienced many admissions and re-admissions. This small group counts for 22% of the cumulative treatment costs at psychiatric hospitals in Denmark. These patients are diagnosed with schizophrenia or bipolar disorder, among other diseases (sundhedsstyrelsen, 2019). They have sparse illness insight, difficulty with treatment adherence, and they experience poor medication effect and substance misuse (sundhedsstyrelsen, 2019).

The literature review by Emsley et al. (2013) reveals a significant correlation between the degree of deterioration and the number of relapses experienced among patients with schizophrenia (Emsley et al.,

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2013). Interestingly, they state that this deterioration might reflect other associated conditions, such as poor treatment adherence and poor social or financial conditions (Emsley et al., 2013). This review shows that the majority of patients that experience deterioration, do not experience neurodegeneration as the cause of the cognitive deterioration (Emsley et al., 2013). In their meta-review Calcedo-Barba et al. (2020) found that the decision making capacity among stable psychiatric outpatients and non-psychiatric individuals can be similar, and evidence indicates that decision making capacity among SMI patients is preserved in the majority of cases (Calcedo-Barba et al., 2020).

The United Nations (UN) convention on rights of persons with disabilities (2012), requires a reconsideration of decision making in mental health care, focusing on patient involvement in the decision making process of treatment planning (Morrissey, 2012). Recent evidence reveals that strategies including training and education, simplification of language and enhancement of information, improve the decisional capacity of patients with SMI. Thus challenging the traditional attitude that severe mentally ill are unable to make decisions (Calcedo-Barba et al., 2020). The capacity to make health related decisions is closely related to personal autonomy and self-governance (Calcedo-Barba et al., 2020). Studies have shown, that patients with schizophrenia or bipolar disorder are able to describe their own early signs of relapse, to state their preferred relapse preventing intervention, and to make treatment plans for crisis situations, in advance (Calcedo-Barba et al., 2020; Fluttert et al., 2010). Calcedo-Barba et al. (2020) states that in situations like this, shared decision making improves self-efficacy and autonomy, and improves treatment outcome (Calcedo-Barba et al., 2020). The mutual respect and collaboration between the health care practitioner and patient during the process of treatment planning, is characteristic of shared decision making, and is considered best practice in mental health care (James & Quirk, 2017); in addition it facilitates treatment adherence, as a result of the joint decision about treatment strategy. A systematic review and meta-analysis revealed, that the most common predictors of relapse (described as recurrence of psychotic symptoms and rehospitalization) in patients experiencing first episode of psychosis, were: Medication non-adherence, substance use disorder, caregiver' critical comments and poor adaptation to the disease (Alvarez-Jimenez et al., 2012). Critical comments and hostility were reported to be significant risk factors for psychotic relapse (Alvarez-Jimenez et al., 2012), also when the hostility and psychosocial stress is experienced in family settings (Hornung et al., 1999; Tomaras et al., 2000). On the contrary, the experience of social support is a protective factor preventing relapse (Alvarez-Jimenez et al., 2012). Including the family in relapse prevention interventions has significantly proven to reduce relapse in both bipolar disorder and schizophrenia (Johansen, Hounsgaard, Frandsen, Fluttert, & Hansen, 2021; Gaebel & Riesbeck, 2014; Herz et al., 2000; Hornung et al., 1999; Miklowitz et al., 2000; Miklowitz et al., 2003; Tomaras et al., 2000).

Relapse as a concept, covers the state of deterioration, with an outcome of increased symptoms (Gaebel & Riesbeck, 2014). However, the individual course of disease and the ambulant setting, complicates measurable criteria for a relapse definition (Gaebel & Riesbeck, 2014). Almond et al. (2004) present alternative definitions of relapse, such as number of hospital admissions, attendance at acute care centers or an increase in needed staff support (Almond et al., 2004). The character of transition from remission to relapse is an individual process, making it difficult to assess precursors for relapse on a large scale (Emsley et al., 2013). It requires frequent and individual monitoring, to detect early warning signs of relapse (Emsley et al., 2013). Early Recognition Method (ERM) is a highly individualized strategy for identification and monitoring of early warning signs of relapse, building on Birchwood' concept of "signature" signs (Birchwood et al., 2000; Fluttert et al., 2008). Birchwood refers to "signature" since the early signs of psychosis are personal to the individual patient, equivalent to a fingerprint. The ERM strategy is applied in collaboration between the contact nurse and the patient, and invites patient-participation in decision making, concerning

the management of early warning signs (Frans Fluttert et al., 2008). Previous studies conducted using ERM in the monitoring and prevention of relapse among patients with SMI in a forensic setting, have shown significant reduction of both number and severity of incidents (Fluttert et al., 2010). A recent study on the application of ERM in community mental health care, suggests the method to be valuable in the understanding and management of patients' deteriorating behaviors and beliefs (FAJ Fluttert et al., 2020).

#### *Rationale for this study*

ERM was initially designed to provide a systematic risk management strategy in forensic mental health care. The first ERM study suggested that the strategy is also appropriate to use in community settings (FAJ Fluttert et al., 2020).

Therefore, as a mean to improve relapse prevention in community mental health care (CMHC) and to include the patients in shared decision-making, the ERM treatment strategy has been applied in a non-forensic community mental health care setting. The aim of this study is to investigate if there is a relationship between participating in the Early Recognition Method (ERM) intervention applied in CMHC and relapse, which is defined as spending at least one night at the psychiatric hospital. The Danish Data Protection Agency (2008-58-0035) and the Regional Scientific Ethics Committee, Southern Denmark (S-20160117) approved the study prior to the start of the study.

#### **Method**

##### *Design*

This study is described by a naturalistic longitudinal design, involving Community Mental Health Care (CMHC) centers. It compares the number of re-admissions during the ERM-intervention period with the respective numbers during a period of treatment as usual (TAU) immediately before the intervention. The approach was intention to treat. A multiple baseline design in terms of intervention start was applied, both at the level of the various care centers involved and at the patient inclusion level.

##### *Setting and participants*

Six CMHC centers in the Region of Southern Denmark were involved in the study, and constituted the settings for the intervention and application of the ERM strategy. The last author carried out ERM training of the nurses. The teams in the study were assertive community treatment teams and teams for affective disorders, and included trained nurses. The patient met the following inclusion criteria: Aged between 18 and 64 years and diagnosed with schizophrenia or bipolar disorder, according to ICD-10 diagnostic codes F20 or F31. The patients were affiliated with the CMHC center, living in their own home or in supported housing. In case of an incident requiring enforced treatment, the patient in accordance with Danish legislation, had to exit the study, but could re-enter after repeal of enforcement. The intervention took place at the usual location for patient nurse interaction, which was either at the patient's home or at the CMHC center. During the intervention, the first author provided continuous support to the nurses involved, according to their needs.

##### *Procedure*

The intervention was the application of the ERM strategy in CMHC. When the management team at each center had consented to center-participation in the study, the involved nurses received one full day of ERM-training. Through the training, the nurses were enlightened in the conceptual background of ERM and the link between the early warning signs and the risk management strategy of ERM, application of the ERM

protocol and ERM plan for patients accordingly. The nurses approached the patients to participate in the intervention study, in connection with an appointment at the CMHC center. The ERM intervention was added on the usual treatment. In case a patient experienced enforced admission, he or she would be excluded from the study, according to Danish legislation. After discharge the patient could reenter the study, according to his or her wish.

The first author developed a patient information pamphlet that informed about the ERM strategy, the project, and patient rights in research. Developing the pamphlet was a thorough process where account was taken to adjust the text and design of the pamphlet, and articulate the message. The nurses had agreed to go through the content of the pamphlet with each patient, to ensure they understood the content and purpose of the study, and what they gave consent to. Especially, that declining or withdrawing the consent (quit) would have no consequence, neither for their regular treatment, nor for the therapeutic relationship between patient and nurse.

The ERM plan was used for the description of the individual early warning signs of relapse for each participant, and for monitoring the presence of the described signs. Identification of the individual early warning signs and the monitoring process, was done in collaboration between the nurse and the patient, including a member of the patients social network (family or friend) according to patient's desire. The purpose is that by hearing about the patients warning signs and plan of action, the person would be able to support the patient if needed. The nurses record information which are part of the intervention, such as the patient's personal involvement in ERM, the identified early warning signs and the content of the action plan. The researcher collects the data for research.

The intervention was single patient sessions, at the usual location for patient-nurse interaction, and without a predefined session-duration. Sessions were adjusted to the individual needs and capacity for each patient.

#### *The Early Recognition Method*

The ERM is a risk management strategy with emphasis on the interaction between nurse and patient, aiming at prevention of patients' risk (Frans Fluttert et al., 2008). In this study, 'risk' refers to relapse requiring re-admission, to regain stability. In applying ERM, nurses teach patients how to explore and describe their personalized early warning signs of relapse in their ERM-plan. The FESAI (Forensic Early Signs of Aggression Inventory) is a 44-item list within ERM, covering the most frequently occurring early warning signs, related to relapse in forensic care (Fluttert et al., 2013). This list assists the nurses to identify and describe early warning signs in the ERM-plan. The patient and nurse evaluate the patient's behavior systematically, to recognize the presence of warning signs at an early stage. When early warning signs occur, nurses encourage the patient and a member of his/her social network, to carry out preventive actions, to stabilize their behavior. In ERM training, nurses are encouraged to maintain a balanced and nonjudgmental attitude toward patients, and encourage the patient and a member of the patient's social network to be involved in the decisions made, in identifying early warning signs, determine stabilizing actions and in monitoring patient's behaviors.

#### *Data collection*

The nurses recorded all the information that was part of the intervention. The researcher collected these as data for the study. The collected data contain information from the patient records on number of contacts to the psychiatric emergency ward, number and duration of admissions as well as demographic data. This information was collected during a 12-month period prior to the intervention baseline (TAU-period), and during the intervention (ERM-period). Moreover, data was collected from the ERM-plan such as patient engagement, description

and monitoring of individual early warning signs and content of action plan. Two ERM monitoring-plans were used for each included patient. One for the patient and one for the nurse. Completion of the ERM plan took place in collaboration between the patient and the nurse. For each patient, up to five individual early warning signs (EWS) of relapse were identified and described at three levels of severity, in the ERM monitoring-plan. A plan of action was described for each identified EWS, developed in collaboration with the patient and the contact nurse. The monitoring plan was filled-in according to the presence and severity of any of the identified EWS. The data collection period varied among patients, according to their individual endurance in cooperation.

#### *Participants and recruitment*

The enrollment of CMHC centers into the program took place from January to December 2017. Patients were enrolled in the study from January 2017 until June 2019. The nurses at the CMHC centers screened their patients for eligibility, according to the inclusion criteria. All patients eligible to the inclusion criteria were included, based on intention to treat. Exclusion from the study would be based on an estimate of the nurses, that the patient was not suited to participate in the study, due to e.g. cognitive impairment or psychosis.

The nurses presented the program information to the patients who consented, both orally, as learned during the training session, and written, as provided in flyers. Data collection was completed by August 2019. No control group was enrolled, as each patient was compared to his/her own historic period as control. The historic period was described as a 12 months period immediately prior to enrollment. Sixty-seven patients were approached for participation. Eleven declined for various reasons, see Fig. 1.

The optimal frequency of interaction was once a week, but due to case overload among the nurses, and variation in patients need for interaction, there was a large variation in session frequency.

#### *Data analysis*

To address different durations of follow-up periods, the observed numbers of re-admissions and admission days were converted to mean numbers per year. The mean number of re-admissions per year and the mean number of admission days per year during the ERM treatment period, were compared to the historic period using linear regression. The comparisons made were stratified on diagnosis (bipolar disorder and schizophrenia), as well as for the combined patient population. Further, tests for effect modification of sex on the associations, were conducted for patients with bipolar disorder and schizophrenia combined. Cluster robust standard errors were used in all linear regression analyses to account for the repeated measurements of the same patient, and for minor deviations from the normal distribution. The time to first re-admission during the first year of ERM treatment and during historic period were compared using Kaplan-Meier plots and Cox proportional hazards model, with cluster robust standard errors to account for the repeated measurements of the same patients. The survival analyses were made stratified on diagnosis (bipolar disorder and schizophrenia), as well as for the combined patient population.

#### *Ethical considerations*

All participants received written and oral information about the intervention and their rights by their nurse, consistent with the Danish scientific ethical committee guideline. All participants signed informed consent. The study was conducted in accordance with the Declaration of Helsinki (The World Medical Association, 2018). The completed ERM-plans were kept in a locked filing cabinet in a locked room. The extracted data were anonymized and no identifiers, except information on the community mental health care center was used. All personal identifiable data were removed.

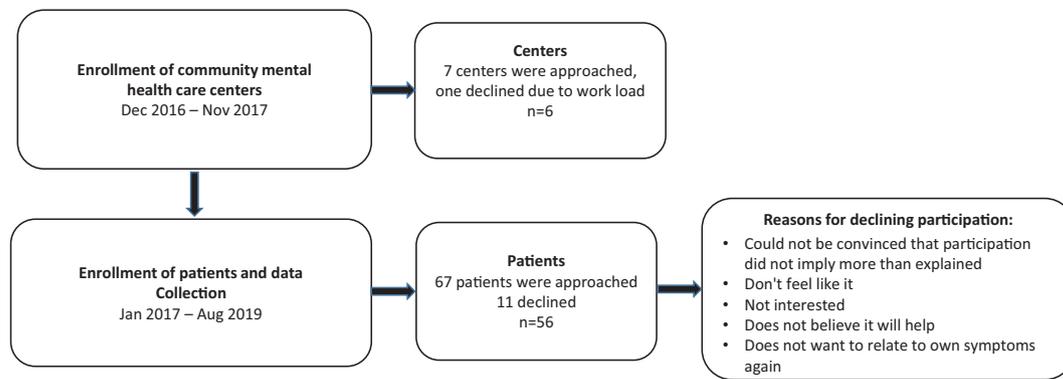


Fig. 1. Flowchart of intervention enrollment.

Results

Participants

The patient characteristics are displayed in Table 1. The duration of disease is displayed in intervals. In the 0–5 years interval, 7 patients had a duration of less than one year, and one patient had a duration of less than 180 days (139 days equal to 4.5 months). In the group of patients not living alone, the vast majority (23) were married or living with a partner, the remaining were living with parents or in supported housing facilities.

Re-admission

Applying the ERM strategy in treatment of this patient population, lead to a marginally significant reduction in number of re-admissions, and a statistically significant ( $p = 0.003$ ) reduction in number of re-admission days, when comparing the intervention period with the historic period (Table 2). The risk of experiencing the first re-admission is 58% less during the intervention period, compared to the historic period during the first year ( $p = 0.008$ ). See Table 2 and Fig. 2. Sex did not modify the effect of ERM, neither in terms of number of admission days

Table 1  
Patient characteristics.

	Patients
Sex, n (%)	
Male	22 (39.3)
Female	34 (60.7)
Age <sup>a</sup> , mean (SD)	39.7 (12.5)
Diagnosis, n (%)	
Schizophrenia	34 (60.7)
Bipolar disorder	22 (39.3)
Duration of disease <sup>a,b</sup> (in months), mean (SD)	97 (64)
Duration of disease <sup>a,b</sup> , n (%)	
0–5 years	21 (37.5)
6–10 years	14 (25.0)
>10 years	21 (37.5)
Cohabitation status <sup>c</sup> , n (%)	
Living with family or partner	27 (48.2)
Living alone	29 (51.8)
Nationality, n (%)	
Ethnic Danish	49 (87.5)
Other Ethnicity	7 (12.5)
Substance abuse <sup>c</sup> , n (%)	
None	40 (71.4)
At least one type	16 (28.6)

<sup>a</sup> Measured at the end of ERM follow-up period.  
<sup>b</sup> For two patients only the year of onset of disease was available. These patients were included with an approximate month of onset of disease of 6.5, i.e. the midpoint between months 1–12 (between June and July).  
<sup>c</sup> Measured at the time of inclusion in ERM treatment.

Table 2

Re-admissions and relapses for all patients<sup>a</sup> in ERM treatment compared to historic period.

	Mean number of events per year <sup>b</sup>	Difference in number of events per year <sup>b</sup>		HR of first event, censored at one year	
	Mean (SD)	Difference (95%-CI)	p-Value	HR (95%-CI)	p-Value
Number of re-admissions <sup>c</sup>					
Historic (TAU)	0.97 (1.36)	Ref.		Ref.	
Current	0.57 (1.40)	–0.40 (–0.81, 0.01)	0.057	0.42 (0.22, 0.79)	0.008
Number of admission days					
Historic (TAU)	17.38 (26.73)	Ref.		N/A	
Current	6.25 (19.63)	–11.13 (–18.32, –3.94)	0.003*	N/A	N/A

<sup>a</sup> Comprising both patients with bipolar disorder and patients with schizophrenia.  
<sup>b</sup> Numbers of events during follow-up are standardized to numbers of events per year.  
<sup>c</sup> Re-admission comprises admissions spending at least one night in a psychiatric hospital.  
 \*  $p < 0.05$ .

( $p = 0.547$ ) nor in number of re-admissions ( $p = 0.825$ ).  
 N/A: not applicable.  
 TAU: treatment as usual.

When looking at the patient population grouped according to diagnosis, Table 3 displays the intervention benefit, in terms of numbers and duration of re-admissions for the two groups. The results for patients with schizophrenia show a reduction in mean duration of hospitalizations, although not statistically significant. For patients with bipolar disorder, the results show a statistical significant reduction in both mean number of re-admissions ( $p = 0.032$ ) and mean duration of re-admission ( $p = 0.011$ ). See Table 3. The risk of first re-admission is significantly higher in the historic period than the intervention period during first year for patients with schizophrenia, but not for patients with bipolar disorder (Fig. 3 and Table 3).

Discussion

This study was carried out to determine the relationship between participating in the ERM intervention and relapse, measured as number

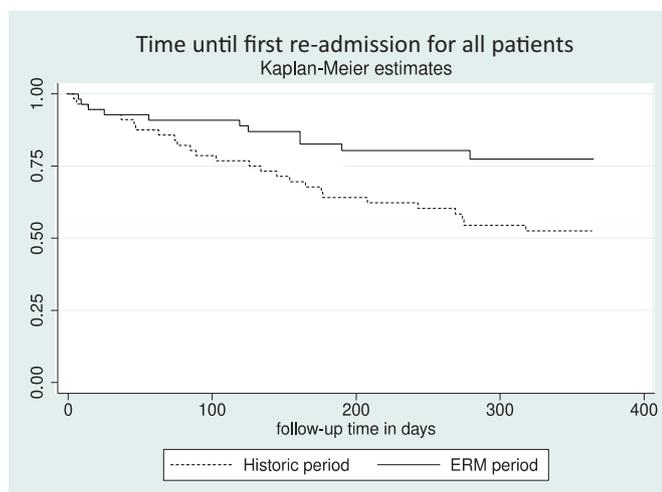


Fig. 2. Kaplan-Meier curves for time of first re-admission in all patients<sup>a</sup> during ERM treatment compared to historic period, censored at one year.

and duration of hospitalizations. The main finding of the study is the change in relapse discovered in the patients with bipolar disorder when comparing the ERM period with the historic period. The number of events per year was significantly reduced, in terms of both number and duration of admissions. For patients with schizophrenia, the reduction was not significant. For the combined group, the change in number of admissions was not significant whereas the duration of admissions (admission days) was significantly reduced. Our study support previous results showing that for both schizophrenia and bipolar disorder patient education and plan of action have a beneficial effect on number and duration of relapse, particularly for patients with bipolar disorder (Bauml et al., 2007; Candini et al., 2013; Schmidt-Kraepelin et al., 2009).

Considering this discrepancy between diagnostic groups, it should be mentioned that some patients use a brief voluntary admission as a coping strategy for re-stabilization, when they experience early stages of instability. However, we do not have data to substantiate this as a diagnosis dependent strategy. Instead, difference in cognition is relevant to consider as a contributory factor, to the difference in results between patients with schizophrenia and patients with bipolar disorder. Measurements of cognition were not part of this study. However a recent study examined cognition across the bipolar/schizophrenia diagnostic spectrum, among outpatients associated with community mental health

care (Lynham et al., 2018). The study revealed that a lifetime history of psychosis was associated with poor cognition, and a difference in level of cognitive impairment when comparing patients with schizophrenia and patients with bipolar disorder (Lynham et al., 2018). Thus, patients in this study probably had the same cognitive impairments. This difference in cognition is supported in a study, which showed that patients with schizophrenia who experience mood fluctuations exhibit more pronounced cognitive impairments during the fluctuations compared to stable periods. This is not the case for patients with bipolar disorder (Ceylan et al., 2020). The impaired cognitive performance is seen in both medicated and un-medicated patients, although in some areas to a slightly lesser degree in un-medicated individuals, suggesting that the cognitive impairments are aspects of schizophrenia, rather than the result of medication (Moran et al., 2020). The cognitive impairments associated with schizophrenia include a deficient explicit and intact implicit learning (Ceylan et al., 2020; Lynham et al., 2018). Based on the evidence it could be suggested that interventions advantageously be tailored to the specific diagnosis group, in particular interventions targeting patients with schizophrenia. Thus providing an intervention approach including measures to stabilize mood and considering the need of the deficient explicit and intact implicit learning capacity (Danion

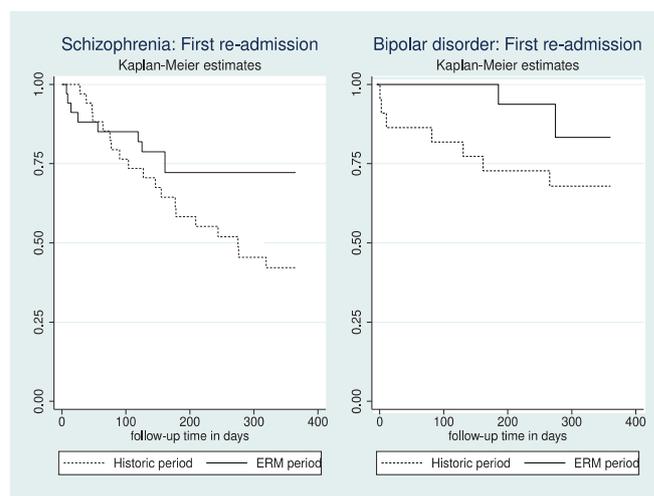


Fig. 3. Kaplan-Meier curves for time of first re-admission during ERM treatment compared to historic period, censored at one year. Stratified on patient diagnosis: Schizophrenia and bipolar disorder.

Table 3

Re-admissions and relapses for patients in ERM treatment compared to historic period, stratified on patient diagnosis: Bipolar disorder and schizophrenia.

	Schizophrenia, N = 34			Bipolar disorder, N = 22						
	Mean number of events per year <sup>a</sup>	Difference in number of events per year <sup>a</sup>		HR of first event, censored at one year		Mean number of events per year <sup>a</sup>	Difference in number of events per year <sup>a</sup>		HR of first event, censored at one year	
	Mean (SD)	Difference (95%-CI)	p-Value	HR (95%-CI)	p-Value	Mean (SD)	Difference (95%-CI)	p-Value	HR (95%-CI)	p-Value
Number of re-admissions <sup>b</sup>										
Historic	1.18 (1.51)	Ref.		Ref.		0.63 (1.04)	Ref.		Ref.	
Current	0.89 (1.71)	-0.29 (-0.90, 0.32)	0.337	0.46 (0.22, 0.97)	0.042	0.07 (0.34)	-0.56 (-1.07, -0.05)	0.032	0.31 (0.07, 1.34)	0.117
Number of admission days										
Historic	18.21 (27.15)	Ref.		N/A		16.07 (26.65)	Ref.		N/A	
Current	10.24 (24.51)	-7.98 (-17.35, 1.40)	0.093	N/A	N/A	0.07 (0.34)	-16.00 (-27.98, -4.03)	0.011*	N/A	N/A

N/A: not applicable.

<sup>a</sup> Numbers of events during follow-up are standardized to numbers of events per year.

<sup>b</sup> Re-admission comprises admissions spending at least one night in a psychiatric hospital.

\* p < 0.05.

et al., 2001). Tailoring the application and the content of an intervention, such as ERM, is likely to enhance the effect of the tool provided. Another aspect of the complexity of schizophrenia is that the majority of patients with schizophrenia are dependent on either alcohol or illicit drugs. The extent of substance abuse in the patients in our study match the evidence presented in the literature (Awad & Voruganti, 2005; Fergusson et al., 2005; Winklbaur et al., 2006). A comorbidity exist between schizophrenia and substance abuse, and for optimal treatment, both issues must be addressed. The substance abuse in the patients with schizophrenia in this study may be a contributing factor in the shown behavior.

When considering the Kaplan Meier estimate for schizophrenia in Fig. 3, it appears that the later stabilization of the curve, compared to the estimate for bipolar disorder, corresponds well with the characteristic needs of deficient explicit learning, such as the need for more repetitions (Danion et al., 2001). Moreover it could be speculated that it also reflects a cognitive capacity affected by repeated psychosis and substance abuse. A more tailored application may improve the outcome in relapse prevention for patients with schizophrenia.

Previously, a study on ERM has been conducted in a forensic in-patient setting, including adult males with the diagnoses schizophrenia, autism spectrum disorder and antisocial personality disorder. In this study the number and severity of incidents, in a period before and during exposure to ERM, were compared. The results showed a statistically significant reduction in seclusion and severity of incidents, for all patients involved. The largest effect was seen among patients with schizophrenia and patients with substance abuse (Fluttert et al., 2010). The duration of the intervention was comparable to this study. These results differ, from the results in the present study. A discrepancy possibly caused by the difference in context. In a recent literature review, it was revealed that patients with schizophrenia need support on more parameters, than patients with bipolar disorder, in order to achieve equal comparable results (Johansen, Hounsgaard, Frandsen, Fluttert, & Hansen, 2021). These parameters include, acquiring skills to manage illness and a regular lifestyle, as well as personal support.

In the forensic hospital setting mentioned above (Fluttert et al., 2010), patient-needs as regular lifestyle and illness management, may be facilitated by the assistance from the staff mentor at the institution, possibly counting for the significant reduction in relapse, whereas patients in the community setting do not receive the same amount of professional support. They experience the stress and challenges of living their everyday life, which from time to time may provoke relapse, not leaving mental capacity or energy to invest in an intervention, which they may regard as an add-on chore.

At this stage of studying the impact of ERM, we can only estimate the difference in results based on existing literature. Investigating the impact of various factors in the treatment of patients with schizophrenia, comparing community and in-patient setting, might reveal evidence on what is most important to address in treatment strategies such as ERM.

Another intervention, aiming at reducing the use of coercive measures, among in-patients with SMI is Patient Focused Intervention model (PFI) (Goetz & Taylor-Trujillo, 2012). PFI showed a significant reduction in seclusion and restraints (Goetz & Taylor-Trujillo, 2012). The intervention core was trauma informed care, and the focus was, apart from elements targeting the staff and management, establishing patient centered care, including patient staff collaboration, identification of triggers and early warning signs and developing a crisis plan (Goetz & Taylor-Trujillo, 2012). PFI appears to be comparable to ERM as described for the in-patient forensic setting, both in terms of the personalized approach and the results, supporting the relevance of investigating the approach in an outpatient setting. Dahm et al. (2015) reviewed the literature and found that interventions for reducing coercion in mental health care are complex and context dependent (Dahm et al., 2015). They describe that regular evaluation of aggressive behavior appears to be an effective tool, in addition to staff education in

communication and de-escalation skills (Dahm et al., 2015). This may cause a change in attitude among hospitalized patient, which in turn, may cause a reduction in use of coercive measures. Combining this, with complex interventions tailored according to diagnosis and individual needs and capacity (Johansen, Hounsgaard, Frandsen, Fluttert, & Hansen, 2021) appears likely to provide the best treatment outcome. These findings suggest that addressing other parameters related to deterioration, in addition to early warning signs, may improve intervention outcomes.

#### Strengths and limitations

A strength of this naturalistic study is that the ERM strategy was integrated into the routine interaction between patients and contact nurses, and used in real life treatment settings. Therefore, there is reason to suggest that applying ERM in a similar, but non-research setting, would provide comparable results. This study also has limitations. One limitation is the variation between community mental health care (CMHC) centers, in terms of how frequent nurses and patient meet. This is reflected in the differences in intensity of patient support during the monitoring of patient's own early warning signs. Nevertheless, the ERM training and the ERM protocol contributed to shape the ERM strategy to a coherent intervention across centers which allow for comparable outcome.

This study does not include data on medication changes or adjustments during the ERM intervention period. This is a limitation of the study, which may have influenced the results. However, we would not expect medication changes, as this is not part of the nursing care process. Minor adjustments in medication are normal, but their impact on the results is expected to be marginal.

The lack of standardized record keeping, in terms of registering pre-psychotic incidents in the patient record, constitutes a limitation. The availability of such records from the historic period versus the intervention period, would have provided a more detailed and complete picture of a change in mood stability in the involved patients. Future research in this area should include a standardized patient recording system, for a more detailed and complete result on mood stability. Another limitation is the event of nurses leaving the CMHC center during the intervention, rendering it impossible to retrieve the ERM-plan, resulting in some data missing. In addition, the low number of included patients constitutes a limitation, however the research design and method were adapted to the sample size and variables accordingly. A circumstance, rather than a limitation, when doing research including patients with severe mental illness, is their vulnerability to the challenges of everyday living. Some patients were periodically unable to spend the time with their nurse on the intervention, as fundamental needs of life occupied their available time.

#### Conclusion and implication for clinical practice

This study showed a reduction in number and duration of hospitalizations during the period the patients participated in the ERM intervention, in particular among patients with bipolar disorder. The design of stepwise implementation and patient inclusion ensure, in our opinion, that seasonal dependent improvement is not a causal factor of the results. However, we cannot rule out improvements due to other treatment factors.

The systematic approach of ERM applied in an ambulant setting, is likely to have improved the patient and staff awareness of the early signs of patient deterioration, as expressed in the outcome. The flexibility of the ERM strategy made it easy to customize to the individual patient, in terms of need for key person support, the number of early warning signs focused on, and duration of the individual sessions. The intervention is uncomplicated to implement in the community mental healthcare setting, and can be applied in the regular interaction between patient and nurse.

The difference in outcome between the two diagnostic groups, require further tailoring of the application of the strategy. Adjustment, based on diagnosis and the individual needs and capacity at either end of the bipolar- schizophrenia diagnostic spectrum, might improve the outcome in future implementation of the ERM strategy in ambulant mental health care.

### CRedit authorship contribution statement

All authors have contributed to the study design, critically reading and approving the submitted version. Acquisition of data, data analysis and drafting the article was accomplished by the first and the last author.

### Statement of ethical approval

The Danish Data Protection Agency (2008-58-0035) and the Regional Scientific Ethics Committee, Southern Denmark (S-20160117) approved the study. The study was conducted in accordance with the Declaration of Helsinki(1).

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### Declaration of competing interest

The authors declared no conflicts of interest or ethical issues with respect to the research, authorship and publication of this article.

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