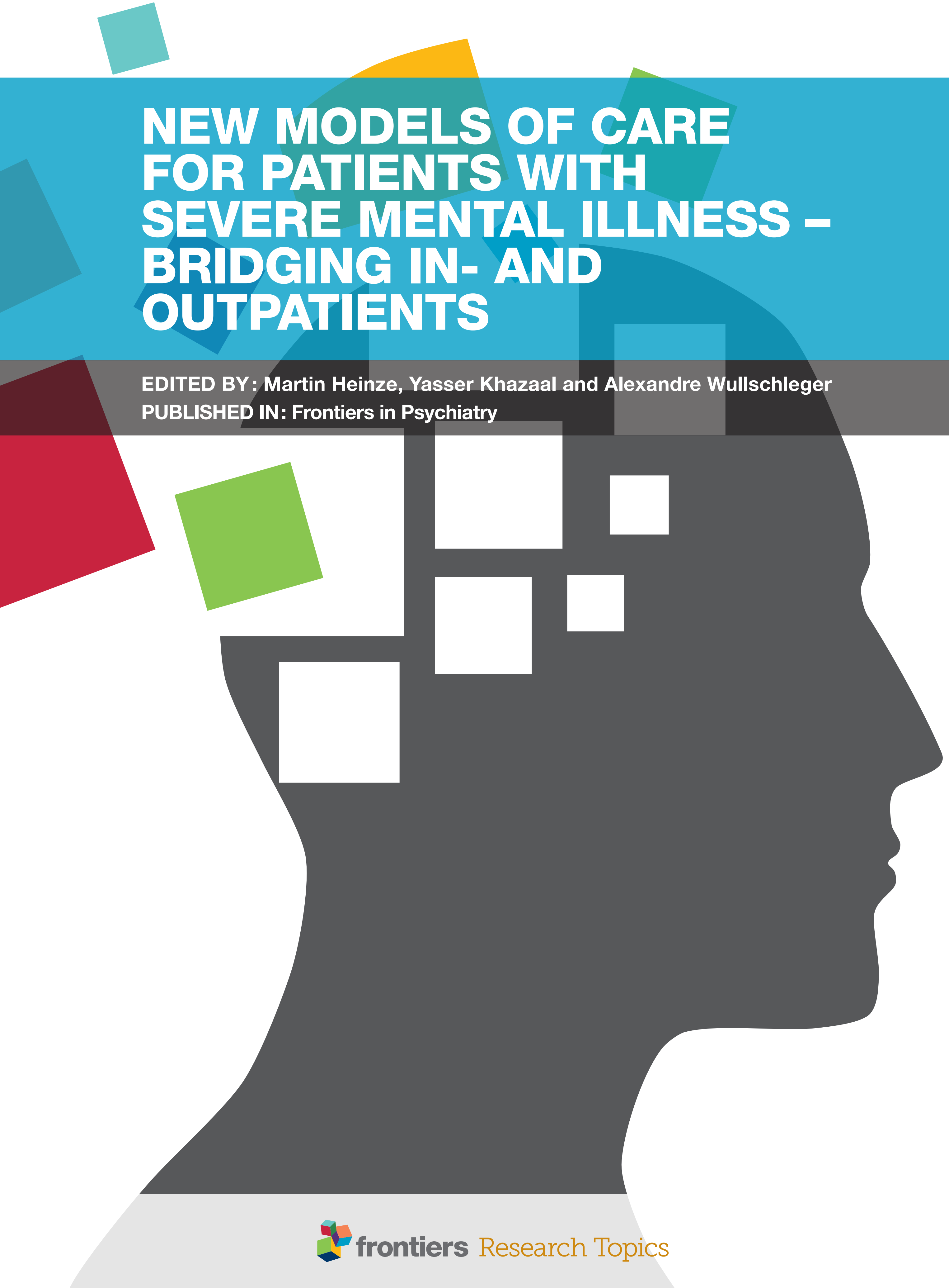

NEW MODELS OF CARE FOR PATIENTS WITH SEVERE MENTAL ILLNESS – BRIDGING IN- AND OUTPATIENTS

EDITED BY: Martin Heinze, Yasser Khazaal and Alexandre Wullschleger
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NEW MODELS OF CARE FOR PATIENTS WITH SEVERE MENTAL ILLNESS – BRIDGING IN- AND OUTPATIENTS

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Over the past years, psychiatric services have been continuously faced with the challenge of providing comprehensive care to people suffering from severe mental illnesses. Legal and conceptual advances like the UN convention on the rights of persons with disabilities or the concept of recovery have rendered this challenge more actual and urgent than ever. However, psychiatric institutions often show only low levels of cooperation and integration between their different services. Hence, they need to develop new ways of bridging all sectors of care in order to help people most in need on their way to recovery and full inclusion in society.

In this research topic, European researchers and clinicians present new ways of dealing with this essential issue by developing strategies and interventions on both institutional and non-institutional levels. The nine contributions of this ebook thus reflect actual clinical and conceptual considerations. They all aim at improving quality of care and providing adequate support to people suffering from severe mental illness.

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EDITORIAL
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Editorial: New Models of Care for Patients with Severe Mental Illness—Bridging In- and Outpatients

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Keywords: models of care, case management, severe mental illness, outpatient treatment, integrated care

Editorial on the Research Topic

New Models of Care for Patients with Severe Mental Illness—Bridging in- and Outpatients

In accordance with the concept of recovery (1, 2) and since the UN convention on the rights of persons with disabilities (3), psychiatric services are compelled to provide comprehensive and flexible care to persons suffering from severe and chronic psychiatric disorders, in order to help them overcome the barriers they meet, and support their full and effective participation and inclusion in society. This requires a high level of cooperation between different sectors and care providers working in this field, most notably between the in- and outpatient sectors. Unfortunately, most countries and institutions are characterized by a pervasive fragmentation of services and a lack of integration of different treatment and support options. Because of these insufficiencies, many severely ill patients cannot benefit from the comprehensive care they need. These patients often show high rates of treatment drop-outs and comorbid disorders. They are, notably, more frequently unemployed and often receive long-term disability. Although these unfavorable and complicated courses of disease have been mostly accepted as normal in the past, there nowadays is no doubt that persons suffering from severe mental illnesses (SMIs) can also fully recover and that the quality and organization of the mental health services plays a central role in this process (4).

Psychiatric services must, therefore, ensure that the most severely ill patients have access to high-quality care. As a response, many new models aiming at bridging existing services and offering need-adapted, flexible psychiatric care have been developed over the last years across Europe. On the institutional level, they encompass strategies to evaluate the needs of service users, transitional models to provide intensive support after hospital stays as well as outreach and assertive outpatient models. All these models need to adapt to the local particularities of the care system and tailor their interventions to reach all patients including those suffering from severe conditions. As for the non-institutional level, they aim at developing new practices that encourage and support individual recovery through all sectors of care, and that prevent to a maximum the use of interventions such as informal coercion hindering patients in their self-determination.

Hence, the aim of this Research Topic is to reflect on new models of care and compare how the institutionally difficult question of combing in- and outpatient-service is solved in the psychiatric care systems in different European countries. All the contributions to this topic underline different aspects of this problem and should stimulate further research and debate.

In their systematic review, Morin et al. show that many rehabilitative interventions such as cognitive remediation, psycho-education, or social skills training have a positive effect on promoting recovery for people suffering from schizophrenia and thus argue for a greater integration of these interventions in all sectors of psychiatric services to reach all concerned patients. In a similar way, Hotzy et al., in their systematic review, advocate about informal coercion for a stronger

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cooperation between services, to ensure that more attention is warranted for this subject and to allow clinical and ethical guidelines to be used when applying informal coercion in all sectors of care. Only in this way can the assumed negative effects of informal coercion such as increased stigma, impairment of the therapeutic relationship, and avoidance of mental health care be prevented.

The assessment of patients' needs is also a central issue in the development and implementation of new models of care. In their review article, Zaninotto et al. underline the need to thoroughly assess psychiatric conditions in patients who suffered from traumatic brain injury in order to provide adapted treatment contributing to their full recovery and coordinate rehabilitative interventions. In a contribution dedicated to the evaluation of integrative models of care in Germany, Ignatyev et al. present a new scale aiming at including the views and opinions of patients in the evaluation of new models of integrative care. This evaluation should contribute to taking this essential perspective into account while implementing and developing such projects.

Case management also receives particular attention in this topic as a way of bridging in- and outpatient care. Penzenstadler et al. in a systematic review report on the possible effects of case management for people suffering from substance use disorders. They show that case management can positively influence global functioning and adherence to treatment, thus underlining the importance of such models linking different care sectors. Beside this review, two original research articles studied the effects of transitional case management (TCM) after inpatient stay. Bonsack et al., in their contribution, describe a positive effect of TCM on short-term engagement in outpatient care, but no effect of such an intervention in readmission rates. Similarly, Hengartner et al. showed, in their study, that a short-term TCM led to no effect on readmission rates, psychopathology, and quality of life. Both articles argue that TCM is probably most effective for people suffering from SMIs and advocate for specific interventions designed to reach this particular patients group.

Finally, the issue of integrative care models as implemented in Germany over the last years is addressed in two articles. Wullschleger et al. report on the effects of the implementation of such a model linking in- and outpatient sectors. Although the model reached the most severely ill patients, it failed to lead to the expected decrease in the average length of hospital stays, thus underlining the difficulties inherent to the implementation of new models of care. As for the second article, Mayer-Amberg et al. show that a new model of care, the Integrative Care Initiative Schizophrenia, led to a significant reduction of the duration of hospital stays and to high patient satisfaction, thus proving that such models can be successfully implemented.

All these contributions show how vast and complex the issue of enhancing the cooperation between different sectors of care is, in order to provide comprehensive help to the most severely ill patients. They call for further research and discussion about the best ways of overcoming the obstacles and barriers that unfortunately too often characterize psychiatric services.

AUTHOR CONTRIBUTIONS

AW wrote the main part of the editorial. YK and MH reviewed the manuscript and added significant modifications.

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REVIEW
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Rehabilitation Interventions to Promote Recovery from Schizophrenia: A Systematic Review

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Only one out of seven patients recovers after a first episode of psychosis despite psychiatric care. Rehabilitation interventions have been developed to improve functional outcomes and to promote recovery. We conducted a systematic review of the effectiveness of the main psychiatric rehabilitation interventions following a search of the electronic databases Pubmed, ScienceDirect, and Google Scholar using combinations of terms relating to cognitive remediation, psychoeducation, cognitive-behavioral therapies, and schizophrenia. Eighty articles relevant to the topic of interest were found. According to results, cognitive remediation has been found to be effective in reducing the impact of cognitive impairment, social skills in the learning a variety of skills and to a lesser extent in reducing negative symptoms, psychoeducation in improving compliance and reducing relapses, and cognitive therapy in reducing the intensity of or distress related to positive symptoms. All psychosocial rehabilitation interventions should be considered as evidence-based practices for schizophrenia and need to become a major part of the standard treatment of the disease.

Keywords: schizophrenia, recovery, cognitive remediation, cognitive-behavioral therapy, psychoeducation, functional outcomes

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INTRODUCTION

Recovery from mental illness can be defined in two different ways. On the one hand, psychiatric consumers define recovery as the attainment of a meaningful and valued life, rather than the absence of symptoms (1) while on the other, psychiatrists have developed a "medical" model of recovery placing the emphasis on elimination of symptoms and return to normal functioning (2). The latter view is nearer to the concept of remission and is based more on objective criteria.

In the literature, the lack of consensus on the definition of recovery gives rise to heterogeneous data with the proportion of people with schizophrenia achieving recovery varying from 13.5 to 50% (3). Since recovery is a multidimensional concept, some authors suggested that relevant indicators should consider at least two areas: clinical remission and social functioning. The results of one recent meta-analysis using these criteria (3) were less optimistic than those of previous works: the proportion of individuals with schizophrenia who met the criteria for recovery and appeared stable over time was only 13.5%. This suggests that functional outcomes are undoubtedly impaired in schizophrenia and should be a priority target for therapeutic interventions (3).

A large body of literature has studied the factors that may affect these functional outcomes. Neurocognition is one of the first factors described. Early studies showed that neurocognitive variables were significantly related to functional outcomes, accounting for approximately 25–50% of the variance in real-world functional outcomes (4, 5). Other variables such as intrinsic motivation and metacognition are also mentioned in few studies and may serve as mediators between neurocognition and functional outcomes (6, 7). To better explain causal pathways, researchers have built sophisticated models with parameters such as functional capacity, social cognition, and symptoms to take into account the complexity of the functioning.

Functional capacity is defined as the ability to perform tasks relevant to everyday life in a structured environment guided by an examiner. This includes the aptitude to perform in the field of residential functioning, work, and social skills (8). Several works have shown that functional capacity is at least as strongly correlated with real-world functional outcomes as cognitive performance (8, 9). Recent studies have revealed that the impact of cognitive impairment could be mediated by functional capacity (4, 10).

Social cognition is a multidimensional construct that comprises emotional processing, social perception and knowledge, theory of mind and attributional biases. According to most studies, social cognition probably also mediates the effect of neurocognitive impairment on real-life functioning (10, 11). A meta-analysis showed that social cognition may have a stronger impact on variance in community outcome (16%) than neurocognition (6%) (11).

Symptoms have been associated with functional outcomes from the beginning with negative symptoms appearing to interfere more than positive ones (12). Both direct and indirect relationships between negative symptoms and real-life functioning have been reported (13). They seem to mediate the impact of variables such as neurocognition or functional capacity on real-world functioning (9). It appears that symptoms such as amotivation and avolition have the greatest impact (13).

Most recent works confirm these findings and also refer to additional variables more connected with the patients' environments. A study that involved a large sample of patients with schizophrenia ($n = 921$) summarized variables affecting real-life functioning and pooled them into three categories: variables related to the disease (cognition, symptoms, and functional capacities), variables linked to personal resources (resilience and engagement to services), and variables related to the context in which the person lives (internalized stigma and social support). The study showed that resilience, stigma, and engagement with mental health services mediate the relationships between symptomatology, cognition, and real-world functioning (13). Another recent work showed that negative symptoms predict social deficits but not impairment in everyday activities and vocational outcomes contrary to cognition and functional capacity (14).

Models explaining real-world functioning have become increasingly complex over time, with an exponentially growing number of factors. Some authors propose a single pathway, while others, like Galderisi, suggest multiples pathways (13). Hence, the question of one versus multiple pathways to outcomes in schizophrenia is not yet settled (15). **Figure 1** summarizes this evolution. Most of the models cannot explain more than 50% of the functional outcome variance, which means that more variables should be taken into account in the prognosis of severe mental illnesses.

Two suggestions can be made based on these data. First, various factors need to be assessed to establish an individual "functional diagnosis." Some factors are inherent to the patients (cognition, engagement with services, functional capacity, symptoms, resilience, and recovery processes), whereas others are related to their social context (internalized stigma, social support, resources, etc.). Such an assessment would help to determine an individualized intervention plan and to define life goals in collaboration with the patient.

Second, appropriate treatment targeting neurocognition, social cognition, negative symptoms and functional capacity, and integrative interventions combining different therapies need to be instituted taking into account the specific needs of each patient.

Rehabilitation or psychosocial interventions have been developed to complement psychotherapy and psychopharmacological treatments (16, 17). Indeed, drug treatments and supportive therapies do not have a specific effect on cognitive impairment, insight, social skills, and interaction disorders, whereas rehabilitation tools especially target these dimensions (17, 18). Rehabilitation interventions also share common values with the "subjective" model of recovery. Indeed, they promote taking an active position against the disorder, which encourages self-determination and empowerment.

Many tools can be used in the field of rehabilitation: case management, supported employment (SE), cognitive remediation, psychoeducation, and cognitive-behavioral therapies. In this review, we focused on rehabilitation interventions that particularly target the dimensions quoted above. Thus, we studied the three following interventions: (1) cognitive remediation, (2) psychoeducation, and (3) cognitive-behavioral therapies. Each type of intervention has different targets, but each favors functional recovery.

Cognitive Remediation

Cognitive remediation for schizophrenia is "a behavioral training-based intervention that aims to improve cognitive processes (attention, memory, executive function, social cognition or metacognition) with the goals of durability and generalization" (Cognitive Remediation Experts Working Group, 2012) [c.f. Ref. (19)]. Cognitive remediation therefore aims to limit the impact of cognitive impairment on everyday functioning (20).

Cognitive disorders are very common: four out of five patients suffering from schizophrenia display cognitive impairment (21). Moreover, cognitive disorders are a major determinant of functional disability. Since cognitive impairment is very variable in schizophrenia, a neurocognitive assessment should be proposed to all patients to define their cognitive profiles, determine the functional repercussions of the cognitive disorder, and identify their cognitive strengths and weaknesses (21). An assessment of social cognition is also essential (11).

Psychoeducation

The psychotic experience often leads to feelings of inconsistency and loss of direction. In the early course of the disease, people

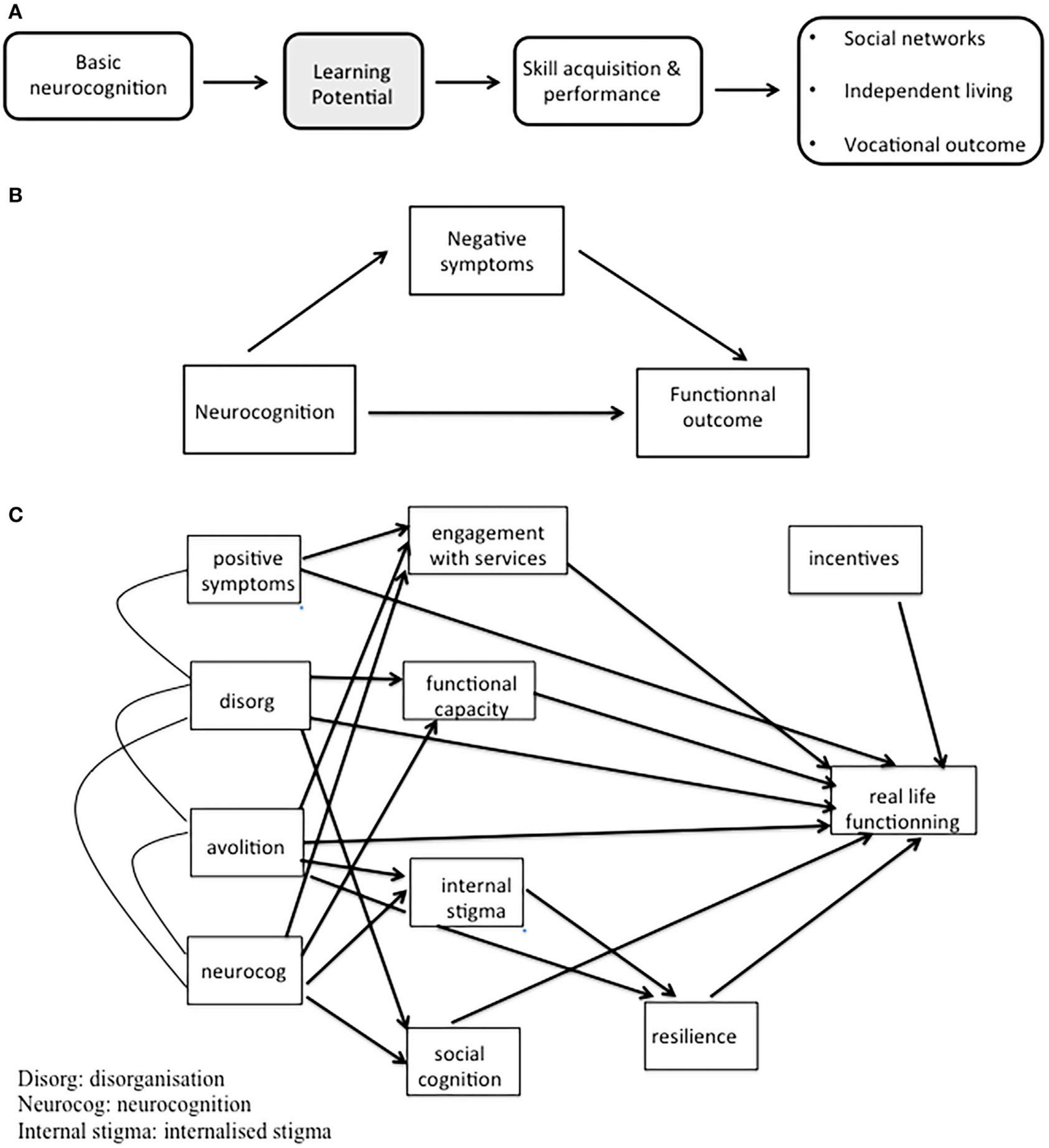

FIGURE 1 | Evolution of models explaining real-world functioning in schizophrenia. **(A)** Adapted from Green et al. (4). **(B)** Adapted from Ventura et al. (12). **(C)** Adapted from Galderisi et al. (13).

often feel like they are passive victims of schizophrenia as they lose their sense of personal efficacy and their hope in recovery.

Psychoeducation is defined as a "systematic, structured, didactic information on the illness and its treatment, and includes integrating emotional aspects in order to enable patients or family to cope with the illness" (22). It features common structural components since each program is designed and led by health professionals. A collaborative relationship is established between the mental health professionals and the patients or their families, to help the latter to share the burden of the illness and work toward the patients' recovery (23). The core elements of psychoeducation programs are information about the signs and symptoms of schizophrenia, relapse prevention, and treatment of psychosis. Another important goal is to help patients to find a meaning to their illness and to adopt a constructive attitude toward their experience of psychosis. Psychoeducation cannot be described as the simple transmission of information; it places people with schizophrenia in a position where they take action (24). Psychoeducation should provide patients with information about the illness and its treatment as well as disease management problem-solving and coping skills and on how to access community mental health-care services, the purpose being to help patients better cope with the disease (22).

Family intervention shares a number of similarities with patient psychoeducation. It provides relatives with information about the nature, symptoms, and diagnosis of the disease to help them to identify its possible manifestations. It underlines that psychosis may be exacerbated by stress or substance use, helps identify signal symptoms announcing a relapse and explores the effect of pharmacological and psychosocial treatments. Family intervention focuses on improving both patient and family outcomes, i.e., on reducing the burden of disease (24).

Psychoeducation aims to help patients and their families understand the disease and treatment, cooperate with caregivers, live healthier lives, and maintain or improve their quality of life; consequently, it has an impact on several functional determinants, such as service engagement (active participation in defining treatment plans, ability to seek service help if needed, etc.), resilience, and self-stigma.

Cognitive-Behavioral Therapy

Cognitive-behavioral therapies (CBT) are an essential part of non-pharmacological interventions for schizophrenia. They constitute a heterogeneous group of therapies sharing common features (**Box 1**) (25) with the main techniques used being social skills training and cognitive therapy (CT).

Social Skills Training

Social skills consist in three main components: receiving skills (social perception), processing skills (social cognition), and sending skills (behavioral responding or expression) (26, 27). Lack of social skills is one of the major deficits among people with schizophrenia. Impaired social skills significantly reduce patient autonomy and may lead to social withdrawal or isolation (28).

Behavioral treatment of schizophrenia is primarily based on the acquisition of new social interaction modalities. Social skills training is rooted in operant conditioning and learning theory (28). It is based on behavioral therapy principles and techniques for teaching individuals to communicate their emotions and requests so that they are more likely to achieve their goals and meet their needs (28). Although social skills training programs differ in implementation setting, duration and content, they all use a similar approach for teaching skills, including goal setting, role modeling, behavioral rehearsal, positive reinforcement, corrective feedback, problem-solving techniques, and home assignments to practice skills and promote generalization (29). Patients are usually given social skills training in groups led by two therapists. Training patients in a group provides an opportunity for self-help and peer support and enables participants to learn from each other's real-life experiences and efforts at problem solving (28).

Social skills training targets social, independent living skills and thus probably has an impact on factors such as social cognition, functional capacity, or symptoms.

BOX 1 | Principles of cognitive-behavioral therapies.

- Modification of behavior and/or content of dysfunctional thoughts based on learning theory and data from experimental psychology;
- Collaborative approach: the patient plays an active role in the therapy;
- Priority is given to the experiences, needs, and demands of the patient;
- Therapeutic alliance;
- Goals for therapy defined in consultation prior to beginning treatment;
- Short and defined duration.

Cognitive Therapy

Reasoning and attributional biases, including jumping to conclusions and lower belief flexibility, are well described in psychosis (30). People experiencing psychosis are more likely to exhibit a personal, external attributional style. CT for psychosis aims at modifying dysfunctional beliefs by helping people to understand the links between perceptions, beliefs, and emotional and behavioral reactions (31). It allows the patient to question evidence supporting his/her beliefs and brings them to self-observe, to record their thoughts and behaviors, and to explore various coping strategies (31). Patients learn to cope with psychotic symptoms not controlled by medication and to reduce their impact on everyday life using structured techniques (**Box 2**).

Initially, work in CT for psychosis targeted positive symptoms but recently, greater attention has been focused on negative symptoms. Cognitive models of negative symptoms have been conceptualized as maladaptive strategies aiming to protect individuals from expected pain associated with engagement in constructive activity. Treatment of negative symptoms uses the same techniques as those used for positive symptoms; in this case negative symptoms are conceptualized as negative self-beliefs (31). CT may be an efficient way to reduce the functional impairment associated with symptoms.

We conducted a systematic review of the literature for four of these treatments targeting effectiveness: cognitive remediation, psychoeducation, social skills training, and CT. Specific attention was paid to the functional effects of the treatments.

METHOD

Search Strategy

Electronic databases (PubMed, ScienceDirect, and Google Scholar) were searched for studies published in English between 1995 and 2017 that examined the effects of cognitive remediation, psychoeducation, and cognitive-behavioral therapies. After experimentation, the following terms were defined and searched for in the screening: ("schizophrenia") AND ("cognitive remediation" OR "psychoeducation" OR "family psychoeducation" OR "social skills training" OR "cognitive behavior therapy"). To ensure no important review was overlooked, we proceed with an additional search using the terms ("schizophrenia") AND ("cognitive remediation"); ("schizophrenia") AND ("psychoeducation"); ("schizophrenia") AND ("Family psychoeducation"); ("schizophrenia") AND ("social skills training"); ("schizophrenia") AND ("cognitive behavior therapy").

Since the literature on this subject is very abundant, we only selected review articles and meta-analyses. We especially focused on the effectiveness of each technique and on real-life

BOX 2 | Techniques used in cognitive therapy (31).

- Education about the disease;
- Normalization of psychotic symptoms;
- Application of symptom-management techniques;
- Questioning of evidence underlying beliefs;
- Engagement in reality testing.

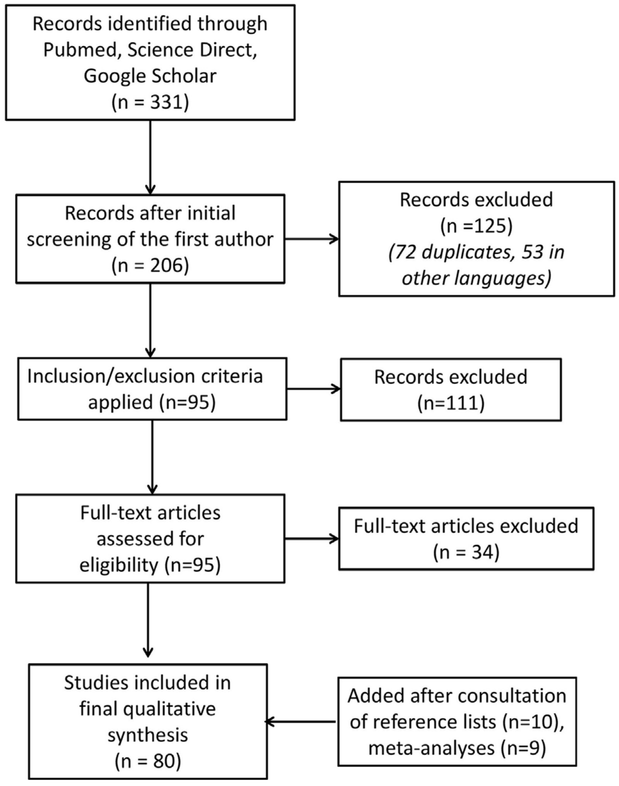

FIGURE 2 | Study flow diagram.

functioning. The search was also limited to peer-reviewed journal articles.

A total of 331 articles were initially identified as potential candidates for inclusion. After an initial review by the first author, 125 articles were excluded from the analysis (72 duplicates, 53 in other languages).

We then independently assessed the remaining studies for inclusion or exclusion from the systematic review. One inclusion criterion was that the patients had to be adults (18+) with schizophrenia or a schizophrenia spectrum disorder. Studies based on samples including children or teenagers were excluded from the review. The full text of the manuscript had to be available. A total of 95 papers met the inclusion criteria and were eligible for the review; 111 articles were excluded from the analysis (30 referring to other diagnoses, 10 without the full text available, 71 on other topics).

The articles found to be relevant to the topic of interest ($n = 95$) were reviewed and checked for methodological rigor and validity by the two authors (Laurent Morin and Nicolas Franck); 34 papers were excluded from the analysis: in 12 articles, the topic was too specific—for example, "cognitive remediation in India," in 14 other articles, the diagnoses were too heterogeneous, and in the last eight articles, the main topic was not the effectiveness of the rehabilitation tools.

All reference lists of the selected articles were also searched to identify further relevant trials: we added 10 more articles to the records. In order not to lose any other meta-analyses, we conducted a new search for each technique with the terms ("schizophrenia") AND ("cognitive remediation") AND ("meta-analysis"); ("schizophrenia") AND ("psychoeducation or family psychoeducation") AND ("meta-analysis"); ("schizophrenia") AND ("socials skills training ") AND ("meta-analysis"); ("schizophrenia") AND ("cognitive behavior therapy") AND ("meta-analysis"); nine more works were thus identified. Altogether, a total of 80 articles were finally reviewed in this work (**Figure 2**).

RESULTS

Efficacy of Cognitive Remediation

Two meta-analyses (19, 32) showed the effectiveness of cognitive remediation in the management of neurocognitive disorders. Regarding effect size (ES), McGurk et al. showed that cognitive remediation had a significant impact on cognition with a medium ES (0.41) (32). The other meta-analysis (19) confirmed these results, demonstrating an overall ES of 0.45 for cognitive performance.

Cognitive remediation is also effective on psychosocial functioning. Two meta-analyses (19, 32) reported positive results with a small to medium ES (around 0.36) for social functioning and a small ES for symptoms (0.28). The impact of cognitive remediation on the patients' ability to work is also positive (33). People who benefit from cognitive remediation work longer hours and have more opportunities to maintain work than people who do not (33, 34). Cognitive remediation is almost ineffective on symptoms. Even if patients with marked symptoms may improve their cognitive performances, the benefits of cognitive remediation are more significant in less symptomatic patients (19). A recent meta-analysis focused on the effect of cognitive remediation on negative symptoms. In this work, cognitive remediation was found to have a significant effect on negative symptoms (0.36) (35). Compared to the Wykes et al.'s meta-analysis (19), the effect was close to their ES of 0.18 for symptoms. As in the Wykes et al.'s meta-analysis, cognitive remediation programs associated with adjunctive psychiatric rehabilitation including psychoeducation and training to develop social, vocational, and daily living skills had a significantly more positive effect on functioning than cognitive remediation programs delivered alone (19, 35).

The effect of cognitive remediation seems generally homogeneous regardless of the method used (computer or paper-and-pencil tasks) and program duration (19, 36). Nevertheless, one study outlined the importance of adjusting the level of computerized exercises to the patients' cognitive performances (37). Even if each cognitive remediation program is specific in terms of number of sessions, it seems that mild improvement may be observed with remediation of limited duration (from 5 to 15 h). Concerning the role of the patients' age, results are more heterogeneous. Some authors suggest that younger people are more likely to benefit from cognitive remediation (38–40). More recent studies show that cognitive remediation in early psychosis has an impact on various aspects of schizophrenia such as cognition, functioning, and symptoms (41, 42). According to other works, cognitive remediation appears less effective in young populations than in patients with chronic conditions (43).

It seems that the majority of meta-analyses published in the last 5 years were adequate in terms of methodological quality; this is encouraging considering the concerns about the reliability of the results of cognitive remediation (44).

Efficacy of Psychoeducation for Patients

The main criteria used to assess the efficacy of psychoeducation are relapse rate, decrease of symptoms, treatment adherence, knowledge of the disease, and functioning in the community. Most large-scale works on psychoeducation do not differentiate between information provided to the family from that provided to the patient. A Cochrane meta-analysis comparing the efficacy of psychoeducational interventions in schizophrenia to standard treatment in 10 randomized controlled trials (RCTs) showed that psychoeducational interventions significantly decreased relapse or readmission rates at 9–18 months follow-up compared with standard treatment (45). The authors estimated that 12 relapses could be avoided, or at least postponed, if 100 patients with schizophrenia received psychoeducation (45). Secondary outcomes such as knowledge gain and overall level of functioning indicated that psychoeducation had a positive effect on these dimensions (45).

Another meta-analysis including 18 studies showed the benefit of psychoeducation on relapse after 12 months (medium ES, 0.48) and on knowledge of the disease (medium ES, 0.48), but no effect on symptoms and on psychosocial functioning (46). A more recent review published in the Cochrane database and involving more than 5,000 patients (mostly inpatients) included in RCTs ($n = 44$) highlighted that psychoeducation improves patient compliance compared to standard treatments and reduces rate of relapse and hospitalization in the short term (6 months) (47). In these works, the median length of psychoeducation therapies was around 12 weeks, which is very costly in terms of time. Some works seem to indicate that short psychoeducation programs (<8 sessions) also reduce relapse and promote medication compliance, but these results have to be confirmed by further high-quality studies (48). It is also difficult to get a consistent view of the various measures of functioning as the data were very heterogeneous. For the global functioning outcome "no clinically significant improvement" was found, but in the medium term, the authors found that treating four people with psychoeducation instead of standard care resulted in one additional person showing improvement. Short-term and long-term data also favored the psychoeducation group, but results were not statistically significant. Overall, it seems that global functioning is helped by the psychoeducation approach (47).

Merinder's review including seven studies confirmed an improvement of knowledge about the disease with small effects on adherence and relapse rates (49). A study quoted by several reviews showed that psychoeducation is effective in reducing readmission rates after 5 years in patients with medium duration illness (4–7 years) (24, 50). It seems that the content of psychoeducation programs needs to be adapted to the different stages of the disease. According to some authors, psychoeducation is especially adapted to patients in the early stages of disease when the content of the session tries to establish links with their own experience (50).

Psychoeducation could also play a major part in interventions to reduce internalized stigma. In a recent meta-analysis, psychoeducation was the most commonly used technique in controlled randomized studies on stigma intervention. This work could not statistically determine which interventions significantly reduced internalized stigma outcomes due to the scarcity of the studies; but most of the studies similarly found that psychoeducation and cognitive challenging were key components (51).

Efficacy of Family Psychoeducation

A review on psychosocial treatment for schizophrenia showed that long-term family psychoeducation reduces the patients' "vulnerability" to relapses over a period of 1–2 years (52). Other works mentioned the long-term effectiveness of psychoeducation (a combination of family and individual approaches). Patients suffering from schizophrenia benefiting of a brief eight-session psychoeducational program had significantly lower hospitalization rates after 12 and 24 months compared with standard treatment without psychoeducation (50). In the long term (7 years), readmission rates were lower in the psychoeducation group (54%) compared to the control group (88%) (24). Another study including 150 participants confirmed these results. People with schizophrenia participating in short psychoeducation programs for patients and family were also less often hospitalized over a 1-year period (50).

Several large-scale studies also confirmed the efficacy of psychoeducational family approaches. They showed that the interventions led to a 20% reduction in relapse rates with results being particularly clear for family interventions lasting over 3 months (53, 54). A recent review of 50 RCTs showed that family interventions were effective in various areas (55):

- Knowledge of the relatives about the disease;
- Reduced relapse rates after 2 years;
- Support and patient compliance

Psychosocial functioning was difficult to measure; the different ratings seem to support that hypothesis that family intervention does improve general functioning. Continuous data from the social functioning scale were in favor of the family intervention group, but doubts remain about the study's robustness given the small number of participants (55). A review on psychoeducation quoted several studies investigating the impact of family psychoeducation on psychosocial functioning: it concluded that family interventions may have a significant impact on functional outcomes in patients with schizophrenia (on global and social functioning, social relationships, interest in obtaining a job, and management of social conflicts) and their families (on social contacts and perception of professional support) (50).

The effectiveness of family psychoeducation as an "evidence-based practice" has been established by several studies (54, 56, 57). Conclusions regarding hospitalization and relapse rates from randomized trials on family psychoeducation are reliable. Results are more contrasted as regards the alleviation of family burden (58). However, short-term psychoeducational interventions may still have positive effects on subjective burden, depression and anxiety, and could be especially useful for low expressed emotion families (59, 60).

Efficacy of Cognitive-Behavioral Therapies

Efficacy of Social Skills Training

More than 23 controlled trials and several literature reviews have been published about the impact of social skills training. They show that patients with schizophrenia can learn a variety of skills (conversational, interpersonal problem-solving strategies, etc.) and that acquired skills are usually still present after 2 years (the maximum duration of the studies) (61–64).

In 2002, Pilling et al. conducted a meta-analysis of nine RCTs on social skills training and concluded that there was little evidence of benefit in any outcomes (63). However, the conclusion was contested by Mueser and Penn (64) and Bellack (62). Bellack reviewed four meta-analyses of skills training and concluded that social skills training has a significant effect on behavioral skills, social role functioning, and client satisfaction but not on symptom reduction and relapse (62). The results of several meta-analyses are consistent with these results. Pfammatter et al. (65) examined 19 controlled trials and found positive effects on social skills acquisition (ES = 0.77) and social functioning (ES = 0.39). However, they found only a mild effect (ES = 0.23) on relapse. Kurtz and Mueser (66) studied 22 RCTs including 1,521 patients with schizophrenia and found that skills training programs produce moderate but significant improvement in social functioning (ES = 0.52) and negative symptoms (ES = 0.40) and reduce hospitalization rates over a 1- to 2-year follow-up period (ES = 0.48–0.52). These results were consistently and sustainably maintained during the follow-up period. However, the effects of social skills training on other areas of psychopathology such as psychotic symptoms, relapse rates, and cognitive function are not consistent (65, 66). Two recent reviews on the treatment of negative symptoms in schizophrenia showed similar results. Five RCTs quoted in these reviews found that social skills training was associated with an improvement in negative symptoms. The gains were maintained after a 3- to 6-month follow-up period (67, 68). A recent meta-analysis also found social skills training to be superior to other interventions (69). Although social skills training was not initially conceptualized as a treatment for negative symptoms, these studies suggest that the technique could be effective for improving negative symptoms in the short term.

Conversely, the results of three Cochrane reviews (70–72) investigating life skills programs (teaching skills in budgeting, communication, domestic living, personal self-care, and community living) were contrasted and concluded that "compared to standard care, social skills training may improve the social skills of people with schizophrenia and reduce relapse rates but, at present, the evidence is very limited with data rated as very low quality."

Efficacy of CT

There have been more than 40 controlled trials and several reviews on CT for psychosis, and most of them reached similar conclusions: CT is effective in reducing positive symptoms and improving social functioning (25, 27, 73). Several studies (74–77) also reported that the effects of CT were long-lasting (>1 year) and impacted positive symptoms. A meta-analysis ($n = 33$ studies) confirmed the positive effects of CT on positive symptoms with a moderate ES (ES = 0.37) but also showed its effectiveness on negative symptoms (ES = 0.44) and social functioning (ES = 0.38) (77). Granholm et al. (78) supported these results by studying 18 RCTs including measures of social functioning. Two-thirds of the studies showed significant improvement after CT, whereas the other meta-analyses reached less favorable conclusions (79–81). Later studies show a small ES on positive symptoms and little effect on relapse rate. The Lynch et al. study (79) was criticized for selecting works that did not specify the inclusion criteria, and for failing to monitor the effects in the selected studies. The studies were also criticized for the small size of the samples (approximately 600 patients) (82, 83). Several studies, published mostly in 2014, also seemed to support the efficacy of CT in reducing positive symptoms with an overall average ES (around 0.40). Recent meta-analyses highlighted the benefits of CT on both positive and persistent symptoms (77, 84, 85). The effectiveness of CT on negative symptoms seems less convincing. Meta-analyses using negative symptoms as a secondary outcome measure indicate that the effect of CT on negative symptoms is significant (77, 86). However, the moderate ES found in the first studies (77) is not as good in more recent studies (86). Also, only few studies have focused primarily on negative symptoms.

It seems that CT should comprise at least 20 sessions to be fully effective (87). Conversely, a recent meta-analysis showed that low intensity CT (fewer than 16 sessions) could have an effect on symptoms of psychosis ($d = 0.46$); these results were consistent with those found in other meta-analyses studying CT (88). In this meta-analysis, no significant between-group post-intervention differences were found for secondary outcome measures such as depression and anxiety or functioning; nevertheless, at follow-up, a statistically significant difference was observed between groups for depression and functioning. This may be an important finding as there could be delayed beneficial effects that may not always be seen immediately post-intervention (88).

Overall, CT is the most effective psychosocial intervention for psychotic symptoms while social skills training shows a modest but relatively robust effect on reducing negative symptoms compared to other psychosocial interventions (69).

Table 1 summarizes the main results of the studies with the largest samples of patients.

DISCUSSION

Numerous results show that cognitive remediation, psychoeducation, and CBT are efficient rehabilitation tools. Data in the literature concerning cognitive remediation are homogeneous and show that it is efficient on cognitive functioning and psychosocial functioning, in particular the ability to work (20, 21, 23, 29). According to most studies, the impact of cognitive remediation on social functioning is more important both when combined with other rehabilitation techniques and when therapy is based on learning strategies (32, 19, 89).

Data on the effect of cognitive remediation on symptomatology are more heterogeneous. It probably has no effect on positive symptoms, and, in fact, severe positive symptoms can be an obstacle to improvement during cognitive remediation

TABLE 1 | Conclusions from meta-analyses including the largest samples of patients.

Psychosocial intervention	Meta-analyses	Description	Mains conclusions
Cognitive remediation	Wykes et al. (19)	40 Randomized controlled trials (RCTs), population with diagnosis of schizophrenia >70% ($n = 2,104$)	Cognitive remediation benefits people with schizophrenia and when combined with psychiatric rehabilitation, the benefit extends to functioning
Psychoeducation for patients	Xia et al. (47)	44 RCTs, patients with a diagnosis of schizophrenia or schizoaffective disorder ($n = 5,122$) (mostly inpatients)	Psychoeducation programs enhance treatment adherence, social functioning, and reduce relapse rates and readmission compared to standard care
Family psychoeducation	Pharoah et al. (55)	53 RCTs, patients with a diagnosis of schizophrenia or schizoaffective disorder ($n > 4,800$)	Family interventions decrease the frequency of relapses up to 2 years, and increase drug compliance, knowledge of the disease in the family, and reduce family burden
Social skills training	Kurtz and Mueser (66)	23 RCTs, patients with a diagnosis of schizophrenia or schizoaffective disorder ($n = 1,521$)	Large effect size (ES) for content learning and social skills, moderate ES for social functioning and negative symptoms
Cognitive therapy	Wykes et al. (77)	34 RCTs, patients with a diagnosis of schizophrenia or schizoaffective disorder ($n = 1,964$)	Moderate ES for global and positive symptoms (0.4). Effects inflated for less rigorous studies

sessions. Data concerning negative symptoms are more complex since they are impacted by cognitive remediation. The effectiveness on negative symptoms is probably indirect, hypothetically due to a reduction of defeatist beliefs, avoidant behavior, and poor motivation, and, consequently, improvement in self-esteem (35).

Further studies should try to specify the effects of cognitive remediation, the active elements of interventions, the factors that lead to positive responses and the persistence of benefits over time (38). It seems, however, that factors such as motivation, social cognition, and metacognition may play a key role in the success of this remediation technique (20, 21).

Psychoeducation for families and patients proved to be effective in preventing relapses, readmission, and also in increasing drug compliance. Interventions with the highest level of evidence seem to be those involving relatives. Actually, psychoeducation for patients showed its effectiveness, but with a lower level of proof compared to patient and family psychoeducation (46). It is important for patient and family psychoeducation not only to transmit information but also to provide practical skills such as concrete problem-solving techniques.

Although methodological reductionism restricts psychosocial rehabilitation to a single intervention, it appears that interventions combining psychoeducation, cognitive and behavioral techniques, and homework strategies are more effective at increasing treatment adherence than unidimensional approaches (24, 90, 91). Future research should focus on the development of new kinds of programs such as peer-led psychoeducation. It seems essential for participants to receive information from and exchange with peers. Conversely, providing too much information about the disease can cause defensive reactions (50, 58). Uncertainties still remain about the efficiency of psychoeducation in areas such as global functioning, awareness of the disorder, need for care, and quality of life, especially in the long term (2 years) (22, 24). Other parameters need to be clarified by better designed studies, such as the minimum effective "dose" of psychoeducation and the specificity of the psychoeducational format according to patient status (50, 58).

Social skills training produced contradictory results. The lack of consistency is due to methodological problems in some studies including small samples, sampling biases, and lack of blinding to treatment allocation (18). However, there are few methodological issues with the Cochrane reviews, and many other studies are coming to the same conclusions. Social skills training was found to be efficient on social skills, on psychosocial functioning and on negative symptoms. With regard to more distal outcomes, existing reviews and meta-analyses do not consistently support the positive effects of social skills training on outcomes such as relapse rate, psychotic symptoms, and quality of life (18). Additionally, it has been found that various factors may influence the effectiveness of social skills training. For example, Mueser et al. (29) noted that deficits in attention may limit the effects of social skills training approaches. It also seems crucial to note that transferring the skills learned during therapy sessions to everyday life is not always easy, which is why generalization techniques (home-based exercises) are very important. They provide patients with the opportunity to practice skills in natural situations (18, 26, 28).

Social skills training has proved to be very efficient when associated with cognitive remediation or SE which is why the three rehabilitation interventions are often bundled (18, 92). Besides enabling patients to practice newly acquired skills in everyday life, it gives them appropriate feedback and provides social reinforcement (23).

The data in the literature concerning CT are quite homogeneous, indicating that CTs are efficient in reducing positive symptoms (73–77). Cognitive therapies may be used as adjuvants to chemotherapy in patients in remission or in patients with active symptoms and may also be effective in reducing negative symptoms. However, further controlled trials with negative symptoms as the primary outcome measure are required. The quality and effectiveness of cognitive therapies is partly determined by the training and the supervision of therapists (81). Additional studies on CT and minimal dosing are still required. Few works seem to show effectiveness of low intensity CBT, but low and high intensity CBT should be compared in future studies (88). It also seems important to consider for future research that patients do not always need their symptoms to be eradicated, and such observations are common in the literature on recovery from psychosis or schizophrenia. Recovery means being able to live with symptoms, i.e., being able to cope with the "voices." Thus, although CT analyses focusing only on psychotic symptom reduction are important, further studies should focus on secondary outcomes such as reduced distress or self-defined recovery. We should also concentrate on changing how people relate to their thoughts and feelings, as the third-wave approaches do (30, 31).

In this review, we were particularly interested in the effect of the techniques on psychosocial functioning. The techniques that led to the most robust improvement in psychosocial functioning were cognitive remediation (32, 19) and socials skills training (63–66). With both techniques, improvement of social functioning depends a lot on a common characteristic that consists in supporting practice with rehabilitation activities (e.g., SE) or opportunities to reflect on how to apply the skills to everyday life. The programs also require frequent personal contact with a therapist. It is likely that by providing these elements, the programs facilitate learning consolidation by making new cognitive or social skills accessible in everyday life. Programs that use supported practice and other methods to maximize transfer of therapy-learned skills to everyday life and those involving a therapist may be more likely to have an impact on functioning (35, 67). A study showed the efficacy of CT on psychosocial functioning (77). Improvement in both positive and negative symptoms may lead to better functioning by limiting the consequences of the symptoms. The results suggest that there is a relationship between different outcomes and that targeting one outcome (e.g., positive symptoms) may have positive effects on others (e.g., functioning) (77). Regarding patient or family psychoeducation, the effect on psychosocial functioning seems limited, but that does not mean that the interventions have no effect on functioning, but rather that functioning assessments are rarely reported in works about psychoeducation intervention and when they are, functioning is not a priority outcome. Further research should investigate the effect of psychoeducation on functioning as a primary outcome measure. Since psychoeducation seems to be effective on variables influencing real-world functioning (engagement in service and internalized stigma), interpreting results on functioning were rather difficult because psychosocial functioning assessment is very heterogeneous in the literature. Most of the works reviewed here included studies using different scales. It seems that future research on psychosocial interventions could focus more on functional outcomes. Another important issue is how to assess real-world functioning: it would be useful to find a common set of criteria that would enable its assessment.

All these interventions are always delivered within the framework of rehabilitation and are not intended to be standalone treatments. Several programs combining interventions proved to be efficient, such as CBT and skills training, SE and skills training, cognitive remediation and social skills training (i.e., integrated psychological therapy) (92, 93), or social cognitive training and CBT and skills training (i.e., social cognition and interaction training).

The impact of psychosocial interventions on functional outcomes seems to be improved by combining elements from each therapeutic approach (16, 17, 94, 95). Clinical experience showed the relevance of combining techniques based on patient issues and the stage of the disease. These techniques seem to be complementary: on the one hand, psychoeducation and CBT allow patients to gain knowledge about their illness and play an active role in the recovery process while on the other, social skills training and cognitive remediation may enhance adaptive skills. Nevertheless, further research is needed to identify the synergistic effects of combined interventions and the active ingredients of successful therapeutic modalities.

CONCLUSION

Recovery from schizophrenia seems to depend partly on functional outcomes such as neurocognition, social cognition, negative symptoms, and functional capacity. It therefore appears essential to assess these variables for each patient and to develop efficient rehabilitation interventions. According to the literature, some psychosocial interventions have proven their effectiveness: cognitive remediation for reducing the impact of cognitive impairment, social skills training for reducing negative symptoms, psychoeducation for improving compliance and reducing relapses, and CT for reducing the intensity of or distress related to positive symptoms. In addition, the techniques also try to promote the recovery process by encouraging self-determination and active empowerment.

Care is organized according to these scientific data and the local environment. Rehabilitation structures should be organized so the interventions are accessible to the largest possible number of patients and so research may be coordinated on the therapeutic effects of psychiatric rehabilitation, as is already the case in some French regions (Auvergne-Rhône-Alpes and Nouvelle-Aquitaine in particular) (96). Structures such as these offer the most varied rehabilitation care facilities, but they remain experimental, and their effectiveness has yet to be evaluated.

AUTHOR CONTRIBUTIONS

NF has defined the organization of care and the development of the psychosocial intervention in France. LM drafted the paper and both the authors approved the final version.

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REVIEW
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Clinical Relevance of Informal Coercion in Psychiatric Treatment—A Systematic Review

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Introduction: Although informal coercion is frequently applied in psychiatry, its use is discussed controversially. This systematic review aimed to summarize literature on attitudes toward informal coercion, its prevalence, and clinical effects.

Methods: A systematic search of PubMed, Embase, PsycINF, and Google Scholar was conducted. Publications were included if they reported original data describing patients' and clinicians' attitudes toward and prevalence rates or clinical effects of informal coercion.

Results: Twenty-one publications out of a total of 162 articles met the inclusion criteria. Most publications focused on leverage and inducements rather than persuasion and threat. Prevalence rates of informal coercion were 29–59%, comparable on different study sites and in different settings. The majority of mental health professionals as well as one-third to two-third of the psychiatric patients had positive attitudes, even if there was personal experience of informal coercion. We found no study evaluating the clinical effect of informal coercion in an experimental study design.

Discussion: Cultural and ethical aspects are associated with the attitudes and prevalence rates. The clinical effect of informal coercion remains unclear and further studies are needed to evaluate these interventions and the effect on therapeutic relationship and clinical outcome. It can be hypothesized that informal coercion may lead to better adherence and clinical outcome but also to strains in the therapeutic relationship. It is recommendable to establish structured education about informal coercion and sensitize mental health professionals for its potential for adverse effects in clinical routine practice.

Keywords: informal coercion, leverage, attitudes, prevalence, clinical effect, mental health, therapeutic relationship

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INTRODUCTION

Informal coercion is ubiquitous in the health-care system, especially in mental health and psychosocial services. It comprises a large range of treatment pressures and interventions that can be applied by the professional with the intention to foster treatment adherence or avoid formal coercion. The degree of coercion adherent to several interventions ranges between full autonomy and formal coercion that is regulated by the law. Generally, informal coercion is intertwined with the therapeutic relationship and frequently applied by the professional unintentionally (1). The intensity of coercion that is perceived by the patient consecutively interacts with various aspects, such as transparency, fairness, dignity, trust, and the quality of the therapeutic alliance itself (2). Therefore, perceived coercion does not necessarily correlate with factual coercion, both formal and informal (3, 4).

The spectrum of informal coercive measures constitutes a continuum of phenomena, ranging from subtle interpersonal interactions to obvious demonstrations of force. Several graduations of informal coercion have been described, and the most commonly used categorizations are as follows: Szmukler and Appelbaum (5) defined a hierarchy of treatment pressures with: (I) persuasion; (II) interpersonal leverage; (III) inducements; (IV) threats; and (V) compulsory treatment. More detailed, Lidz et al. (6) defined nine graduations of coercion: (I) persuasion, (II) inducement, (III) threats, (IV) show of force, (V) physical force, (VI) legal force, (VII) request for a dispositional preference, (VIII) giving orders, and (IX) deception.

Beyond full autonomy, persuasion and conviction are the least problematic interventions on the spectrum of treatment pressures as it relies on respect for the patient's values and arguments. It is a very common phenomenon in the interaction of patients and professionals and is also compatible with a therapeutic relationship that aims at an informed consent and a shared decision-making process (7). Persuasion can be differentiated from conviction by the nuance that conviction targets on the result that the patient comes to own conclusions during a reciprocal discussion while persuasion results in the adoption of the professional's opinion by the patient.

Ascending in the hierarchy of treatment pressures, the notion of professional force becomes more obvious resulting in a more asymmetrical therapeutic relationship. There is a range of utilitarian interventions that are applicable on the basis of emotional or factual dependency of the patient within the professional relation. Interpersonal leverage may occur if the patient shows emotional dependency on the professional which may be used for interpersonal pressure. The clinician expresses verbally or nonverbally his or her expectations or demonstrates disappointment. The patient is tempted to react in a way that he or she assumes would please the clinician. A more factual form of leverage is the use of inducements within a framework of negotiation. Thereby, the patient is demanded to comply with treatment in exchange for a desired asset. Several goods or values can be used as leverage tools. Monahan et al. (8) described four specific types of leverage: housing, money, children, and criminal justice. Other types, such as work, non-monetary goods, attention, and care, are probably common in the health-care system as well. A fluent transition from offer to threat in this context seems obvious. A distinction can be made considering the normative basic entitlement. If the patient could receive a desired good in addition to standard care or basic rights, it can be called an offer. If some basic right or standard good is withheld from the patient, it is considered a threat (9). Thus, the classification of the proposition made by the professional strongly depends on the factual, legal, or moral baseline (10, 11). Although the differentiation between offer and threat may be difficult within the spectrum of leverage tools, there are a range of obvious threats comprising a more subtle demonstration of force up to announcement of negative sanctions.

To date, there is no comprehensive digest on informal coercion in mental health-care systems. Therefore, the aim of this study was to review the literature on prevalence of treatment pressures and informal coercion and the attitudes toward and clinical consequences of these interventions from the perspective of patients and professionals.

Our hypothesis was that evidence on informal coercion is scarce and mainly refers to prevalence and attitudes rather than to clinical effects. Additionally, we hypothesized that the literature relies mostly on cross-sectional studies, and studies of higher quality such as randomized controlled trials would be absent due to the complexity of operationalization and ethical reasons that might prevent an interventional study.

MATERIALS AND METHODS

A systematic strategy was used to search the electronic databases PubMed/Medline, Embase, PsycINFO, and Google Scholar for studies published after the year 2000. A subject and text word search strategy was used with the words "informal coercion," OR "treatment pressure," OR leverage. Those words were combined with psychiatr* OR psychiatry OR "mental health." References of the included studies and other reviews related to this topic were also inspected and relevant articles were included (referred to as "other sources" in **Figure 1**).

Inclusion and Exclusion Criteria

Studies containing original data describing patients' and/or clinicians' attitudes toward informal coercion were included. Also studies evaluating the prevalence and clinical effects of informal coercion were included. Regarding the low number of publications in this very specific topic, no quality threshold for inclusion was set. Only studies published after the year 2000 were included. Relevant articles were filtered according to the Prisma-statement (12) (**Figure 1**). Studies focusing on formal/legal coercion were excluded except when they did have explicit aims to investigate informal coercion in the context of legally involuntary in- or outpatient treatment. Studies on perceived coercion were included when conducted in the context of informal coercion, but excluded in the context of formal coercion.

Analysis

The following categories were built to classify studies by themes. (I) Attitudes of staff to informal coercion in in- and outpatient settings. (II) Attitudes of patients toward informal coercion in in- and outpatient settings. (III) Prevalence of informal coercion. (IV) Clinical effects/aspects of informal coercion.

The quality of the included studies was assessed according to a hierarchy of evidence (categorizing studies by the attributes of their design) and the relevance for the topic as described in the results chapter. The results are partially categorized and summarized in a narrative way.

RESULTS

The search procedure yielded 162 articles. Of these, 21 met the inclusion criteria (**Figure 1**). The 21 publications referred to 15 studies [1 study resulted in 2 (13, 14), another study in 6 publications (15–20), and 13 studies in 1 publication (21–33)].

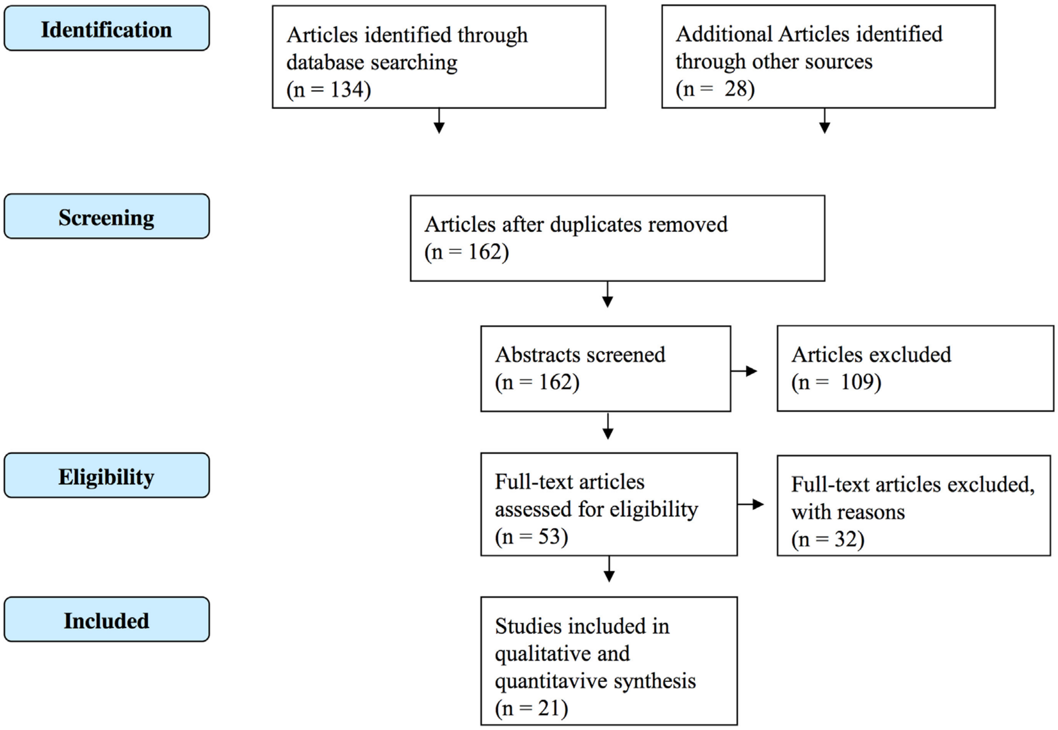

FIGURE 1 | **Prisma-based flow diagram**.

Quality of the Studies Included

All studies included were cross sectional (**Table 1**). No experimental or quasi-experimental studies were found. Four studies assessed mental health professionals only, thereof two using focus group interviews, one using case vignettes and one using structured interviews. Two studies used focus groups with professionals and patients. Nine studies assessed patients only, most of them using structured individual interviews, and one using focus groups, another using individual qualitative interviews. The sample sizes varied between 24 and 1,011 participants. Professionals were from several settings including in- and outpatient services, ACT, and housing institutions. Most patients were recruited in outpatient setting, three studies also included inpatients.

All publications had explicit *a priori* aims, and 17 discussed their data in the context of generalizability. None of the studies used a sample size calculation or justified the number of participants (**Table 2**). None of the studies declared dropouts. The nature of funding sources was disclosed in 13 out of 21 publications. The questionnaires were described conclusively in all publications that used structured interviews. Most studies assessed demographic parameters of the participants. Some studies found and discussed cultural differences in the prevalence of informal coercion and discussed these findings. One study especially aimed to investigate cultural differences in the prevalence of informal coercion between the UK and the US.

Almost all studies examined attitudes toward informal coercion. Four studies, one from the UK, two from the US, and one from Switzerland, evaluated the prevalence of several interventions comprising informal coercion, mostly leverage tools. Most of the studies examined leverage as one form of informal coercion in one of the following categories: housing, justice, childcare, employment, and money. Studies searching for informal coercion in general or leverage without categorization were rare. There were no interventional studies assessing the clinical effect of informal coercion.

The Perspective of Mental Health Professionals on Informal Coercion

Studies assessing mental health professionals did not evaluate specific prevalence rates. The four publications consistently stated that "most" of the professionals used informal coercion in daily routine practice (**Table 3**). The study investigating housing facilities found that about 60% of malcompliant residents were excluded from the program suggesting a frequent and incisive use of pressure to treatment adherence (24). Professionals intended to foster their patients' ability to take responsibility for their lives and considered informal coercion as a justifiable method to reach this goal (23). Concerning clinical effects, participants considered informal coercion to be effective in the therapeutic process with respect to promotion of adherence resulting in avoidance of decompensation as well as formal coercion. Nevertheless, one study revealed that interventions with stronger informal coercion were less accepted by mental health professionals (22), and mental health professionals tended to avoid informal coercion and to respect the patients' decisions if possible although some stated to feel being pressured to use it. Some participants used informal

TABLE 1 | Study characteristics (*N* = 15).

Reference	Design	Participants	Sample size	Clinical setting	Outcome measure	Country/state/city
Study population: professionals						
Valenti et al. (21)	Qualitative design using focus groups	Mental health professionals	248	Inpatient and outpatient	Attitudes and experiences	10 countries[a]
Jaeger et al. (22)	Quantitative design using questionnaires with case vignettes	Mental health professionals	39	Inpatient	Attitudes and experience; attribution of degree of coercion	Switzerland
Rugkasa et al. (23)	Qualitative design using focus groups	Mental health professionals	48	Community mental health services	Attitudes and experiences	UK
Wong et al. (24)	Quantitative design using structured interviews	Staff in housing institutions	27	Housing institutions	Attitudes and prevalence of housing as leverage	Pennsylvania
Study population: professionals and patients						
Priebe et al. (25)	Qualitative design using focus groups	Mental health professionals, other mental health service stakeholders, and patients	Professionals: 92 Patients: 27 Other: 20	Outpatients	Attitudes on money as leverage tool	UK
Appelbaum and Le Melle (26)	Qualitative design using focus groups	Mental health professionals and patients	Professionals: 23 Patients: 21	ACT services	Attitudes and experiences	New York
Study population: patients						
Norvoll and Pedersen (27)	Qualitative design using focus groups	Patients	24	Inpatient and outpatient	Attitudes	Norway
Canvin et al. (28)	Qualitative design using semi-structured interviews	Patients	29	Outpatient	Attitudes	UK
Burns et al. (29)	Quantitative design using structured interviews	Patients	417	Outpatient	Prevalence and patterns of leverage; Comparison to a US sample	UK
Jaeger and Rossler (13, 14)	Quantitative design using structured interviews	Patients	187	Inpatient and outpatient	Prevalence of several leverage tools, attitudes, perceived coercion	Switzerland
McNiel et al. (30)[b]	Quantitative design using structured interviews	Patients	198	Outpatient	Influence of leverage on treatment relationship and adherence	San Francisco
Angell et al. (31)[b]	Quantitative design using structured interviews	Patients	201	Outpatient	Influence of money as leverage tool on treatment relationship	Chicago
Redlich et al. (15) Robbins et al. (16) Swanson et al. (17) Appelbaum and Redlich (18) Van Dorn et al. (19) Monahan et al. (20)	Quantitative design using structured interviews	Patients	1,011	Outpatient	Prevalence of several leverage tools In consequent publications: prevalence of money as leverage tool; prevalence of housing as leverage tool; prevalence of leverage in patients with violent behavior	5 states in the US[c]
Elbogen et al. (32)	Quantitative design using structured interviews	Patients	104	Outpatient	Attitude on money as leverage tool	North Carolina
Elbogen et al. (33)	Quantitative design using structured interviews	Involuntary admitted patients	258	Inpatient	Perceptions of financial coercion	US

[a] *Canada, UK, Croatia, Germany, Chile, Mexico, Italy, Spain, Norway, and Sweden.*

[b] *Publication refers to a single subgroup of the US multicentre study (20).*

[c] *Chicago, IL, USA; Durham, NC, USA; San Francisco, CA, USA; Tampa, FL, USA; Worcester, MA, USA.*

TABLE 2 | Qualitative evaluation of the included publications (*N* = 21).

Study	Explicit *a priori* aim	Sample size calculation	Inclusion/ exclusion criteria stated	Research independent of routine care/practice	Original questionnaire available	Response/ dropout rate specified	Discussion of generalizability	Demographic data	Cultural differences	Funding disclosed
Valenti et al. (21)	+	–	–	+	–	–	–	–	+	–
Jaeger et al. (22)	+	–	+	+	+	+	+	+	–	–
Rugkasa et al. (23)	+	–	+	+	–	–	+	–	–	+
Wong et al. (24)	+	–	–	+	–	–	+	+	–	+
Priebe et al. (25)	+	–	–	+	–	–	+	+	–	+
Appelbaum and Le Melle (26)	+	–	+	+	–	+	+	+	–	+
Norvoll and Pedersen (27)	+	–	+	+	–	–	+	+	–	–
Canvin et al. (28)	+	–	+	+	–	–	+	+	–	+
Burns et al. (29)	+	–	+	–	+	+	+	+	+	–
Jaeger and Rossler (13)	+	–	+	–	+	–	+	+	–	–
Jaeger and Rossler (14)	+	–	+	–	+	–	+	+	+	–
McNiel et al. (30)	+	–	+	–	+	–	–	+	+	+
Angell et al. (31)	+	–	+	–	+	–	+	+	–	+
Redlich et al. (15)	+	–	+	–	+	+	+	+	+	+
Robbins et al. (16)	+	–	+	–	+	–	+	+	+	–
Swanson et al. (17)	+	–	+	–	+	–	+	+	+	+
Appelbaum and Redlich (18)	+	–	+	–	+	–	–	+	+	+
Van Dorn et al. (19)	+	–	+	–	+	+	+	+	+	+
Monahan et al. (20)	+	–	+	–	+	–	+	+	+	+
Elbogen et al. (32)	+	–	+	–	+	–	+	+	–	–
Elbogen et al. (33)	+	–	+	–	+	+	+	+	+	+

TABLE 3 | Findings.

Study	Prevalence	Attitudes	Clinical effect
Study population: professionals			
Valenti et al. (21)	Most participants used informal coercion	Rather positive, effective tool, participants feel pressured to use informal coercion and describe unpleasant feelings when it is used	Promotion of adherence, avoid formal coercion
Jaeger et al. (22)	–	Higher degrees of informal coercion were grossly underestimated but less accepted; participants with a negative attitude toward informal coercion overestimated the degree of coercion A trend to differences between professional groups	–
Rugkasa et al. (23)	Most participants used informal coercion	Necessary tool to achieve treatment goals	Informal coercion may lead to promotion of adherence and achievement of a healthy live Potential threat to relationships
Wong et al. (24)	59% of the supported independent living residents who refused to take prescribed medication resulting in decompensation were excluded from the program	Most programs considered medication non-compliance to be unacceptable when it resulted in decompensation Consumption of alcohol and/or other drugs and inviting other people was not accepted by most programs	Informal coercion helps to avoid decompensation
Study population: professionals and patients			
Priebe et al. (25)	–	Use of financial incentives is likely to raise similar concerns (e.g., value of medication, source of funding, how patients would use the money, effectiveness, impact on therapeutic relationship) in most stakeholders	Unclear responsibilities for potentially harmful medication effects, especially in the long term
Appelbaum and Le Melle (26)	Little evidence of significant use of leverage or perceptions of coercion	Staff and patients had quite similar opinions about treatment methods with supporting patients and building relationships being preferred mechanisms Few patients identified the least effective methods as scare tactics, threats and violating patients' personal space	Importance of constant reflection over staff behavior to recognize unintended use of informal coercion
Study population: patients			
Informal coercion in general			
Norvoll and Pedersen (27)	Coercion unfolds in health, child and social services, which, when acting together, contribute to increasing the coercive pressure of compliance	Gray zone between formal and informal coercion How extensive, negative or legitimate coercion is viewed depends on several aspects before, during, and after the coercive incidents Strong impact of coercive measures on the patients self and identity Few participants saw informal coercion as helpful for their mental health problems and life situations	
Canvin et al. (28)	Participants experienced pressure not only from health professionals but also from family and friends and even themselves	Relationship with the mental health team was experienced as interpersonal pressure to accept treatment Three features of leveraged pressures: conditionality, a lever and direct communication	–
Burns et al. (29)	35% any leverage 24% housing 15% justice system 8% childcare 2% financial	–	Unable to draw any conclusions as to the efficacy of leverage

(*Continued*)

TABLE 3 | **Continued**

Study	Prevalence	Attitudes	Clinical effect
Jaeger and Rossler (13)	29% any leverage 19% housing 11% justice system 7% childcare 3% financial	Experience with informal coercion combined with a schizophrenic disorder was associated with higher perceived coercion; informal coercion was associated with lower perceived fairness; experience of informal coercion did not lead to different appraisal of its effectiveness; higher levels of perceived fairness and effectiveness were associated with higher insight into illness	–
Jaeger and Rossler (14)	29% any leverage 19% housing (55% of those who ever lived in supported housing) 11% justice system (27% of those with criminal sentence) 7% childcare (29% of those with children under the age of 16) 3% financial (8% of those with representative payee)	34–70% approved informal coercion in general, independently of own experience; justice system was the most and childcare the less approved form of informal coercion	–
McNiel et al. (30)	37% any leverage 17% housing 22% justice system 2% financial 3% outpatient commitment	Experience of leverage was not associated with medication adherence Higher treatment satisfaction was associated with a better working alliance, lower psychological reactance, and less perceived coercion	Better adherence to medication was associated with higher perceived coercion but also with a more positive experience of medication effects Benefits in medication adherence due to informal coercion may come at the cost of decreased treatment satisfaction on the basis of side effects
Redlich et al. (15)	41–55% any form of leverage 15–21% housing 11–23% justice system 3–7% childcare 6–20% financial 2–10% employment Health service providers were the most frequent source of pressures (49%), followed by family members and friends (28%)	–	–
Van Dorn et al. (19)	–	55–69% perceived treatment leverage to be fair 48–60% perceived leverage to be effective Patients with psychosis and high barriers to care tend to view leverage as unfair Patients with less perceived coercion and better insight believe that they benefit from formal and informal sanctions Participants with experience with leverage were significantly more likely to endorse its effectiveness whereas higher perceived coercion was associated with lower perceived effectiveness	–
Monahan et al. (20)	44–59% any leverage 23–40% housing 15–30% justice system 7–19% financial	–	–
Housing leverage			
Robbins et al. (16)	22–40% housing leverage In 43% the landlord applied housing leverage, in 29% mental health professionals, more seldom family (11%) or friends (6%), unstated rule (18%) or "self" (9%)	Housing leverage led to higher scores of perceived coercion but had no influence on treatment satisfaction Patients who experienced housing leverage rated its use to help people stay well more often than those without experience	–

(*Continued*)

TABLE 3 | **Continued**

Study	Prevalence	Attitudes	Clinical effect
Judicial leverage			
Swanson et al. (17)	Violent offenders had experienced leverage twice as likely as other patients Experience of both legal and social welfare leverage was significantly associated with higher rates of serious violence	–	Concerns about safety and non-adherence to treatment may influence clinicians and judges to apply legal leverage
Financial leverage			
Angell et al. (31)	53% of the patients had a payee or money manager, which was in 79% a clinician payee 40% of patients with a clinician payee perceived financial leverage	Respondents with clinician payees (relative to those with family or friend payees or no payees) reported more conflict in the therapeutic relationship but had no difference in their bond scores in comparison with the other respondents	Payeeship may lead to strain in the therapeutic relationship when it is used for promoting adherence
Appelbaum and Redlich (18)	31–53% ever had a representative payee Between 13 and 29% of those who had experienced financial leverage	No significant relationship between money leverage and treatment satisfaction Patients who experienced money leverage rated its use as effective more often than those without experience Those with a family member as the representative payee were more satisfied and felt significantly less pressure	–
Elbogen et al. (32)	–	Patients rated money as leverage helpful if they also felt that other pressures were helpful for improving adherence 81% of the patients found legal pressures as helpful to keep them in treatment 65% reported that withholding money was not a useful method to improve treatment adherence	The use of money as leverage to improve adherence can lead to disturbance of the therapeutic relationship
Elbogen et al. (33)	30% perceived financial leverage 14% of clinicians and family members reported giving money warnings	–	Perceived financial coercion is increased in the presence of other forms of mandated treatment

In order to improve legibility, publications are listed in accordance with their topic.

coercion more often than they were aware to use it (21), and one study revealed that the degree of coercion was underestimated in the whole study population. Detailed analysis showed differences in the underestimation of professions with physicians showing the least underestimation of the degree of coercion followed by nurses and other professions (22). Telling patients what to do, being judgmental, and threatening them were rated as the least successful methods (26). If informal coercion was used in the framework of negotiation and asserting authority, it was referred to as suitable to reach treatment goals.

In summary, professionals rated informal coercion to be effective and useful in some situations, especially if it concerned interventions with less obvious and strong coercion. But the use of informal coercion was regarded as a critical intervention, and some participants stressed the importance of continuous reflection on the usage of informal coercion within treatment teams (to "keep each other in check") (26) as well as individually. Possible alternatives, including less influence and coercion, were consistently favored. Nevertheless, it seems to be a frequently applied interventional approach within therapeutic interactions in psychiatric health care.

The Perspective of Patients on Informal Coercion

As opposed to the studies focusing on professionals, some publications investigating patients' perspective on informal coercion were able to number the prevalence among the samples. Similar to the studies focusing on the professional perspective, these publications mainly reported results concerning leverage, rather than other forms of informal coercion. Most studies investigated the prevalence of leverage tools in general as well as the prevalence of specific forms of leverage (**Table 3**). Money, housing, and work are used as leverage tools to induce treatment adherence within the social welfare system. An individual with mental disorder would only gain access to the desired support if psychiatric treatment, and/or medication, was accepted. In the context of the judicial system, similar circumstances might emerge when a psychiatric patient agrees to adhere to treatment in order to avoid prosecution or an unfavorable judicial order, such as incarceration. Individuals with children also might face restriction of their parental rights if they do not consent to psychiatric treatment. Twenty-nine to fifty-nine percent of the patients from several study sites reported the experience of any form of leverage. The lowest rates were found in Switzerland and the highest in the US. The most frequently used leverage tool was housing with rates from 15 to 40% of all patients. Financial leverage was reported by 2–30%. Employment was only assessed in one US study, and 2–10% of the study participants reported experience. The prevalence rates of judicial leverage tools ranged from 11 to 23% and childcare was used in 3–8%. Health-care providers were identified as the most prevalent sources of treatment pressures next to family members, friends, and payees among others. Canvin et al. (28) found that patients experienced pressure not solely in mental health care but in everyday life with family and friends.

Attitudes toward informal coercion were examined by most of the studies including general appraisal, evaluation of fairness, and effectiveness. Thirty-four to eighty-one percent of the patients described different forms of leverage as helpful and approved its usage independently of their own experience (14, 19). The particular forms of leverage were rated differently with justice as most approved and children as less approved form (14). In one US study, 55–69% of the patients perceived the use of leverage as fair and 48–60% as effective (19). In some publications, those patients who experienced informal coercion tended to rate its effectivity higher than those without experience of informal coercion (13, 14, 16, 18, 19). Controversially, some qualitative studies reported that only a few patients found coercion to be helpful (27), and informal coercion was rated as the less successful compared to interventions on a merely voluntary basis (26).

Some studies which tended to characterize the participants showed that informal coercion was rated more positive by patients with higher insight (13, 19) and less perceived coercion (19) whereas experience of informal coercion and a schizophrenic disorder were associated with higher perceived coercion scores and lower perceived fairness (13, 19).

No study aimed primarily to evaluate the clinical effect of informal coercion in an experimental or quasi-experimental setting. Only subjective ratings on the effectiveness of informal coercion were assessed in some studies as mentioned above.

DISCUSSION

Prevalence of Informal Coercion

This systematic review shows that informal coercion is used as a method to enhance treatment adherence in different countries and with a high prevalence according to investigations among patients as well as professionals. Most frequently, different forms of leverage were evaluated rather than other interventions comprising informal coercion (i.e., persuasion, threat). One-third to half of the patients reported having been subjected to some sort of leverage within interactions in psychiatric therapy and care. Also, most of the professionals stated to use leverage and other forms of informal coercion within their therapeutic activities. The supported housing sector appeared to be associated the most with the use of leverage next to the criminal and civil justice sectors. Money and work were not as frequently reported as leverage tools. The most prevalent requirement to adhere to psychiatric treatment and medication for getting access to a supported housing facility might be regarded as structural informal coercion within the mental health-care system (34). The use of leverage within the justice system on the other hand works as a coercive informal admission to the mental health-care sector. Both pathways supposedly lead to an increased rate of patients who are at least not completely voluntarily in treatment. This routine link between mental health care and other societal sectors most likely contributes to the stigma that coercion is inherently attached to mental health care. Vice versa, this stigma of coercion might induce the use of the mental health-care system as a leverage tool to achieve non-medical aims. Nevertheless, informal coercion seems to result in a higher rate of psychiatric treatment of those in need (35) and to better outcome according to the opinions of both, patients and professionals.

Attitudes toward Informal Coercion

Next to a rather high appraisal by patients and professionals of at least weaker forms of informal coercion, such as persuasion and leverage, the use of informal coercion was considered critical to interfere with the therapeutic relationship. If inducing high levels of perceived coercion and having a notion of unfairness, informal coercion might impede the therapeutic relationship and lead to dropouts from treatment (1). Moreover, by increasing the association of psychiatric care with the notion of coercion, informal coercion might result in avoidance of the mental health-care system of others (36). It is not known if the number of individuals conducted into the mental health-care system by informal coercion outweighs the number of those who refrain from mental health care due to fear of being subjected to coercion. Thus, the effect of informal coercion (as well as formal coercion) on public mental health and health-care costs is unknown.

If applied transparently and fairly, informal coercion was considered helpful and beneficial for personal recovery. Positive effects comprised improvement of adherence and clinical outcome as well as avoidance of decompensation and formal coercion. One-third to two-third of the patients approved informal coercion independently of their own experience (14, 19). Lucksted and Coursey showed that retrospectively some participants understood forced treatment to be in their best interest although they reported negative effects from it and wished to maintain the right to refuse treatment (37). These findings underline the controversy regarding informal coercion, which was also outlined by Norvoll and Pedersen where participants described informal coercion as part of a gray zone and only a few found it to be helpful for their mental health (27). Patients and other stakeholders with critical attitudes toward coercion would decidedly challenge the use of informal coercion at all and emphasize the importance of the reciprocal therapeutic relationship (38). The representativeness of the patients included in the studies of this review has to be considered as limited. It mostly comprises individuals who were in treatment within the mainstream public mental health-care systems (mostly institutional) rather than complementary, private, or other services. Also, the study patients consented to participate in the studies what implies a certain willingness to cooperate with the services. This is commonly considered a major limitation for representativeness of study participants in research on coercion in psychiatry.

Albeit, most professionals tended to avoid the use of informal coercion due to the ethical problems attached to interventions utilizing (formal and informal) coercion, and staff underlines the effectiveness of informal coercion to achieve better clinical outcomes in patients. In order to stay aware and reduce the use of informal coercion, continuous discussions on the issue and supervisions are rated to be helpful. However, it has to be assumed that many situations in which informal coercion is applied in routine practice the acting clinician would not be aware of using informal coercion (22). Corresponding to the included studies on patients' perspective, professionals' study participants might not be representative for mental health professionals in general. The willingness to participate in a study on the issue of coercion might be higher in professionals who are prone to critically reflect on delicate subjects as well as their own attitudes and routines.

Clinical Relevance of Informal Coercion

Our review revealed that no study evaluated the clinical effects of informal coercion as a primary outcome in an appropriate study design. This may be due to methodological as well as ethical problems attached to such a study. Psychiatric treatment is a complex and multifaceted process including many factors that may help the patient to recover. It seems difficult to set up a study design that would allow for a comparison of two similar groups of patients with one undergoing a treatment process including the use of informal coercion and another receiving the same treatment without informal coercion. It might be feasible to study different therapeutic attitudes in the treatment of a selected group of patients, e.g., individuals with psychosis concerning certain decision-making processes, such as choice of medication. In this context, an operationalized negotiation process could be applied to two groups of patients with one including persuasion and inducements and one on a merely informative basis. However, this would be highly artificial and disregard the individual nature and dynamic constitution of a sound therapeutic relationship that would be the basis of a realistic decision-making process. This would be a considerable limitation for the validity of the results of such a study.

Thus, it seems comprehensible that the studies reviewed in the present article refrain to the subjective evaluation of effectiveness of informal coercion interventions by professionals and patients. Although there are several studies reporting rather positive evaluations of clinical effects in terms of fostering adherence, clinical stability, and avoiding relapse, it is not possible to draw convincing conclusions. It seems highly dependent on some process-related aspects if informal coercion is accepted by patients as beneficial for their recovery. This includes a low level of perceived coercion, high perceived fairness, and sound procedural justice (39). Mental health professionals might miss the importance of these process-related factors and tend to hold a rather utilitarian attitude toward informal coercion. Thereby, professionals are at stake to contribute to the stigma of coercion in psychiatric treatment that might lead to avoidance of the mental health system (37). The use of financial or other forms of leverage may lead to unclear responsibilities for potentially harmful medication effects, especially in the long term (25). Additionally, benefits of coercively taken medication may be extenuated by decreased satisfaction with treatment (30).

Ethical and clinical guidelines for the use of informal coercion are crucial for raising and keeping awareness on the issue similarly to formal coercion. In fact, few contemporary guidelines on the use of coercion in health care amplified their scope beyond formal coercion on informal coercion (40). Accordingly, coercive interventions including informal coercion should only be applied under the restriction of commensurability, i.e., if less invasive interventions are not available or have proven not to be effective and the expected benefit outweighs the potential harm by the intervention itself. Autonomy of the patients must always be respected and prioritized when making a decision for a treatment or care intervention. Communication and documentation has to be transparent and appropriate (40). However, applying informal coercion in an ethically, legally, and therapeutically sound procedure requires the awareness that leverage and other forms of informal coercion are very frequently used in daily mental health-care routine. Mental health professionals should, therefore, be competent to realize when they apply informal coercion and know about the impact of informal coercion as well as ethical guidelines for the use of coercion. A more prominent place for the issue of informal coercion and the therapeutic relationship in educative curricula of mental health professionals as well as more in-depth qualitative and quantitative research on informal coercion have to be strongly recommended.

Limitations

The present systematic review provides a general overview on studies evaluating the prevalence, attitudes, and clinical effect concerning informal coercion. With respect to some important limitations, the results have to be interpreted with care. This review is merely descriptive, and no meta-analysis was intended or possible to conduct. Although the research was performed systematically, it is not known if all available publications were detected, especially the gray literature (i.e., research produced outside the academic publication channels). Most studies were conducted in the US and Europe. And although one study also included study sites in Canada, Chile, and Mexico, the results cannot be easily transferred to other countries or even regional contexts. Moreover, the methodological quality of the studies is limited, and no causal associations concerning clinical effects and consequences of informal coercion can be deducted. The use of informal coercion is supposedly interrelated with societal context, organization of the health-care system, the educational level of professionals, and many other factors that were not comprehensively controlled for in the included studies. Additionally, the representativeness of the samples was not evaluated. However, despite multiple limitations of the present review, some important aspects on informal coercion in mental health care can be concluded.

CONCLUSION

This is the first review on informal coercion in mental health care. Most studies focus on leverage in general and specific leverage tools in various clinical and non-clinical contexts. Remarkably, frequent experience with informal coercion was reported by both, professionals as well as patients. The attitudes were rather positive in professionals as well as in patients at least if informal coercion was applied according to a number of procedural aspects that are also included in ethical guidelines for coercive practices in medicine (respect for patient's autonomy, procedural fairness, and transparency in communication). There is no evidence on the clinical effects of informal coercion but subjective evaluations on potential consequences, i.e., enhancement of adherence, promotion of clinical stability, and avoidance of relapse. Negative consequences such as increasing stigma of psychiatric services, impairment of the therapeutic relationship and consequent avoidance of mental health care are considered potential adverse effects.

AUTHOR CONTRIBUTIONS

Conception and design; data collection, analysis, and interpretation; drafting the article and revising it critically for important intellectual content: FH and MJ.

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REVIEW
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Updates and Current Perspectives of Psychiatric Assessments after Traumatic Brain Injury: A Systematic Review

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Neuropsychological and psychiatric disorders represent a major concern and cause of disabilities after the trauma, contributing to worse recovery after traumatic brain injury (TBI). However, the lack of well-defined parameters to evaluate patient's psychiatric disorders leads to a wide range of diagnoses and symptoms. The aim of this study was to perform a review of literature in order to gather data of the most common scales and inventories used to assess and diagnose depression, anxiety, and posttraumatic stress disorder (PTSD) after TBI. We conducted a literature search *via* MEDLINE, PubMed, and Web of Science. We included reviews, systematic reviews, and meta-analysis studies, and we used the following keywords: "traumatic brain injury OR TBI," "depression OR depressive disorder," "anxiety," and "posttraumatic stress disorder OR PTSD." From 610 titles, a total of 68 systematic reviews or meta-analysis were included in the section "Results" of this review: depression ($n = 32$), anxiety ($n = 9$), and PTSD ($n = 27$). Depression after TBI is a more established condition, with more homogeneous studies. Anxiety and PTSD disorders have been studied in a heterogeneous way, usually as comorbidity with other psychiatric disorders. Some scales and inventories designed for the general community may not be appropriate for patients with TBI.

Keywords: traumatic brain injury, psychiatry, depression, anxiety, posttraumatic stress disorder, assessment, scales, inventory reporting, questionnaires

INTRODUCTION

Globally, traumatic injuries are responsible for more than five million deaths annually, and traumatic brain injury (TBI) is one of the leading causes of disabilities and death. It is estimated that 1.7 million cases of TBI occur each year in the United States (USA), resulting in 52,000 deaths (1). Therefore, TBI represents around one-third (30.5%) of all injury-related deaths in the USA (1).

Traumatic brain injury usually results in brain disorders, leading to a heterogeneous spectrum of morbidities, ranging from transitory disturbances to permanent symptoms (2–6). Cognitive and psychiatric disorders are the common causes of disabilities and may cause difficulties in recovery after TBI (7–10). In diffuse axonal injury, disruption of the neural circuitry between the prefrontal cortex and limbic system (11, 12) can result in mood disorders arising even weeks or months after the initial injury (13).

Gordon et al. (14) reviewed rehabilitation in TBI and highlighted the need for a better understanding of the dynamics of recovery. They argue that only a few studies used measures accepted as "gold standards" (14). In 2010, the National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDE) was created to develop data standards for clinical research in patients with TBI (15). However, even with the proposal of some guidelines, psychiatric functions are still being assessed in a heterogeneous manner (16, 17). Therefore, the aim of this study is to summarize the literature, including reviews, systematic reviews, and meta-analyses, regarding the scales and inventories most commonly used to diagnose and evaluate depression, anxiety, and posttraumatic stress disorder (PTSD) in patients with TBI. To assess a large number of published articles, we used an original method in order to have a global view of the instruments used in diagnosis over the years.

METHODS

We conducted a literature search *via* online databases including MEDLINE, PubMed, and Web of Science. We included reviews, systematic reviews, and meta-analysis studies. In our search, we used the following keywords: "traumatic brain injury OR TBI," "depression OR depressive disorder," "anxiety," and "posttraumatic stress disorder OR PTSD." Abstracts and full text were carefully read, and studies were included in our review if they fulfilled the following inclusion criteria: (a) description/citation of the scale, questionnaire, or inventory used, (b) published in a peer-reviewed journal, (c) description of quantitative assessment for diagnosis, (d) full text written in English, and (e) adult participants. We selected studies published up to February 2016.

Searching and data analysis were performed by Ana Luiza Zaninotto and Jessica Elias Vicentini, both of whom have experience with mental health intervention and clinical research in TBI. All reviews and full text were read by the two reviewers and were included if they met the above-mentioned inclusion criteria. This selection method follows previous literature (18).

RESULTS

We reviewed 610 titles and abstracts and selected studies according to our inclusion and exclusion criteria. Of those, 362 studies were excluded, of which 248 were reviewed entirely (full text). Sixty-nine studies were included in the review focusing on one or more aspects of the following three topics of interest: (a) depression ($n = 32$), (b) anxiety ($n = 9$), and (c) PTSD ($n = 27$). Of the 68 studies, 11 studies had overlapping topics of interest, since they met criteria for more than one psychiatric disorder (17–27). The abstracts and full text that did not meet the inclusion criteria were excluded from the review ($n = 541$). The main reasons for exclusion were that the studies did not report the instruments used to assess the psychiatric disorders and/or the psychiatric assessment was not the center of the study ($n = 447$). The remaining excluded articles ($n = 94$) were either not related to TBI samples, focused on the neurological basis of the psychiatric disease, discussed pharmacological interventions, or did not focus on psychiatric disorders (depression, anxiety, or PTSD).

Each step of the search and review process is detailed in a flow diagram (**Figure 1**), based on the PRISMA work group (28).

In **Table 1**, we present studies ($n = 31$) that assessed depressive symptoms or diagnosed depression following TBI. Five of these were meta-analyses. Seven studies analyzed assessments of depression related to TBI in veterans, military personnel, or war-related injuries. We observed that the Beck Depression Inventory (BDI) was presented in all the studies, followed by Structured Clinical Interview for DSM (SCID) and Diagnostic and Statistical Manual (DSM) diagnosis criteria. For TBI populations, the BDI, Symptoms Checklist (SCL), and Center for Epidemiologic Studies-Depression Scale (CES-D) were the most cited self-reported scales. For diagnosis of depression, DSM criteria were the most commonly used, followed by International Classification of Diseases (ICD). The most commonly used instrument was the Hamilton Depression Rating Scale (HAM-D). **Table 2** shows different instruments were cited to assess depression.

Table 3 shows the nine studies that assessed anxiety disorders after TBI. Eight of these studies overlapped with other psychiatric conditions. Just one review focused on the anxiety sequelae after TBI (99). The Hospital Anxiety and Depressive Symptoms Scale (HADS) was the most cited instrument to assess anxiety, followed by State-Trait Anxiety Inventory (STAI). The DSM criteria were most commonly used to diagnose anxiety. **Table 4** shows the instruments cited in the anxiety reviews that were analyzed.

In our search, we found 26 reviews and meta-analyses related to PTSD and TBI. We identified two types of studies, one focusing on military veterans or war-related TBI ($n = 13$), and another focusing on a non-specific TBI population ($n = 13$) (**Table 5**). **Table 6** shows a summary of the scales and inventories used to assess PTSD in TBI populations. The PTSD Checklist (PCL) is most commonly used to assess PTSD in veteran and military samples, followed by the Clinician-Administered PTSD Scale (CAPS). PTSD Checklist – Military version (PCL-M) and PTSD Checklist – Civilian version (PCL-C) were the most cited self-reported scales. DSM criteria were used to diagnose PTSD, while ICD was not cited in any of the studies we analyzed.

DISCUSSION

Depression

Major depression and dysthymia are frequently diagnosed using structured clinical interviews meeting DSM or ICD criteria. Depression often occurs in the first year after TBI (12). Estimates for posttraumatic depression range from 6 to 77% (151, 152), depending on diagnostic criteria, assessment methods, and timing post-trauma (22, 23, 152). Concomitant brain injury is a strong predictor of depression after TBI (13). In addition, poor mental health after TBI involves several factors, including young age at the time of injury, short duration between the injury and assessment, pain, lower levels of social support (153), and lack of hope (40). For those patients, consequences of depression include greater interpersonal difficulties, higher rates of unemployment (152), increased rates of distress, and problems with rehabilitation (154).

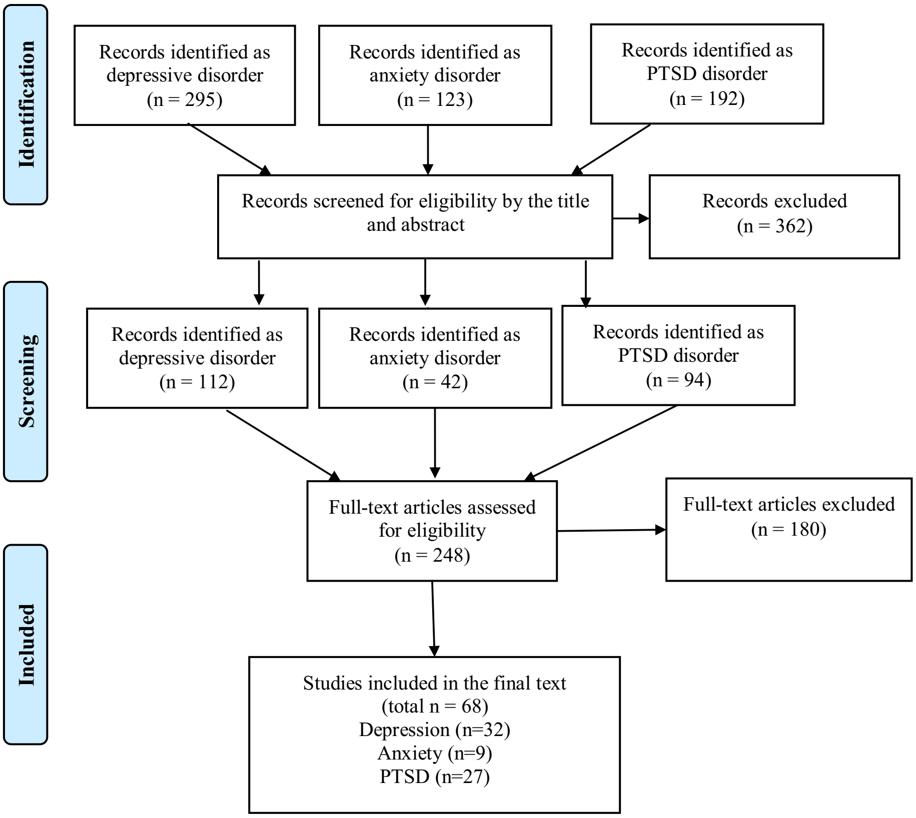

FIGURE 1 | **Flow diagram**.

Some studies focus on specific TBI populations including the elderly, women, and veterans. Menzel (38) reviewed depression in the elderly after TBI, but the author found only one original study (104), leading to inconclusive findings. In their study, Levin et al. (104) assessed depressive symptoms by the Geriatric Depression Scale (GDS). Since this scale has been designed and standardized for geriatric populations with no history of TBI, there is a potential risk of overlapping the symptoms of TBI and depression. In addition, GDS cannot be used as a criterion for diagnostic assessment.

Seven studies addressed combat veterans with sustained TBI (18, 19, 22, 23, 31, 33, 36). They reported limited evidence that deficits and symptoms are distinct between veterans with or without a history of mild TBI (mTBI). O'Neil et al. (23) also highlighted a study (155) that showed an increased risk of suicide post-TBI compared to the non-TBI population. As we reported before, the BDI was the most cited inventory used in this sample. It contains 21 symptoms correlated with self-reported depression. The newer version of the BDI, the Beck Depression Inventory II (BDI-II), produced scores two points higher when compared to the oldest version for psychiatric outpatients (49). For this reason, comparisons between studies need to be carefully done.

One study addressed the literature focusing on women with TBI, comorbidity with depression, and hopelessness (40). The study analyzed symptoms both qualitatively and quantitatively. They concluded that mental health seems to deteriorate after TBI. Social isolation is of particular concern as a consequence of poor emotional functioning in these patients. In their study, the authors also reported on sex-based differences and limited data on the incidence of sex-specific depression.

Osborn et al. (17) showed the prevalence of major depression disorder (MDD) and dysthymia ranged from 14% using International Classification o Diseases (ICD-10) criteria to 43% using DSM-III criteria. For self-reported scales, the range of depression was between 16 and 33%. They found higher prevalence rates of depression using NFI than SCID-I, Schedules for Clinical Assessment in Neuropsychiatry (SCAN), or Mini-International Neuropsychiatric Interview (MINI). The occurrence of MDD and dysthymia appears to rise in the first 5 years after brain injury (from 21 to 43%). However, the majority of the studies used mixed TBI severity samples and did not report separate outcomes for these subgroups (17). Still, the HAM-D is wildly used to diagnose MDD in patients with TBI.

It is appropriate to use the standard diagnostic criteria for depression when evaluating persons with TBI. The CDE recommends scales and inventories to assess symptoms of depression in adults with TBI (15): the BDI-II, Brief Symptom Inventory-18 (BSI-18), CES-D, and Patient Health Questionnaire-9-Item (PHQ-9).

TABLE 1 | Characteristics of the studies and the scales and inventories used to assess depressive disorder after TBI.

Reference	Study design	Study population	Number of analyzed studies/ total of studies	Instruments
Adamson et al. (29)	Meta-analysis	Neurologic patients	(3/26)	BDI, HADS
Barker-Collo et al. (30)	Meta-analysis	TBI	13	BDI, BDI-II, CES-D, HAM-D, LSSAD, SCL-90-R
Capehart and Bass (19)	Review	Veterans with TBI and PTSD	N/A	HAM-D, BDI
Cooper et al. (31)	Systematic review	Military veterans with mTBI	(4/19)	BDI, BDI-II
Crisp (32)	Systematic review	MDD, SCI, TBI, CBP, MI/CG	(8/54)	BDI, GHQ, CES-D, HAM-D, SCL-90-R
Daggett et al. (33)	Systematic review	Combat veterans who had sustained TBI	(3/17)	BDI, CES-D, CPRS, SCID, VAS-D
Fann et al. (34)	Systematic review	TBI	26	BDI, BDI-II, BPRS, DSM-III-R, HADS, HAM-D, MADRS, PHQ-9, SCL-90-R
Fleminger et al. (35)	Review	TBI	(9/N/A)	BDI, DSM-IV, HAM-D, NFI, SCL-R-90
Garrelfs et al. (20)	Systematic review	ABI	(6/7)	BDI, HADS, HAM-D, SCID-I
Gordon et al. (14)	Systematic review	TBI	N/A	BDI, BDI-II, DSM-IV, CES-D, MCMI, MMPI II, NFI SCL-90-R, SCID
Halbauer et al. (36)	Review	War-related mild to moderate TBI	N/A	BDI, DSM-III, DSM-III-R, DSM-IV-TR, NFI
Hesdorffer et al. (37)	Systematic review	TBI	(4/N/A)	ICD-9-CM; DIS; PSE, SCID
Kim et al. (21)	Systematic review	TBI	(15/66)	BDI, BDI-II, SCID, DSM III, DSM-III-R, DSM-IV, CES-D, NFI, NIMH-DIS, mNIMH-DIS, SCID-I, Wimbledon-SRS
Matarazzo et al. (18)	Systematic review	Veterans with TBI	3	BDI-II, SCID
Menzel (38)	Systematic review	TBI in elderly	1	GDS
Nowrangi et al. (39)	Review	TBI with suicidal risk	N/A	BDI, HAM-D, SCID
O'Neil et al. (22)	Systematic review	Veterans/military population with mTBI	(8/31)	BDI-II, DSM-IV, HADS, SCID-I
O'Neil et al. (23)	Systematic review	Veterans/military population with mTBI	(8/31)	BDI-II, DSM-IV, HADS, SCID-I
Osborn et al. (17)	Meta-analysis	Closed TBI	93	BDI-II, BDICES-D, CIDI, CIS, DIS, DSM-III, DSM-IV, GDS, HADS, ICD-10, LSSAD, MADRS, MINI, SCAN, SCID, PSE, PHQ-9, NFI, SADS-L, SCID, ZSDS
Oyesanya and Ward (40)	Systematic review	Woman with TBI	12	BDI-II, Adaptation of BRFSS, CES-D, HADS, DSM-IV
Panayiotou et al. (24)	Meta-analysis	mTBI	(9/11)	BDI, CES-D, HAM-D, NBAP, POMS, SCL-90, SCL-90-R, ZSDS
Rogers and Read (25)	Systematic review	TBI	(13/N/A)	CES-D, CID, CID-9-CM, DSM-III, DSM-IV, DIS, HAM-D, MMPI, NFI, PSE, PTSD-I, SCAN, SCL-90-R
Rosenthal et al. (41)	Systematic review	TBI	30	BDI, BPRS, CAQ, DSM-III, DSM-III-R, LSSAD, HSCL, HAM-D, MMPI, NIMH-DIS, PACL, PAI, PSE, POMS, SCL-90-R, ZSDS
Sherer et al. (42)	Systematic review	TBI	23	BDI, HADS, NEO-PI-R, Wimbledon-SRS
Simpson and Tate (43)	Review	TBI	19	BDI, BHS, DSM-III-R, PSE
Soo and Tate (26)	Systematic review	mTBI	3	BDI, SCL-90-R
Stalder-Luthy et al. (44)	Meta-analysis	ABI	13	BDI, BDI-II, CIQ, CES-D, CSA, DASS-21, DDS, ERS, GAS, GSI, HADS, MHLC, POMS, PSS, PHQ-9, RSE, SCL-90, SIP, TSK
Steel et al. (45)	Systematic review	Traumatic injury	N/A	BDI, BSI-18, CES-D, DISCs, HADS, HAM-D, HSCL-20, NFI, PHQ-9, SCID, ZSDS
Vahle et al. (46)	Review	People with disabilities	(7/N/A)	BDI, BSI, CES-D, DACL, MEDS, TBDI, ZSDS
van Velzen et al. (47)	Systematic review	Traumatic and non-traumatic ABI	22	BDI, NFI, SCID
Warden et al. (27)	Systematic review	TBI	(7/14)	BDI, HAM-D, DSM-IV

ABI, acquired brain injury; BDI, Beck Depression Inventory 2nd edition; BDI, Beck Depression Inventory; BHS, Beck Hopelessness Scale; BPRS, Brief Psychiatric Ranting Scale; BRFSS, Behavioral Risk Factor Surveillance System; BSI, Brief Symptom Inventory; BSI-18, Brief Symptom Inventory-18; CAQ, Clinical Analysis Questionnaire; CBP, chronic back pain; CES-D, Center for epidemiological studies; CIDI, Composite International Diagnostic Interview; CIS, Clinical Interview Schedule; CPRS, Compreensive Psychopathological Rating Scale; DACL, Depression Adjective Checklist; DASS-21, Depression Anxiety Stress Scale, DIS, Diagnostic Interview Scale; DISCs, Depression Intensity Scale Circles; DSM-III, Diagnostic and Statistical Manual 3rd edition; DSM-IV, Diagnostic and Statistical Manual 4th edition; GDS, Geriatric Depression Scale; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; HAM-D, Hamilton Depression Rating Scale; HSCL, Hopkins Symptom Checklist; HSCL-20, Hopkins Symptom Checklist-20; ICD- 10, International Classification of Diseases 10th revision; ICD-9, International Classification of Diseases 9th revision; LSSAD, Leeds Scale for the self-assessment of Anxiety and Depression; MADRS, Montgomery–Asberd Depression Rating Scale; MCMI, Millon Clinical Multiaxial Inventory; MDD, Major depressive disorder; MEDS, Medical-Based Emotional Distress Scale; MINI, Mini-International Neuropsychiatric Interview; MI/CG, myocardial infarction/coronary bypass grafting; MMPI, Minnesota Multiphasic Personality Inventory; MMPI-2, Minnesota Multiphasic Personality Inventory 2; mNIMH-DIS, Modified NIMH's Diagnostic Interview Schedule; mTBI, mild traumatic brain injury; NEO-PI-R, NEO Personality Inventory Revised; NFI, Neurobehavioral Functioning Inventory; NIMH-DIS, NIMH's Diagnostic Interview Schedule; PACL, Personality Adjective Checklist; PAI, Portland Adaptability Inventory; PHQ-9, Patient Health Questionnaire-9; POMS, Profile of Mood State; PSE, Present State Examination; SADS-L, Schedule for Affective Disorders and Schizophrenia (lifetime); SCAN, Schedules Clinical Assessment in Neuropsychiatry; SCI, spinal cord injury; SCID, Structured Clinical Interview for DSM; SCL 90-R, Symptoms Checklist 90-Revised; STAI, State-Trait Anxiety Inventory; TBDI, Talbieh Brief Distress Inventory; VAS-D, Visual Analog Scale for Depression; Wimbledon-SRS, Wimbledon Self-Report Scale; ZSDS, Zung Self-Rating Depression Scale.

TABLE 2 | Scales and inventories used to assess depressive disorder after TBI.

Name of the scale	Abbreviation	Clinical utility
Beck Depression Inventory (48)	BDI	Interview schedule
Beck Depression Inventory 2nd edition (49)	BDI-II	Interview schedule
Beck Hopelessness Scale (50)	BHS	Interview schedule
Behavioral Risk Factor Surveillance System (51)	BRFSS	Interview schedule
Brief Psychiatric Rating Scale (52)	BPRS	Interview schedule
Brief Symptom Inventory (53)	BSI	Interview schedule
Brief Symptom Inventory-18 (54)	BSI-18	Interview schedule
Center for Epidemiologic Studies – Depression form (55)	CES-D	Interview schedule
Clinical Analysis Questionnaire (56)	CAQ	Interview schedule
Clinical Interview Schedule (57)	CIS	Interview schedule
Composite International Diagnostic Interview (58)	CIDI	Interview schedule
Comprehensive Psychopathological Rating Scale (59)	CPRS	Interview schedule
Depression Adjective Checklist (60)	DACL	Interview schedule
Depression Anxiety Stress Scale 21 (61)	DASS-21	Interview schedule
Depression Intensity Scale Circles (62)	DISCs	Interview schedule
Diagnostic and Statistical Manual 3rd edition [DSM-III (63)]	DSM-III	Diagnose
Diagnostic and Statistical Manual 4th edition [DSM-IV (64)]	DSM-IV	Diagnose
Diagnostic Interview Scale (65)	DIS	Interview schedule
General Health Questionnaire (66)	GHQ	Interview schedule
Geriatric Depression Scale (67)	GDS	Interview schedule
Hamilton Depression Rating Scale (68)	HAM-D	Diagnose
Hopkins Symptom Checklist (69)	HSCL	Interview schedule
Hopkins Symptom Checklist-20	HSCL-20	Interview schedule
Hospital Anxiety and Depression Scale (70)	HADS	Interview schedule
International Classification of Diseases 9th revision (71)	ICD-9	Diagnose
International Classification of Diseases 10th revision (72)	ICD-10	Diagnose
Leeds Scale for the self-assessment of Anxiety and Depression (73)	LSSAD	Interview schedule
Mayo-Portland Adaptability Inventory (74)	MPAI	Interview schedule
Medical-Based Emotional Distress Scale (75)	MEDS	Interview schedule
Millon Clinical Multiaxial Inventory (76)	MCMI	Interview schedule
Mini-International Neuropsychiatric Interview (77)	MINI	Interview schedule
Minnesota Multiphasic Personality Inventory – 2 (78)	MMPI-2	Interview schedule
Minnesota Multiphasic Personality Inventory (79)	MMPI	Interview schedule
Montgomery–Asberg Depression Rating Scale (80)	MADRS	Diagnose
NEO Personality Inventory Revised (81)	NEO-PI-R	Interview schedule
Neurobehavioral Functioning Inventory (82)	NFI	Interview schedule
NIMH's Diagnostic Interview Schedule (83)	NIMH-DIS	Diagnose
NIMH's Diagnostic Interview Schedule modified (84)	mNIMH-DIS	Diagnose
Patient Health Questionnaire-9 (85)	PHQ-9	Interview schedule
Personality Adjective Checklist (86)	PACL	Interview schedule
Present State Examination (87)	PSE	Interview schedule
Profile of Mood State (88)	POMS	Interview schedule
Schedule for Affective Disorders and Schizophrenia (lifetime) (89)	SADS-L	Interview schedule
Schedules Clinical Assessment in Neuropsychiatry (90)	SCAN	Interview schedule
State-Trait Anxiety Inventory (91)	STAI	Interview schedule
Structured Clinical Interview (92)	SCID	Diagnose
Symptoms Checklist 90-Revised (93)	SCL 90-R	Interview schedule
Talbieh Brief Distress Inventory (94)	TBDI	Interview schedule
Visual Analog Scale for Depression (95, 96)	VAS-D	Interview schedule
Wimbledon Self-Report Scale (97)	Wimbledon-SRS	Interview schedule
Zung Self-Rating Depression Scale (98)	ZSDS	Diagnose

Anxiety

Anxiety disorders are frequently comorbid after TBI; there is a complex and multifaceted relationship, considering that premorbid anxiety is a predictor of the development of depression and anxiety disorders post-TBI (156).

Anxiety disorders post-TBI have multiple etiologies, from environmental to biological/genetic. Anxious reactions usually follow brain injury occurring in the setting of traumatic events, such as motor vehicle accidents, falls, and assaults (157). We observed in our results that just one study aimed to analyze the

TABLE 3 | Characteristics of the studies and the scales and inventories used to assess anxiety disorder after TBI.

Reference	Study design	Study population	Number of analyzed studies/total of studies	Instruments
Garrelfs et al. (20)	Systematic review	ABI (TBI = 4)	(3/7)	HADS, HAM-A, NRS, STAI
Moore et al. (99)	Review	mTBI	N/A	BAI, MMPI, MCMI-III, STAI
O'Neil et al. (22)	Systematic review	Veterans/military with mTBI	(6/31)	HADS, NSI
O'Neil et al. (23)	Systematic review	Veterans/military with mTBI	(6/31)	HADS, NSI
Osborn et al. (17)	Meta-analysis	Closed TBI	41	BAI, HADS, DSM-IV; DSM-III-R, DSM-IV; ICD-10, LSSAD, MINI, SCID-I, SCAN, SADS-L; STAI
Panayiotou et al. (24)	Meta-analysis	mTBI	(5/11)	BAI, CAPS, GHQ, HTQ, IES, POMS, SCL-90-R
Rogers and Read (25)	Review	TBI	N/A	BEC, BSQ, DES, DIS, DSM-III, MMPI, PCSSC, DSM-IV, SCAN, SCL-90-R
Soo and Tate (26)	Systematic review	mTBI	3	BAI, IES, SCL-90-R, STAI-S
Warden et al. (27)	Systematic review	TBI	(1/14)	Y-BOCS

ABI, acquired brain injury; mTBI, mild traumatic brain injury.

Scales: BAI, Beck Anxiety Inventory; BEC, Behavior Evaluation Checklist; BSQ, Body Sensations Questionnaire; DES, Dissociative Experience Scale; DIS, Diagnostic Interview Schedule; DSM-III, Diagnostic and Statistic Manual 3rd edition; DSM-IV, Diagnostic and Statistic Manual 4th edition; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; HAM-A, Hamilton Anxiety Scale; HTQ, Harvard Trauma Questionnaire; ICD-10, International Classification of Diseases; IES, Impact of Events Scale; LSSAD, Leeds Scale for the Self-Assessment of Anxiety and Depression; MCMI-III, Millon Clinical Multiaxial Inventory 3rd edition; MINI, Mini-International Neuropsychiatric Interview; MMPI, Minnesota Multiphasic Personality Inventory; NRS, Neurobehavioral Rating Scale; NSI, Neurobehavioral Symptom Inventory; PCSSC, Post-Concussion Syndrome Symptom Checklist; POMS, Profile of Mood State; PTSD-I, PTSD Interview; SADS, Schedule for Affective Disorders and Schizophrenia; SCAN, Schedules for Clinical Assessment in Neuropsychiatry; SCID-I, Structured Clinical Interview; SCL-90R, Symptoms Checklist, 90R; STAI, State-Trait Anxiety Inventory; Y-BOCS, Yale–Brown Obsessive Compulsive Scale.

TABLE 4 | Scales and inventories used to assess anxiety disorder after TBI.

Name of the scale	Abbreviation	Clinical utility
Beck Anxiety Inventory (50)	BAI	Interview schedule
Diagnostic Interview Schedule (65)	DIS	Interview schedule
Diagnostic and Statistic Manual 3rd edition [DSM-III (63)]	DSM-III	Diagnose
Diagnostic and Statistic Manual 3rd edition-revised [DSM-III-R (100)]	DSM-III-R	Diagnose
Diagnostic and Statistic Manual 4th edition [DSM-IV (64)]	DSM-IV	Diagnose
General Health Questionnaire (66)	GHQ	Interview schedule
Hamilton Anxiety Scale (68)	HAM-A	Diagnose
Hospital Anxiety and Depression Scale (70)	HADS	Interview schedule
Impact of Events Scale (101)	IES	Interview schedule
International Classification of Disease (102)	ICD-10	Diagnose
Leeds Scale for the Self-Assessment of Anxiety and Depression (103)	LSSAD	Interview schedule
Millon Clinical Multiaxial Inventory 3rd edition (76)	MCMI-III	Interview schedule
Mini-International Neuropsychiatric Interview (77)	MINI	Interview schedule
Minnesota Multiphasic Personality Inventory (79)	MMPI	Interview schedule
Neurobehavioral Rating Scale-Revised (104)	NRS-R	Interview schedule
Profile of Mood State (88)	POMS	Interview schedule
Schedule for Affective Disorders and Schizophrenia (89)	SADS	Interview schedule
Schedules for Clinical Assessment in Neuropsychiatry (90)	SCAN	Interview schedule
State-Trait Anxiety Inventory (91)	STAI	Interview schedule
Structured Clinical Interview (105)	SCID-I	Diagnose
Symptoms Checklist – 90R (106)	SCL-90R	Interview schedule
Yale–Brown Obsessive Compulsive Scale (107)	Y-BOCS	Interview schedule

sequelae of anxiety disorders after TBI (99). The other studies focused on the overall mental condition, including assessment of anxiety. One study analyzed the overall mental condition in a heterogeneous sample of patients with acquired brain injury (20). Three studies selected homogeneous samples: patients with closed TBI (17) and veterans/military personnel with mTBI (22, 23).

Osborn et al. (17) did a meta-analysis focusing on the prevalence of post-TBI generalized anxiety disorder (GAD). The results showed that approximately 11% of the patients were diagnosed with GAD after TBI, ranging from 2 to 28%. Taking into consideration the type of instrument used, the diagnostic scale ICD-10 was related to a lower prevalence rate (2%) of GAD after TBI, whereas the DSM-III-R was related to a higher prevalence (19%) of GAD (17). For interview schedules, SCAN showed a lower prevalence of GAD (2%), while the Schedule for Affective Disorders and Schizophrenia (SADS) showed a higher prevalence (28%) (17). The authors report differences in anxiety rates depending on the stages of TBI recovery. Thus, the timing of assessment may impact the number and severity of the symptoms, leading to bias in the results (158). The meta-analysis also

TABLE 5 | Characteristics of the studies and the scales and inventories used to assess PTSD after TBI.

Reference	Study design	Study population	Number of analyzed studies/type of studies	Instruments
Betthauser et al. (108)	Systematic review	Military veterans with TBI	(30/47)	CAPS, DSM-IV, DSM-IV-TR, DTS NSI, PCL, PCL-C, PCL-M, PC-PTSD, TSI
Brady et al. (109)	Review	Veterans with PTSD, SUD, TBI	N/A	CAPS, IES-R, MPSS-SR, M-PTSD, NWS-PTSD, PCL-M, PSEI, SUD
Capehart and Bass (19)	Review	Veterans with TBI and PTSD	N/A	PCL
Carlson et al. (110)	Systematic review	TBI	31	BSI, CAPS, CIDI, IES, IES-R, PCL-M, PCL, PTSD-I, PDS, PSS, PSE, SCID
Carlson et al. (111)	Systematic review	mTBI/PTSD	34	CAPS, IES, PDS
Cooper et al. (31)	Systematic review	Military veterans with mTBI	(10/19)	CAPS, MPAI-4, NSI, PCL, PCL-C, PCL-M, PHQ
Daggett et al. (33)	Systematic review	Veterans/military with TBI	(1/17)	PCL-C, SCID
Garrelfs et al. (20)	Systematic review	ABI (TBI = 4)	(1/7)	SCID-I
Gill et al. (4)	Systematic review	TBI	28	CAPS, CIDI, IES, IES-R, SCID, PCL, PDS, PSS, PTSD-I
Harvey et al. (112)	Review	TBI	N/A	CAPS, CIDI, DIS, DSM-IV, ICD-10, IES, PSS, PSE, Penn Inventory, PTSD-I, SCID
Hesdorffer et al. (37)	Systematic review	TBI	(5/N/A)	CIDI, CAPS
Karr et al. (113)	Systematic review	Blast-related mTBI	9	CAPS
Kennedy et al. (114)	Review	Military veterans with mTBI or PCS	N/A	DSM-III, DSM-III-R, DSM-IV, DSM-IV-TR
Kim et al. (21)	Systematic review	TBI	(16/66)	CAPS, DSM-III-R, PSE, IES, CIDI, DSM-IV, PDS, PTSD-I, SCID
Matarazzo et al. (18)	Systematic review	Veterans/military with TBI	3	CAPS, PCL-S
Moore et al. (99)	Review	mTBI	N/A	DSM-III-R, MCMI-III, MMPI
O'Neil et al. (23)	Systematic review	Veterans/military with mTBI	(17/31)	CAPS, PCL, PCL-C, PCL-M, PCL-S, SCID
O'Neil et al. (22)	Systematic review	Veterans/military with mTBI	(17/31)	CAPS, PCL, PCL-C, PCL-M, PCL-S, SCID
McMillan et al. (115)	Review	TBI	N/A	DSM-III, DSM-III-R, DSM-IV, IES
Rice and Sher (116)	Review	Veterans with TBI	N/A	DSM, PCL, PHQ
Rogers and Read (25)	Review	TBI	(7/N/A)	BEC, IES, HSCL, PTSD-I, SCL-90-R, SCID
Soo and Tate (26)	Systematic review	mTBI	(1/3)	CAPS, IES
Steel et al. (45)	Systematic review	Traumatic injury	N/A	PTSD-I, CAPS, CIDI, SCID, SI-PTSD, DIS, PDS, IES-R, PC-PTSD, PCL, HTQ, M-PTSD, Civilian-MSS, Purdue PTSD, Penn Inventory, TSI
Tanev et al. (117)	Systematic review	TBI	N/A	ANAM, CAPS, DTS, NSI, PSS, PCL, SI-PTSD, TSI
Trachtman (118)	Review	Veterans with TBI	N/A	DSM-IV, Halstead-Reitan test, ICD-9, MMPI, PCL-M, PDHA, PDHRA
Wall (119)	Systematic review	TBI in military and veteran population	20	ANAM, BSI, DSM-IV, ICD-9, ICD-10PCL, M-PTSD, NSI, PCL-M, PCL-C, PDHA, PDHRA, PHQ

PTSD, posttraumatic stress disorder; mTBI, mild traumatic brain injury.

Scales: ASDI, Acute Stress Disorder Interview; CAPS, Clinician-Administered PTSD Scale; CIDI, Composite International Diagnostic Interview; CSQ, Coping Style Questionnaire; Civilian-MSS, Civilian Mississippi Scale; DTS, Davidson Trauma Scale; DIS, Diagnostic Interview Schedule; M-PTSD, Mississippi Scale for Combat-Related PTSD; IES, Impact of Events Scale; IES-R, Impact of Events Scale-Revised; HTQ, Harvard Trauma Questionnaire; PCL, PTSD Checklist; PCL-C, PTSD Checklist – Civilian version; PCL-M, PTSD Checklist – Military version; PCL-S, PTSD Checklist – Stressor specific; PC-PTSD, Primary Care PTSD Screen; PDS, Posttraumatic Diagnostic Scale; PSE, Present State Examination; PSS, Posttraumatic Stress Scale; PSS-I, PTSD Symptoms Scale-Interview; SI-PTSD, Structured Interview for PTSD; PTSD-I, PTSD interview; SCID, Structured Clinical Interview for DSM; TSI, Trauma Symptoms Inventory.

showed a non-significant increase in the number of anxiety cases in the first 5 years post-trauma (17).

Two anxiety scales are suggested by the CDE for TBI populations: the Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS) and Neuropsychiatric Rating Schedule (NRS). Interestingly, these scales were not extensively reported in this review, and the NRS was not reported in any of them.

The authors also recommend assessing substance abuse as a comorbidity of psychiatric conditions, especially in anxiety disorders (22, 24). The CDE suggests some questionnaires for this purpose: the Substance Abuse Questions from the TBI Model Systems Database, Alcohol Use Disorders Identification Test: self-reported version (AUDIT), and Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST).

Posttraumatic Stress Disorder

Posttraumatic stress disorder and GAD showed high prevalence after TBI and were both classified as anxiety disorders. In 2013, the DSM-5 classified PTSD as a trauma-stressor-related disorder, rather than an anxiety disorder. For this reason, we classified PTSD and anxiety disorders as separate psychiatric conditions.

In TBI patients, PTSD is usually related to a severe accident or injury, violent assault, domestic violence, war, or disaster (Criterion A – DSM-5). Prevalence rates of PTSD after TBI range from 3 to 59% (159, 160), while 43.9% of soldiers who reported loss of consciousness post-TBI met the criteria for PTSD (161). Our findings support previous results in which the heterogeneous range of diagnoses is due to the differences in assessment methods and methodologies of the original studies (111).

TABLE 6 | Scales and inventories used to assess posttraumatic stress disorder (PTSD) after TBI.

Name of the scale	Abbreviation	Clinical utility
Acute Stress Disorder Interview (120)	ADIS	Interview schedule
Brief Symptoms Inventory (53)	BSI	Interview schedule
Civilian Mississippi Scale (121)	Civilian-MSS	Interview schedule
Clinician-Administered Posttraumatic Stress Disorder Scale (122)	CAPS	Interview Schedule
Composite International Diagnostic Interview (58)	CIDI	Interview schedule
Coping Style Questionnaire (123)	CSQ	Interview Schedule
Diagnostic and Statistical Manual 3rd edition [*DSM-III: n* (63)]	DSM-III	Diagnose
Diagnostic and Statistical Manual 3rd edition-revised [DSM-III-R (100)]	DSM-III-R	Diagnose
Diagnostic and Statistical Manual 4th edition [*DSM-IV* (64, 123)]	DSM-IV	Diagnose
Diagnostic and Statistical Manual 4th edition text revision [DSM-IV-TR (124)]	DSM-IV-TR	Diagnose
Diagnostic and Statistical Manual 5th edition [DSM-5 (125)]	DSM-5	Diagnose
Davidson Trauma Scale (126)	DTS	Interview schedule
Diagnostic Interview Schedule (83)	DIS	Interview schedule
Harvard Trauma Questionnaire (127)	HTQ	Interview schedule
Hopkins Symptom Checklist (69)	HSCL	Interview schedule
International Classification of Diseases 9th edition [*International Classification of Diseases (ICD)* (71)	ICD-9	Diagnose
International Classification of Diseases 10th edition (72)	ICD-10	Diagnose
Impact of Events Scale (101)	IES	Interview schedule
Impact of Events Scale-Revised (128)	IES-R	Interview schedule
Mayo-Portland Adaptability Inventory-4 (74, 129)	MPAI-4	Interview schedule
Mississippi Scale for Combat-Related Posttraumatic Stress Disorder (130)	M-PTSD	Interview schedule
Modified Posttraumatic Stress Disorder Symptom Scale (131)	MPSS-SR	Interview schedule
National Women's Study Posttraumatic Stress Disorder module (132)	NWS-PTSD	Interview schedule
Patient Health Questionnaire (85)	PHQ	Interview schedule
Penn Inventory for Posttraumatic Stress Disorder (133)	Penn inventory	Interview schedule
Post-Deployment Health Assessment (134)	PDHA	Interview schedule
Post-Deployment Health Reassessment (135)	PDHRA	Interview schedule
Posttraumatic Diagnostic Scale (136)	PDS	Interview schedule
Posttraumatic Stress Scale (137)	PSS	Interview schedule
Potential Stressful Events Interview (138)	PSEI	Interview schedule
Present State Examination (87)	PSE	Interview schedule
Primary Care Posttraumatic Stress Disorder Screen (139)	PC-PTSD	Interview schedule
Posttraumatic Stress Disorder Checklist (140, 141)	PCL	Interview schedule
Posttraumatic Stress Disorder Checklist – Civilian version (142)	PCL-C	Interview schedule
Posttraumatic Stress Disorder Checklist – Military version (143)	PCL-M	Interview schedule
Posttraumatic Stress Disorder Checklist – Stressor specific (144)	PCL-S	Interview schedule
Posttraumatic Stress Disorder Interview (145)	PTSD-I	Interview schedule
Self-rating Posttraumatic Stress Disorder Inventory (146)	SIP	Interview schedule
Posttraumatic Stress Disorder Inventory Revised (147)	Revised PTSD inventory	Interview schedule
Posttraumatic Stress Disorder Symptoms Scale-Interview (137)	PSS-I	Interview schedule
Purdue Posttraumatic Stress Disorder (148)	Purdue PTSD	Interview schedule
Symptoms Checklist 90-Revised (106)	SCL-90-R	Interview schedule
Structured Clinical Interview for DSM (105)	SCID	Diagnose
Structured Interview for Posttraumatic Stress Disorder (149)	SI-PTSD	Interview schedule
Trauma Symptoms Inventory (150)	TSI	Interview schedule

Depression, anxiety, and PTSD are usually comorbid conditions following TBI and may facilitate the persistence of its effects (162). Gill et al. (4) showed that psychological well-being is not predictive of the development of PTSD, but evidence suggests that individuals who have a history of psychological difficulties are at greater risk of developing PTSD after TBI.

Posttraumatic stress disorder is one of the most common mental health disorders affecting approximately 15% of veterans with no history of TBI. Nevertheless, the diagnosis rates of PTSD range from 33 to 65% in veterans with a history of TBI (163, 164). For this sample, the PCL is broadly used. The PCL-M and CAPS are the interview schedules most commonly used to assess PTSD in veterans and are recommended by the CDE (15). CAPS is considered the "gold standard" instrument for diagnosing and measuring the severity of PTSD, and it has been used with a variety of traumatized populations, including TBI (109, 165). There are different versions available, including CAPS to assess past-week, past-month, and lifetime symptoms. The PCL is a 17-item self-reported measure of PTSD symptoms and requires less time to complete than CAPS, which consists of a 30-item self-reported questionnaire. PCL is highly correlated with CAPS ($r = 0.93$), and it has favorable diagnostic efficiency (>0.70) and robust psychometric properties (165). For civilians with TBI, the PCL and CAPS are the most commonly used instruments to assess PTSD. However, the PCL-C and PTSD Checklist – Stressor specific (PCL-S) are preferable.

Overall, psychological variables, worsening general health, chronic pain, and somatic symptoms are associated with PTSD, especially in moderate to severe TBI. Comorbidities, such as PTSD and TBI, may unfavorably affect individuals more than suffering from any disorder alone (166). Some factors suggest how individuals with TBI might be more likely to develop PTSD. Somatic conditions and psychiatric disorders, such as PTSD, seem to perpetuate the illness condition in a loop (167). Those somatic conditions may present not only as risk factors but may also contribute to the persistence of other disorders, such as PTSD (4). This highlights the importance of therapy and rehabilitation for PTSD after TBI.

Brain Function and Mental Health Post-TBI

Symptoms of anxiety, depression, and irritability often occur after TBI and affect mood centers, including the hippocampus, amygdala, and prefrontal regions of the brain (168). Psychological factors are potential contributors to poor recovery after mTBI (8). Since TBI etiologies are diverse, understanding the role of the neurobiological basis for behavioral dysfunctions can be complex. The neuroanatomical location of the head injury can play a role in the development of depression (45, 169). However, only a small portion of patients may sustain damage to the particular location and with a severity level necessary to produce a psychiatric syndrome while preserving adequate cognitive function; thus, a biological gradient can be very difficult to detect (25). Premorbid factors associated with psychiatric disorders are inconclusive. Family history of psychiatric disorders seems to be a predictor of depression (169) or PTSD in individuals who have experienced TBI (45). In addition, females have a higher risk of developing acute PTSD after motor vehicle accidents (170). However, some authors did not find this association in premorbid psychiatric illness with the development of PTSD (171).

Acquired brain lesions, especially those involving the prefrontal cortex may have a prominent role in developing and maintaining executive functions. These functions encompass a set of skills that allow for people's adjustment and adaptation in the face of new situations and daily operation. Therefore, changes in executive functions are among the most common consequences resulting from TBI (172, 173). Depressive symptoms can also affect cognitive processes, inhibiting a patient's ability to return to daily activities over the short-term. Prefrontal cortex disruption may result in impulsive behaviors and a higher risk of substance use disorders (174). Thus, there is evidence that TBI may increase the risk of drug or alcohol abuse in persons without a history of substance abuse before the injury, especially if the damage involves the orbitofrontal cortex (175). In our review, only short reports attempted to find associations between mental health and substance abuse. Hesdorffer et al. (37) reported that changes in drug and alcohol use usually preceded the occurrence of TBI, increasing the risk of head injury. One important point is that many of the studies analyzed in the reviews used current alcohol or substance abuse as exclusion criteria, possibly camouflaging their frequency of occurrence.

Perspectives and Future Research

Considering the high incidence of TBI in the elderly (140–200 per 100,000 per year) and the relatively high prevalence of depression following TBI, it is reasonable to address the question of depression in the elderly following TBI (38). There is a gap in the literature addressing the evaluation and monitoring of elderly TBI patients.

One limitation related to veterans and military populations is that most of the analyzed data are from medical registries and clinical databases. It is necessary to have larger cohort studies, and it is also necessary to use standard methodology for the assessment of veterans and military populations.

Even in systematic reviews and meta-analyses, attrition bias may occur, as some studies showed that individuals who did not complete studies generally had more severe TBI (176–179) or, conversely, had less severe TBI (180). In addition, some studies did not control for confounding variables, such as the severity of trauma or the period post-TBI, reducing the generalizability of some results.

Many studies utilized self-report or semi-structured interviews for diagnosis. These results can lead to bias in the reported frequency of depressive disorder in this population. Self-report scales may not be reliable as patients with TBI may be unaware of their disabilities, and lack of awareness may lead to an underdiagnosis of psychiatric disorders (25). Another important variable relates to the recruitment of study participants. Outpatient and inpatient populations tend to vary in the intensity of their symptoms, particularly in the acute stage of trauma, when patients are often confused and disoriented. Many reviews analyzed mixed samples of trauma severity and different recruitment settings (17). Moreover, the majority of the instruments require that patients report their symptoms over the previous 2 weeks, and patients may have difficulty answering such questions or giving reliable responses, particularly in the acute stages of trauma.

Another important issue is the analysis of premorbid psychiatric conditions, a factor that may bias results. Finally, as we are reporting on specific information from selected reviews in the field, there is the risk of publication bias.

CONCLUSION

There is significant variability in the types of assessments used in the evaluation of psychiatric disorders after TBI, and consequently, there is also variability in the reported prevalence of such disorders. We analyzed meta-analyses and systematic reviews focusing on the most prevalent psychiatric conditions, and we observed a heterogeneous pattern related to their assessment and diagnosis in TBI populations. Depression after TBI is a well-established condition with homogeneous studies. Anxiety and PTSD disorders have been studied in a heterogeneous way, usually comorbid with other psychiatric disorders. The variability of clinical findings raises the importance of the instruments used to assess these patients. Finally, some scales and inventories designed for the general community may not be appropriate for patients with TBI (152).

AUTHOR CONTRIBUTIONS

AZ – had the idea of the review, organized the search method, and wrote the manuscript. JV – helped to write the manuscript and did the tables. FF – reviewed the manuscript and helped the elaboration of the manuscript. PR – helped to write the manuscript. CB – helped on the tables review. ML – helped to review the manuscript. WP – reviewed the manuscript.

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METHODS
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Development and Preliminary Validation of the Scale for Evaluation of Psychiatric Integrative and Continuous Care—Patient's Version

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This pilot study aimed to evaluate and examine an instrument that integrates relevant aspects of cross-sectoral (in- and outpatients) mental health care, is simply to use and shows satisfactory psychometric properties. The development of the scale comprised literature research, held 14 focus groups and 12 interviews with patients and health care providers, item-pool generation, content validation by a scientific expert panel, and face validation by 90 patients. The preliminary scale was tested on 385 patients across seven German hospitals with cross-sectoral mental health care (CSMHC) as part of their treatment program. Psychometric properties of the scale were evaluated using genuine and transformed data scoring. To check reliability and postdictive validity of the scale, Cronbach's α coefficient and multivariable linear regression were used. This development process led to the development of an 18-item scale called the "Scale for Evaluation of Psychiatric Integrative and Continuous Care (SEPICC)" with a two-point and five-point response options. The scale consists of two sections. The first section assesses the presence or absence of patients' experiences with various CSMHC' relevant components such as home treatment, flexibility of treatments' switching, case management, continuity of care, cross-sectoral therapeutic groups, and multidisciplinary teams. The second section evaluates the patients' opinions about these relevant components. Using raw and transformed scoring resulted into comparable results. However, data distribution using transformed scoring showed a smaller deviation from normality. For the overall scale, the Cronbach's α coefficient was 0.82. Self-reported experiences with relevant components of the CSMHC were positively associated with the patients approval of these components. In conclusion, the new scale provides a good starting point for further validation. It can be used as a tool to evaluate CSMHC. Methodologically, using transformed data scoring appeared to be preferable because of a smaller deviation from normality and a higher reliability measured by Cronbach's α.

Keywords: cross-sectoral mental health care, service users, validation, psychometric measurement, case management, home treatment, interdisciplinary professional practice

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INTRODUCTION

Cross-sectoral mental health care (CSMHC) in Germany provides care to patients with severe mental disorders (1). The advantage of using CSMHC teams lies in their ability to provide the appropriate level of care depending on the patient's needs. Although CSMHC programs are effective (2), evaluation studies assessing program implementation rarely include a discussion of the implementation measures' validity (3).

Imported scales that were developed for the assessment of comparable mental health services such as Assertive Community Treatment (4–6), Crisis Resolution Teams (7), Case Management (8), and Community Mental Health Teams (9–12) are inadequate as the German CSMHC differs in many respects from that in named health services (1).

In addition, nearly all existing tools for assessing specific care models rely exclusively on administrative data, evaluating characteristics of treatment from the health care providers' perspectives. As a result, they usually do not capture the specific effects and experiences of patients and their kin with treatment programs. Further, among those questionnaires that examine user perceptions, some focus on patient opinions (9), though without registering patient experiences (13–15), while others only evaluate satisfaction with mental health care (16). However, self-rated satisfaction is problematic, as patients' satisfaction was often correlated with the improvement of symptoms or individual characteristics instead of service features (17).

Thus, there is a need for standardized patient questionnaires that allow the concurrent assessment of patients' experiences and evaluations, and that are well suited to monitoring the characteristics of service provision. To our knowledge, no such questionnaires have been published in international or national literature. The purpose of the current paper was to develop a new, simply to use, and widely applicable, self-reporting questionnaire that covers both the patients' experiences and opinions about relevant components of CSMHC. The feasibility of the questionnaire and its scale evaluation as well as first psychometric properties should be investigated, on a preliminary basis using a representative sample of psychiatric patients.

MATERIALS AND METHODS

Development and feasibility testing of the scale was part of the preparations for a study on "Evaluation of Care Models based on the Regional Psychiatric Budget acc. §64b, V Book of German Social Law." Since these care models were new to German psychiatry there was no appropriate questionnaire to ask for patient's evaluation in this setting thus creating the need for developing an own instrument. The study was approved by the Ethics Committee of Medical Chamber Brandenburg [2016, No. S 7 (a)]. All eligible patients were given a comprehensive description of the study and informed that their participation or refusal would not affect their care. After positive patient decision of participation, the written informed consent was obtained.

The development and biometric evaluation of the scale were carried out in construction and pilot testing phases. The construction of the scale included five steps. Firstly, for generating the items, we examined the scientific literature regarding existing scales for assessment mental health services. The most salient themes from these searches were developed into a topic guide for stage 2. Stage 2 consisted of a qualitative study, using the Grounded Theory Methodology (18) in order to extract relevant components of CSMHC: psychiatric patients, their kin and mental health care workers were asked about their experiences with CSMHC and recurrent themes were used to generate items. Thirdly, the first author (Yuriy Ignatyev) created an item pool and a scientific expert panel which consisted of a psychologist and two psychiatrists assessed the content validity of the scale. The expert panel evaluated the wording and item allocation of the tool. In the fourth step, we evaluated face validity. A group of 90 patients from three German hospitals (Imland Klinik Rendsburg, Psychiatrische Klinik Lüneburg, Immanuel Klinik und Poliklinik Rüdersdorf) experienced in with CSMHC were asked to evaluate each item and to indicate if they felt difficulties in replying to the questions. An item was considered to be adapted or excluded if it was problematic for at least five patients. In the fifth step, selected items were checked for reliability, and then items with at least acceptable Cronbach's α values were combined to generate the preliminary version of the scale. The biometric evaluation aimed to take specific experience of patient into account as it was documented by part one of the questionnaire. In addition, intra-rater reliability was estimated by ratings for contradictory questions in part two of the questionnaire. The evaluation method was developed *a priori*, i.e., not based on empirical data.

The testing phase was carried out using a cross-sectional design in mental health departments of 7 from 16 German hospitals (Klinikum Itzehoe, Südharz Klinikum Nordhausen, Imland Klinik Rendsburg, Rudolf-Virchow-Klinikum Glauchau, Westenküstenklinikum Heide, Immanuel Klinik und Poliklinik Rüdersdorf, Psychiatrische Klinik Lüneburg) that offer CSMHC, from June to December 2016. The only criterion for the inclusion of any hospital into the research program was the given consent of hospitals administration. The sampling was conducted on the basis of equal patient strata from different care sectors (stations, day hospitals, outpatients' clinics, and on a number of occasions home treatment). The recruitment process *within* each care sector was based on a randomized design. A study group in each hospital consisted of one or two research doctors/psychologists. The inclusion criteria were: age $\geq$ 18 years, capacity to provide informed consent, ability to read, and understand German. Patients were excluded if they were involuntarily admitted or if their clinical condition limited comprehension (acute mental disorders, severe mental disability, etc.) as judged by their psychiatrist. To assess current psychopathology, a short version of the SCL-90-R (19) was used. The questionnaires were filled out by the participants without assistance. Additionally, some sociodemographic and clinical characteristics (gender, age, education status, employment status, family status, and duration of current mental disorder) were obtained.

A case number of 300 patients was calculated for the preliminary testing of the questionnaire and the biometric method to analyze it. This sample size was calculated to be efficient to detect effect sizes of about 0.333 between two groups of 150 patients or a correlation coefficient of 0.16 between two measures of each patient as significant with $\alpha = 5\%$ and power = 80% which seemed convenient for a feasibility study. A $p > 5\%$ and $<10\%$ were thought to represent a trend toward significance.

Common descriptive statistics (count, mean, SD, min, max, and median) were computed for all examined variables. No imputation for missing ratings was conducted as the rate of missing values was less than 5%. The heterogeneity of the responses to specific items was estimated as a quotient of the theoretical variance of random response (equally distributed) by the empirical variance. With respect to the experience questions only affirmative answers (YES) were taken into account as relevant. Both missing affirmative and negative (YES and NO) answers were interpreted as "no experience."

In order to be able to use the developed ratings as dependent variables for later CSMHC studies, the shape of the resulting distribution of total ratings was checked by estimating skewness and kurtosis and their SDs (20). The relevancy of both statistics was inspected by comparing the quotient of their value by their SD with the numeric value 2. Such procedure has to be interpreted carefully in case of greater deviation from normality (21), however. In our scale, patients are asked to rate therapeutic settings independently of their concrete own experience with these items which is asked for, too. This procedure reflects the fact that patient's opinions about therapeutic settings have a variety of sources such as social contacts and communication with other patients, friends, family, physicians, and media. Patient's opinions affect the therapy decisions and efficacy in a positive or negative way. Thus, they should be regarded even if there is a lack of concrete experience. We expected, however, that both reliability and validity of such ratings is lower in comparison with opinions of more experienced patients. To perform both calibration and validation, an assessment of uncertainty in both the data and the instrument is needed. For this purpose, *a priori* rating transformation and weighting was performed. As an accurate calibration of the scale regarding patient competencies could be difficult and there remains some amount of uncertainty we used a sensitivity analysis (22) to evaluate this procedure. Thus, in order to examine psychometric properties of the scale, both data sets (raw and transformed ratings) were analyzed and compared. Results were interpreted as a sensitivity analysis with exploratory character.

For practical reasons, the estimation of Cronbach's α internal reliability coefficient for only the opinion section of the scale was performed. A Cronbach's α between 0.6 and 0.7 is considered an acceptable value. A value between 0.7 and 0.9 is a good value, and a value of 0.9 or higher indicates excellent reliability (23). To examine postdictive validity of the experience scale with respect to the opinion rating scale, a multiple linear regression analysis using demographic and clinical characteristics (gender, age, education status, current psychopathology, and duration of current mental disorder) was conducted. According to Cohen's guidelines, $f2 \geq 0.02$, $f2 \geq 0.15$, and $f2 \geq 0.35$ represent small, medium, and large effect sizes, respectively (24, 25). The statistical computing was performed using SYSTAT 12.0 and nQuery + nTerim 2.0.

RESULTS

Developing Phase

Items Generation

23 papers were identified in which relevant components of innovative mental health care were explored. We did not find any literature on assessment scales for cross-sectoral mental health care. Nevertheless, a total of 12 papers were found on the relevance for covering assessment aspects for item generation addressing cross-sectoral mental health care. In total, eight papers were included. This search enabled the authors to identify salient concepts in order to produce a topic guide for the qualitative step of development of the scale.

To conduct the qualitative part of the study, two authors (Yuriy Ignatyev and Sebastian von Peter) were as guests in all mental hospitals included in the study. Fourteen focus groups and 12 interviews with mental health care providers were carried out. Additionally, 16 patients were interviewed. Interviews followed a semi-structured format that allowed interviewers to ask spontaneous questions that addressing individual experiences and opinions. On the basis of focus groups and interviews, an item pool was created that consisted of 9 questions relating to the patients' experiences with CSMHC and 30 questions relating to their evaluation of these experiences. The questions involved a wide range of themes such as home treatment, outpatient treatment, flexibility of treatments' switching, case management, cross-sectoral treatment groups' offering, involvement of relatives in the treatment, freely control of therapeutic measures, and interdisciplinary professional practice.

Experts did not suggest any changes of the experience section of the scale. However, they noted that two items from the evaluation section should be removed, as they did not relate to the concept of the scale. Examples of items removed included "*It is good when patients are able to seamlessly transfer between wards of treatment areas*." It was suggested that four items were in need of rewording as they may be too difficult to understand. Examples included "*I get better quickly when I can share the same space with patients from other treatment areas*," which was replaced by "*It is good when outpatients, inpatients, and day patients are cared in the same space*." No additional items were suggested but one expert did comment that a four-point Likert scale for assessing evaluations may be insufficient; the range was changed accordingly to a five-point scale, ranging from 0 "strongly disagree" to 4 "strongly agree." Expert panel discussions resulted in a scale with the experience section from 9 items and the opinion section included 24 items. To control of careless responses (26), eight of opinion items were worded negatively.

Based on the patients' viewpoints, six items of the evaluative section were removed due to difficulties of comprehension. Examples included "*Overlapping competencies among staff from different professions lead to competition and are detrimental to me*." Moreover, patients identified four redundant items and suggested that these items needed rewording. Examples included rewording "*Even patients that are acutely ill can receive home treatment*" to "*Acute patients could also be treated at home* (*i.e., home treatment*)." Two items were suggested as in need of clarifying. For example, "*If I have to change my status* (*i.e.*, *as an inpatient or day patient or outpatient*), *it is important that I have someone who can guide me through the different treatment areas*." was amended to "*If I have to change my status* (*i.e.*, *as an inpatient or day patient or outpatient*), *it is important that I have someone who can guide me through the different treatment areas and coordinates my treatment*." The eight items of the experience section were removed due to the poor reliability. The rest of eight items that had at least acceptable reliability were then grouped in the preliminary version of the section (see Supplementary Material). The section included also two negatively worded control opinion items (R5 and R8). In concordance with the reduction of the opinion section, the experience section was also reduced to five items. The domains involved in the whole scale were: current treatment setting (one experience item: E1with four subitems E1a, E1b, E1c, E1d), home treatment (two experience items: E7 and E8, two opinion items: R4 and R9), case management (two experience items: E3 and E4; two opinion items: R2 and R7), cross-sectoral treatment groups' offering (one experience item: E5, one opinion item: R3), flexibility of treatments' switching (one experience item: E2, two opinion items: R1 and R6), and interdisciplinary professional practice (one experience item: E6, one opinion item: R10). The scale concerns complex health care system and therefore some overlaps between content domains could be recorded. For example, the opinion item R6 (flexibility of treatments' switching) was related not only to experience item E2 but also showed overlapping with experience items E3 und E4 (case management).

Transformation and Weighting

The construction of the questionnaire resulted into eight items within the experience section, called E1–E8 (see Supplementary Material) in the following. With the exception of E1, each of these items requires a YES or NO answer. E1 is dedicated to the current setting and divided up into four subitems (E1a, E1b, E1c, E1d) to be answered with YES or NO, too. In two cases (E3/E4 and E7/E8) two items cover the same domain of experience, the first addresses this experience in a general and the second in a more meticulous way. For example, E7 asks for experience with home treatment and E8 if this experience was longer than 1 week. A score measuring total experience with situations addressed in this questionnaire was defined as the count of all E-items answered with YES.

The 10 items of the opinion section (R1–R10) have to be answered by a range from "strongly agree" to "strongly disagree" (see Supplementary Material), coded as 0–4. Specific experience is accessible for each of these ratings by experience items: The evaluative items R1, R3, R5, R8, and R10 correspond to items E2, E5, E6, E5, and E6 of the experience section, they cover the same domains. Items R2, R4, R6, R7, and R9 correspond to the doubled items E3/E4, E7/E8, E3/E4, and E7/E8. This correspondence between opinion ratings and experiences was used to develop a weighting of the ratings. For evaluation by a sensitivity analysis, we applied weights to the opinion rating scores with respect to the patient's corresponding experience. This weighting is documented in **Table 1**.

TABLE 1 | Weighting of opinion values using patient responses to corresponding experience questions.

	Experience question			**Weight defined**
	Single question[a]	**Two sequent questions[b]**		
		First question	**Second question**	
Response to experience question	YES[c]	YES	YES	1
		YES	Not YES[d]	0.75
	Not YES	Not YES	Not YES	0.5
		Missing[e]	YES	0.25
		NO[f]	YES	0

Corresponding experience (E) and opinion (R) questions.

[a] Item: E2 (R1), E5 (R3), E5 (R8), E6 (R5), and E6 (R10).

[b] Item: E3 (R2), E3 (R7), E3 (R6), E4 (R2), E4 (R6), E4 (R7), E7 (R4), E7 (R9), E8 (R4), and E8 (R9).

[c] YES, presence of experience.

[d] Not YES, absence of experience or missing response.

[e] Missing, missing response.

[f] NO, absence of experience.

The rows present different possible experience answers. Column 1 is dedicated to single experience items, columns 2 and 3 to combined experiences (first item general experience and second item more specific). The fourth column contains the weights as concrete values (default) being used in the sensitivity analysis reported below. The default weights were taken as 1, if the full corresponding experience was documented and positive values below 1 if not. Only the logic contradiction answering YES for the second question and NO for the first question of the same experience were weighted by zero.

The questionnaire allows a quantification of intra-rater reliability of patients' responses by two pairs of contradictory items (R8 contradicting R3 and R5 contradicting R10). R3 and R10 are directed in favor of the CSMHC program intention, R8 and R5 opposite. If a rating X is documented for one of these pair items, the opposite item should be rated as difference between 4 and X in order to proof full consistency. For example, if R3 = 4 ("strongly agree"), then R8 = 0 ("strongly disagree") would be a fully consistent reply. Contradicting responses to these items may be a hint for various factors that might reduce the patient's reliability, such as problematic understanding, distraction, exhaustion, or even cognitive dysfunction. The extent of contradiction may be used to quantify the reliability of the patient's rating. We propose the following grading based on a pair A, B of contradicting opinion scores:

> contradiction score with respect to the pair A, B: $C(A, B) = \mathrm{abs}(4 - (A + B))/4$ as (A, B)− and
> reliability score with respect to A,B: $\mathrm{Rel}(A,B) = 1 - C(A;B)$
> combined reliability score of each patient: $\mathrm{Rel} = \mathrm{Mean}(\mathrm{Rel}(R3, R8), \mathrm{Rel}(R5, R10))$

A combined rating for contradictory ratings is defined by mix $(A, B) = (A + 4 - B)/2$, where A is the rating of the question directing to the goal of the model study and B the rating of the contradictory question.

The weight W (A) for the rating A of a specific patient is then defined by

$$W(\mathrm{A}) = WE(\mathrm{A}) * \mathrm{Rel}$$

Following this definition weighted means may be defined for specific sets of rating items and specific patient samples.

Pilot Testing Phase

Sample Characteristics

N = 420 patients were identified as potential participants. N = 35 rejected participation; N = 385 agreed to participate in the study. The sample consisted of 131 males (34.03%) and 254 females (65.97%). Average age of the participants was 42.1 years (range = 21–88 years, SD = 17.79 years, median = 45.0 years). A majority of patients had high levels of education (50.65% high school graduates) and 29.61% of participants worked for income. A majority of 61.26% was living without partner. The mean score of psychopathological symptomatic using was 1.4, SD = 0.8 (range = 0–3.6). The mean duration of current mental disorder was 10.1 years (range = 0–60 years, SD = 11.2 years).

Patient Experiences and Opinions

Analyses of patient experiences items E1a–E1d concerning specific aspects of CSMHC experienced at the time of filling the questionnaire revealed that a majority of participants was currently treated in outpatients' clinics (34.9%) or day hospitals (35.1%). A fourth of the sample (25.1%) was currently in stationary treatment and only 4.9% participants were currently in home treatment. A majority of patients had experiences with flexibility of treatments' switching (61.8%) and cross-sectoral treatment groups' offering (57.9%) and more than half of participants (55.5%) had experiences with case management including its intensive form (27.5%). Fewer respondents 40.3% had experiences with interdisciplinary professional practice. Only very few patients (9.6%) were at least once treated at home including the treatment of at least 1 week (6.7%).

The patient opinion rating is presented in the upper part of **Table 2**. The counts N in the table indicate a small rate of missing values (368 of 385 missing, i.e., 4.4%). The means presented show a range from 1.65 (R8) to 3.12 (R2). It should be kept in mind that R5 and R8 are negatively formulated with respect to R10 and R3 and used for consistency check only. A consistent reply would be the difference between R4 and R5 corresponding to R10 and the difference between R4 and R8 corresponding to R3. Substituting these values (1.85 for R5 and 2.35 for R8) yields a smaller range from 1.78 (R4) to 3.19 (R2). The SDs range from 1.07 to 1.35 the corresponding variances from 1.15 to 1.88. The theoretical variance of an equally distributed random variable indicating high heterogeneity of (random) responses is 2.0. The F-values of the items (without R5, R8) range from 1.15 to 1.74. Compared with the critical 5%-value of 1.15 the great majority of item may be well interpreted as acceptable heterogeneity although this comparison is not a formal F-test (lack of normality assumption).

Biometric Transformation of Patient Opinion Ratings

As described in Section "Transformation and Weighting," the scores have been weighted and transformed in two steps. Firstly, on the basis of **Table 1** weights and weighted means of opinion scores were calculated. Secondly, the contradictory scores R3 and R8 as well as R10 and R5 were transformed to new scores R3 and R10, respectively, i.e., R3: = mix (R3, R8) and R10: = mix (R10, R5). The results of both these procedures were defined as transformed scores and presented in the lower part of **Table 2**. The difference of transformed and raw means is small ranging from −0.01 to +0.13 with the exception of R10 (difference of −0.49). A greater difference may be expected for R3 and R10 taking the definition as a mixed rating into account but the transformed R3 differs only by 0.09 from the raw value. The reason for the R10 exception is a greater inconsistency between rating R10 and R4–R5 (1.01) compared with R3 and R4–R8 (0.15).

The weighted mean of all opinion ratings calculated for the whole data set on this basis is 2.84 (±0.90). The distribution of these values is demonstrated in **Figure 1**.

Table 3 showed differences between both row and transformed scoring. There were more cases in the transformed rating due to different handling of failing experience. One would expect a higher SD in the transformed case as there is a mix of experienced and not experienced patient ratings but there is less heterogeneity in the transformed scale ($s = 0.63$ versus $s = 0.90$). Additionally, the skewness and kurtosis are smaller and therefore the feasibility of this version to serve as a depending variable in regression analysis is preferable. The quotient of value and SD

TABLE 2 | Means (*M*) and SD for opinion values using raw and transformed scoring.

Item of the opinion section		R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Row scoring	Response[a] number	374	373	373	372	368	372	372	371	373	371
	M	2.61	3.19	2.49	1.76	2.15	2.60	3.15	1.65	2.43	2.86
	SD	1.25	1.09	1.25	1.27	1.19	1.32	1.07	1.35	1.22	1.16
Weight		0.59	0.53	0.58	0.40	NA[b]	0.53	0.53	NA	0.40	0.36
Transformed scoring	*M*	2.67	3.22	2.59	1.88	NA	2.59	3.17	NA	2.56	2.37
	SD	1.78	1.85	1.78	1.73	NA	1.68	1.84	NA	1.28	1.78
Difference between transformed and row *M* values		0.06	0.03	0.10	0.12	NA	−0.01	0.02	NA	0.13	−0.49

[a] *The variation in response number is due to the variation in the number of missing responses.*

[b] *NA, not applicable.*

of skewness and kurtosis may be compared with 2.00 to detect relevant deviations from normality. These quotients are 2.33 and 6.19 in the case of raw ratings and 2.70, respectively, 1.47 for the transformed ratings.

Reliability

As mentioned above, some of the evaluative ratings concern the same content domains: R4 and R9 refer to home treatment, R2 and R7 to case management, and R1 and R6 to flexibility of treatments' switching. The concordance values for the raw ratings as for case management and treatments' switching presented in **Table 4** were not satisfying as they remain below 0.6. The home treatment rating and the total set of ratings show acceptable α values between 0.6 and 0.7. After biometric transformation all α values were higher compared with the raw values, they are greater as 0.6, i.e., acceptable, and with the exception of treatments' switching far above the critical value of 0.7 indicating good concordance.

The reliability estimated by analysis of contradictory ratings (questions to interdisciplinary professional practice: R3 and R8 and questions to cross-sectoral treatment groups' offerings: R10 and R5) resulted in a mean value of 0.72 and was incorporated into the weighting process of ratings.

As the total average of ratings may be offered as dependent variable for coming studies in this field this variable was further analyzed in both ways, based on raw ratings and on transformed ratings. For this purpose, raw ratings were only used if the corresponding experience was documented as YES. No adaption of reliability was performed for these raw ratings.

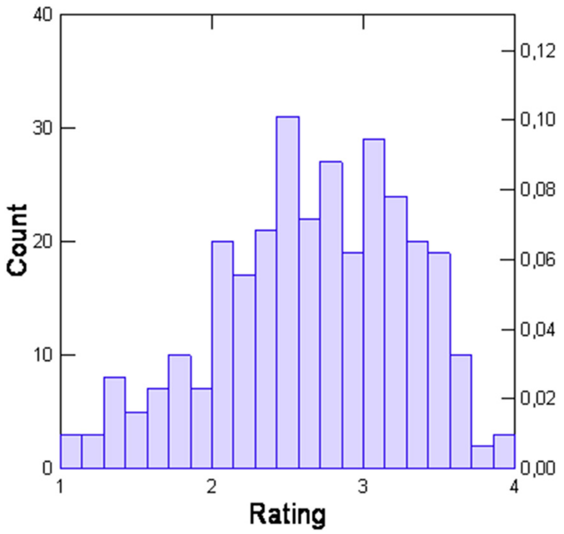

FIGURE 1 | Distribution of transformed total opinion scores of the Scale for Evaluation of Psychiatric Integrative and Continuous Care.

Postdictive Validity

A regression analysis (**Table 5**) was performed for both versions of the total rating. The regression was significant for the transformed rating ($p = 0.0002$, effect size $f^2 = 0.160$) and had a trend toward significance for the raw rating ($p = 0.0560$, effect size $f^2 = 0.075$).

Both regression models proved significant influence of experience. The other factors missed to be significant. This result may be interpreted as a postdictive validity result for the experience evaluation performed here as predictor of the later opinion rating.

DISCUSSION

Main Findings

The development process resulted into an 18-item scale with, in the first section a two-point and, in the second section a five-point response options. The first section is related to the patients' experiences with different relevant components of CSMHC such as home treatment, flexibility of treatments' switching, case management, cross-sectoral treatment groups' offerings, and interdisciplinary professional practice. The second section addresses the patients' opinions regarding these relevant components. Using raw and transformed scoring resulted into comparable results. However, the transformed data showed a smaller deviation from normality and a higher reliability. Therefore, the application of transformed scoring should be preferred.

The developed scale showed a good internal reliability in the measurement of CSMHC. Linear regression analyses demonstrated that the scale has postdictive validity for patient opinions based on their experiences with relevant components of CSMHC. Self-reported experiences with home treatment, flexibility of treatments' switching, case management, cross-sectoral treatment groups' offerings, and interdisciplinary professional practice using the Scale for Evaluation of Psychiatric Integrative and Continuous Care (SEPICC) were positively associated with the approval of these mental health care components.

Strengths and Limitations

To the best of our knowledge, the SEPICC is the first measurement combining differentiated experiences and opinions by

TABLE 3 | Descriptive statistics for total opinion values using raw and transformed scoring.

	N[a]	*M*[b]	SD	Skewness	Skewness SD	Kurtosis	Kurtosis SD
Raw scoring	275	2.84	0.90	−0.91	0.15	0.68	0.29
Transformed scoring	307	2.66	0.63	−0.38	0.14	−0.41	0.28

[a] *N, response number. The variation in the response number is due to the variation of missing responses using different scoring.*

[b] *M, mean.*

patients in regional psychiatric budget hospitals about specific items in relation to the use of CSMHC as part of the treatment program. The tool is brief and simple to use so that it can be applied in mental health care practices. As there is no gold standard for assessing CSMHC, this scale provides a good starting point for further testing and development as well as a pilot scale that can be used in the evaluation of treatment programs. However, the lack of a gold standard metric limits our understanding of the concurrent validity of our tool. Secondly, due to the cross-sectional design of the present study and practical reasons, we were not able to evaluate the test–retest reliability of the scale. Future studies should assess other psychometric properties of the SEPICC such as discriminant validity, construct validity, and criterion validity using administrative records, provider's perception as well as its measurement invariance across different patient groups. Our research group plans to test for divergent validity of the SEPICC using comparison with a scale measuring general patients' satisfaction without health service specification. Thirdly, on the basis of our sensitivity analysis the best results were obtained by using transformed scoring that is different from the traditional raw scoring. However, results from both traditional and transformed scoring largely coincided. Fourthly, the survey was conducted at only seven hospitals, raising the issue of the findings' generalizability. Finally, the majority of the patients in the present study were relatively highly educated. In future studies, it would be necessary to examine the psychometric properties of the SEPICC in patients with different levels of education.

TABLE 4 | Cronbach's α for row and transformed concordant scores of the Scale for Evaluation of Psychiatric Integrative and Continuous Care opinion section ($N = 385$).

Scale domain	Cronbach's α		
	Item included	Raw score	Transformed score
Home treatment	R4, R9	0.61	0.85
Case management	R2, R7	0.56	0.85
Treatments' switching	R1, R6	0.55	0.62
Total score	R1–R10	0.66	0.82

Comparison against the Literature

The comparison of domains which are specific for our scale and analogous international instruments reflects differences between relevant components of mental health care configurations. Whereas several key principles of Assertive Community Treatment such as *holistic approach to services*, *integrated services*, *continuity of care*, *delivery of services in the community*, and *multidisciplinary team* (27) are well incorporated in the German CSMHC, other features, like *full responsibility for treatment services*, *high frequency of contact to patients* are less common in Germany (1).

In many instances, our findings replicate previous studies conducted on the basis of self-reported scales, which showed good criterion validity regarding different relevant components of Assertive Outreach Teams (28), Assertive Community Treatment (29), Crisis Resolution Teams (30), Case Management (31), Disease Management (32), and Community Mental Health Teams (33). Remarkably, existing studies identified primarily positive associations between some experiences with innovative mental health care and patient satisfaction. Whereas existing self-reported satisfaction scales focus on individual treatment aspects such as continuity of care (13, 14), interdisciplinary treatment (34), or communication (9), our tool comprises in short form different dimensions of mental health care, which can be presented as total score.

Several authors (17) reported that psychopathology may account for 3–28% of the variance in patient ratings depending on the specific sample and treatment setting. Another study (35) showed that almost 98% of variance in patients' experiences could be attributed to differences between patients rather than the care unit in which they were treated. For example, younger patients reported significantly less positive perceptions of continuity of care. In another study (36), evidence was found to suggest that satisfaction rates with home treatment were influenced by monthly income and duration of enrollment in the program: individuals with fewer financial resources were in greater need of home care services, hence reporting higher satisfaction, and vice versa. As our scale enabled patients to express their evaluations instead of their degrees of satisfactions, based on the regression analyses, it may be concluded that SEPICC scores may not be dominated by the degree of patient symptom levels or other examined co-variables.

TABLE 5 | Associations between patients' characteristics and total opinion value of the Scale for Evaluation of Psychiatric Integrative and Continuous Care using linear regression analyses ($N = 307$).

Patients' characteristic	Total opinion value using different scoring					
	Raw scoring			Transformed scoring		
	B[a]	SE	*p*-Value	*B*	SE	*p*-Value
Experience of the CSMHC	0.16	0.05	<0.01	0.12	0.03	<0.01
Age	0.01	0.01	NS[b]	0.00	0.00	NS
Gender[c]	–0.18	0.15	NS	–0.07	0.09	NS
Education level	–0.09	0.09	NS	–0.09	0.06	NS
Psychopathology level (SCL-K-9 total score)	0.05	0.09	NS	–0.01	0.05	NS
Mental disorder duration (years)	–0.00	0.01	NS	0.00	0.00	NS

[a] *B, unstandardized regression coefficient.*

[b] *NS, not significant.*

[c] *Reference category is female.*

CONCLUSION

The SEPICC provides a distinct framework of assessing cross-sectional mental health care, with good reliability, and some satisfactory psychometric properties. Additional studies are needed in order to evaluate the full validity and the true usefulness of the scale in psychiatric research. Because transformed scale scoring showed better statistical assumptions, we would suggest using this scoring in the research practice. The scale can be used in research and routine clinical practice. In research, it could be applied to assess the quality of the CSMHC and provide a basis for advancing knowledge about the critical ingredients of this important service model. In clinical practice, the tool may be used for support and evaluate the service improvement intervention as well as for professional training.

ETHICS STATEMENT

Development and feasibility testing of the scale was part of the preparations for a study on "Evaluation of Care Models based on the Regional Psychiatric Budget acc. §64b, V Book of German Social Law." The study was approved by the Ethics Committee of Medical Chamber Brandenburg [2016, No. S 7 (a)]. All eligible patients were given a comprehensive description of the study and informed that their participation or refusal would not affect their care. After positive patient decision of participation, the informed consent was obtained.

AUTHOR CONTRIBUTIONS

YI, JT, and SP substantial contributions to the conception or design of the work and the acquisition and analysis of the data:. MH and SI interpretation of data for the work. YI and MH drafting the work or revising it critically for important intellectual content.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at http://journal.frontiersin.org/article/10.3389/fpsyt.2017.00162/full#supplementary-material.

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MINI REVIEW
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Effect of Case Management Interventions for Patients with Substance Use Disorders: A Systematic Review

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Background: Substance use disorder (SUD) is an important health problem that requires a complex range of care because of the chronic nature of the disorder and the multiple psychosocial problems involved. Current outpatient programs often have difficulties in delivering and coordinating ongoing care and access to different health-care providers. Various case management (CM) models have been developed, first for patients in other psychiatric domains and then for patients with SUD, in order to improve treatment outcomes.

Aim: This paper aims to assess the effectiveness of CM for patients with SUD.

Methods: We performed a systematic review of CM interventions for patients with SUD by analyzing randomized controlled studies published on the subject between 1996 and 2016 found on the electronic database PubMed.

Results and conclusion: Fourteen studies were included in the analysis. Differences between studies in outcome measures, populations included, and intervention characteristics made it difficult to compare results. Most of these studies reported improvement in some of the chosen outcomes. Treatment adherence mostly improved, but substance use was reported to decrease in only a third of the studies. Overall functioning improved in about half of the studies. The heterogeneity of the results might be linked to these differences between studies. Further research is needed in the field.

Keywords: case management, assertive community treatment, substance use disorder, substance abuse, alcohol use disorder

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INTRODUCTION

Substance use disorders (SUDs), which include drug abuse, problematic drug use, drug misuse, and substance misuse, are an important health problem (1). Persons with SUDs are characterized by multiple social and medical needs and are often known for their difficulty in engaging in treatment, partly because access to treatment facilities is limited (2). The chronicity and relapsing nature of SUD, as in other psychiatric disorders, entails frequent hospitalizations (3) and readmissions.

Patients presenting both severe mental illnesses and SUD are typically hospitalized more often than are non-substance users (4, 5). Patients presenting this double diagnosis also have more difficulties entering alcohol and drug outpatient clinics than patients with only SUD (6). This group of patients seems to have less access to aftercare services (7) and higher use of acute services, such as emergency room treatment and hospital services (8).

The period after discharge is characterized by a high risk of relapse, with most cases occurring within the first week of inpatient treatment (9). There is also an important risk of drug-related death (either accidental or intended) following a longer period of abstinence because of lower drug tolerance (10, 11). These patients have multiple psychosocial problems for which they need support. Patient needs often remain unmet in current outpatient treatment programs (2), although the provision of help with legal advice, basic needs, and family services may improve patients' psychosocial functioning. Treatment continuity has been related to higher overall abstinence rates (12, 13) and less frequent readmissions to hospital units (14). Between hospital and community care, treatment continuity is supposed to improve comprehensive support for patients.

Different strategies have been developed to improve treatment adherence and drug-related outcomes (15); among them, case management (CM) has been identified as potentially beneficial as suggested in early clinical studies (16). The definition of CM and its practice varies from place to place. In general, CM can be defined as a "coordinated integrated approach to service delivery, ongoing supportive care and help to access resources for living and functioning in the community" (17). This approach has been widely implemented in many different areas, such as insurance programs, education, and health care.

Given the complex, chronic, and relapsing nature of mental health disorders and SUDs, they require a broad and continuous approach such as can be offered by CM (17). Since the 1980s, this practice has been adapted for persons with SUD (18), but to date, only a few studies have described CM models for persons with SUD in Europe.

The aim of this study was thus to assess the effectiveness of CM for patients with SUD. We searched for published articles in which clinical CM was described for patients with SUD to help maintain treatment continuity and coordinate care after a patient was discharged from hospital or prison (transitional CM) or when a patient entered a treatment program.

METHOD

The electronic database PubMed was searched for empirical studies published between January 1996 and May 2016. The following keywords were used: "case management" AND "addiction"; "case management" AND "substance use disorder"; "case management" AND "substance abuse." The inclusion criteria were as follows: randomized controlled trial, adult participants over the age of 18 years with SUD, and a CM intervention compared to treatment as usual (TAU).

RESULTS

After checking for the inclusion criteria and for duplicates, we analyzed 14 studies (**Figure 1**). Details about the included studies are described in **Table 1**. One paper (19) was reviewed but excluded. It compared assertive community treatment to another form of CM intervention. In absence of a TAU comparison group, the study was not included.

The names of CM interventions varied in different studies. They were labeled "intensive," "community," or "assertive CM" (20–22); "strengths-based" (23–26), "clinical" (27), and "transitional CM" (28); or "coordinated care management" (29) and "probation CM" (30). Although the names and interventions varied, certain common characteristics could be found. CM services were conducted by case managers with a professional background in nursing, social work, or mental health care (22). CM services were delivered mainly in the patients' communities and not at the treatment center or hospital (20–22). The length of interventions varied from 1 month (25) to 3 years (20), although 6 months to 1 year was the most common. The intensity of the CM intervention was rarely noted.

Study Populations

In some studies, the population had SUD and no further differentiation was made, whereas other studies considered specific subgroups such as patients in methadone programs (27), women with SUD (22, 31, 32), and participants with court judgments who were either incarcerated or in court-ordered treatments (23, 28, 30). Most studies were done in the United States, except for the one by Prendergast et al. (28) in Canada and Lindhal et al. (23) in Sweden.

Outcome Measures

The most frequently used outcome measures were change in drug or alcohol use, as well as adherence to SUD treatment (frequently measured in attendance rates) and linkage to other health-care providers. The other important outcome measures were health-care use in terms of days of hospitalization, emergency ward visits, or health costs. On a more general level, some studies measured global functioning; employment rates; reduction of social, legal, and family problems; and client satisfaction. Two studies concerning incarcerated or court-ordered individuals also used the number of post-enrollment arrests as an outcome measure (28, 30).

Most studies considered only SUD as an inclusion criterion. Surprisingly, the importance of comorbid mental health disorders or high service use was not defined as an inclusion criterion in most studies. Slesnick and Erdam's study (32) included only homeless mothers, and Morgenstern et al.'s studies (22, 29, 31) analyzed patients receiving welfare [in one study (22), only women were included]. Only Essock et al.'s study (20) used high service use, severe comorbid mental health disorder, unstable housing, and poor living skills as inclusion criteria. Some studies even excluded psychotic disorders (22, 24), and Morgenstern et al.'s study (29) excluded patients who had been hospitalized more than once for mental health reasons in the past year.

Effect of the Intervention

Only two studies (28, 30) did not find any additional value in CM when treating addicted patients. The other 12 papers found significant improvement of some or all the outcome measures. These improvements were not the same for each survey.

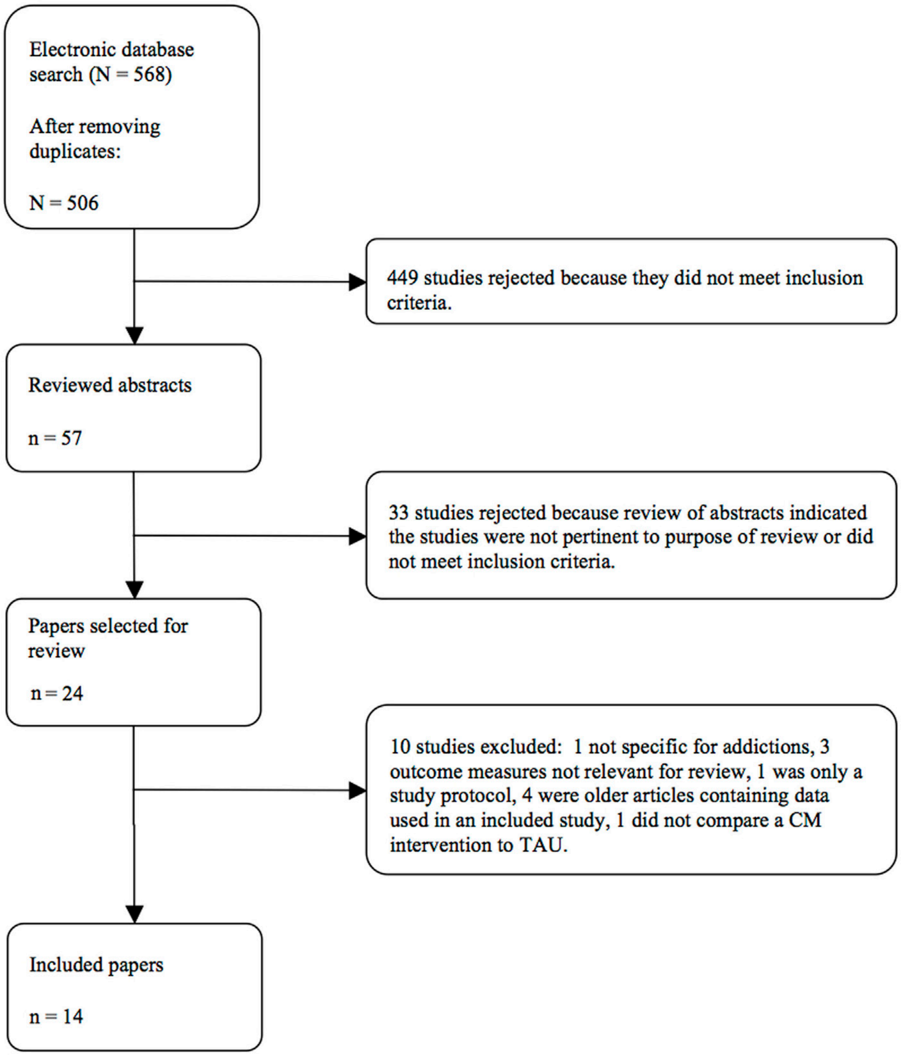

FIGURE 1 | **Study flow diagram**.

Five studies showed that substance use decreased (20, 22, 23, 27, 32), two papers (22, 26) showed that the likelihood of initiating SUD treatment increased, and four publications (22, 23, 27, 33) showed greater treatment retention when a case manager was involved in treatment. Four studies (23, 24, 33, 34) showed improved access to health care and/or linkage between health-care providers. One research showed fewer days spent in hospital (20) but others reported an increased number of days in hospital, which is explained by the higher treatment retention (34). Seven publications showed better global functioning, which was described as more employment days (25, 31, 35). This was further differentiated in Morgenstern et al.'s study of 2008 (29), which showed that women were more likely than men to find employment when assisted by CM, to have fewer legal (21, 35) and family problems (21), and to have better housing stability (32). Lindahl et al. measured very high patient satisfaction with the treatment and 100% treatment retention compared to TAU (23).

DISCUSSION

In most studies, significant improvements were reported in the outcome measures. Substance use decreased in only five papers (20, 22, 23, 27, 32), but treatment adherence and linkage between health-care providers seemed to improve in most surveys, which is an important issue for this population and one of the main aims of CM. Overall functioning improved in more than half of the studies, which is in general linked to higher life satisfaction.

The two publications (28, 30) that did not find significant improvements in one of the outcome measures were both performed with incarcerated or paroled patients. In Guydish et al.'s paper (30), the important factor was the limited face-to-face time. Only 53.6% of participants had seen their CM once or more during the first 6 months. For those participants who had seen their CM two or more times in the first 6 months, there was an improvement in substance use and social problems. This finding shows how important treatment intensity of CM is for the outcome. The

TABLE 1 | Characteristics of the included studies.

Reference, country	Target population	Number of subjects	Control intervention	CM interventions/dose of CM	Outcome measures	Follow-up	Results
Guydish et al. (30), USA	Drug-involved women offenders on probation or awaiting probation who were willing to enter a substance abuse treatment program	*N* = 183 IG: *n* = 92; CG: *n* = 91	TAU = standard probation	12 months of PCM involving uniform assessment procedures, a therapeutic and advocacy orientation, treatment planning, counseling, and home visits. Dosage: at least two contacts per month (visit or phone)	ASI, BDI, BSI, Social Support Evaluation List, service utilization, arrest during 12 months of face time with CM	6 and 12 months	Proportion of women enrolled in SUD treatment or incarcerated was not statistically different for both groups. All other measures were not statistically different between groups. At 6 months, 53.6% of PCM participants met face-to-face with case manager once or more and at 12 months 43.5% did. In CG, this was 11.6 and 8.5%, respectively. This shows that the dosage was often a lot less than twice a month, as described in the intervention. The participants who had two or more contacts with case manager were more likely to have lower ASI rates and lower social severity rates
Essock et al. (20), USA	Alcohol and illicit drug users with a co-occurring major psychotic disorder, who had high service use in the past 2 years, were homeless or unstably housed, and had poor living skills	*N* = 198 IG: *n* = 99; CG: *n* = 99	Standard clinical CM: comprehensive assessment, individual MI, group treatments, and stage-wise interventions	Three years of community-based assertive CM treatment: direct substance abuse treatment by case managers and comprehensive assessment, individual MI, group treatments, and stage-wise interventions. Case managers had half the patient load that they had for CG	Substance use (days of use, ASI, toxicology screens) structured interview and rating scales assessed by case manager; hospitalization rates; Quality of Life Interview; CM dosage: contacts per month with case manager	Every 6 months	Participants in both treatment conditions improved over time in multiple outcome domains, and few differences were found between the two models. Decreases in substance use were greater than would be expected given time alone. At the site that had higher rates of institutionalization, clients who received standard CM were more likely to be institutionalized. However, in the site that had lower rates of institutionalization, no differences in the rate of institutionalization were found between the two treatment conditions. At one site, the IG received a significantly higher dose (time and activities) of services than did the CG. At the other site, the difference was not significant. Integrated treatment can be successfully delivered either by assertive community treatment or by standard clinical CM
Huber et al. (21), USA	Drug or alcohol users who were diagnosed with substance abuse disorder and enrolled at a substance abuse treatment facility	*N* = 598 IG: *n* = 437; CG: *n* = 149	Standard drug abuse treatment	Community-based comprehensive CM intervention: 12 months of CM interventions consisted of four CM conditions with a case manager working as a member of drug-treatment staff (inside), a case manager from an outside social service agency (outside), or a case manager using computerized telecommunication (telecom). CG received standard drug abuse treatment. Five types of CM interventions were assessing, individual solution planning, referral, advocating, and conferencing	CM dosage, ASI	3, 6, and 12 months	Clients who engaged (actively participated) in CM were less likely to have legal and family issues, but more likely to have a chronic medical condition at baseline. Dosage factors differed significantly across treatment conditions. In general, dose was significantly related to outcomes in the legal and family domains

(Continued)

TABLE 1 | **Continued**

Reference, country	Target population	Number of subjects	Control intervention	CM interventions/dose of CM	Outcome measures	Follow-up	Results
Lindahl et al. (23), Sweden (EU)	Court-ordered substance abuse patients	$N = 34$ IG: $n = 13$; CG: $n = 21$	TAU	Six months of CM intervention: case managers offered assessment, transitional care, support of referral services, and intervention to avoid crisis	Substance use (ASI, AUDIT, AUDRUG, SIP, days of alcohol used); psychological functioning; involuntary care (coercive measures); number of days in institutional or hospital care was measured	6 and 12 months after discharge	More patients from the CM group were abstinent compared with those in the CG at the first follow-up at 6 months (46 vs. 14%, $p < 0.051$). Patients in the CM group did not have more contact with health and social services (92%) compared with those in the CG (76%) ($p = 0.23$), nor did they have more medical-assisted treatment ($p = 0.46$) or institutional/inpatient care ($p = 0.27$) to a higher degree than patients in the CG. CM interventions were well received by the patients with no dropout during intervention. Patients with the support of a case manager seemed to sustain abstinence to a higher degree compared with TAU, but no differences were detected regarding use of care. A subgroup analysis showed that patients with continuous drug abuse had access to care from both social welfare and hospital care systems
Morgenstern et al. (22), USA Morgenstern et al. (31): 24-month outcome	Women with SUD receiving temporary assistance for needy families; not psychotic, under methadone treatment or seeking methadone treatment, or already in treatment program	$N = 302$ IG: $n = 161$; CG: $n = 141$	TAU, which was standard substance abuse screening and referral system within welfare department	ICM intervention: CM services were provided throughout the 15-month follow-up period; assessment, planning, motivational enhancement, treatment coordination, peer support, and crisis management. If needed, case managers provided home visiting services. Contact was adapted to needs from daily to two visits per month	Substance use (ASI, toxicology screen). Treatment attendance. Treatment engagement. Treatment retention rate	3, 9, and 15 months; 24 months (article 28)	ICM clients had significantly higher levels of substance abuse treatment initiation, engagement, and retention compared with CG clients. In some cases, ICM treatment attendance rates were double those of CG rates. Additionally, almost twice as many ICM clients were abstinent at the 15-month follow-up compared with CG clients ($p < 0.0025$). After 24 months, abstinence rates were higher in the ICM group than they were for usual care. Additionally, there were greater odds of being employed full time
Morgenstern et al. (29), USA	SUD welfare applicants without acute psychotic symptoms and not more than one hospitalization for mental health problems in the last year	$N = 394$ (66% men) IG: $n = 221$; CG: $n = 173$	Usual care	CCM: continuity of care intervention focused on engaging clients in drug treatment, linking to needed ancillary services, and fostering transition to employment. Biweekly visit at treatment center and regular contact in office or by phone	Employment outcomes (days of employment and percentage of full-time employment), abstinence rates, treatment attendance	1-year follow-up	Overall, men were more likely to work than women. There was no difference between groups. CCM increased women's employment over time. Among women only, greater SUD treatment attendance and abstinence in the first 6 months of CCM predicted higher rates of later employment
Plater-Zyberk et al. (27), ON, Canada	Patients enrolled in a methadone maintenance treatment program	$N = 1,704$ IG: $n = 396$; CG: $n = 1,308$	TAU: standard outpatient treatment	Clinical CM: duration and frequency varied according to clients' needs	Drug-positive urine samples, missed daily methadone doses, missed methadone physician appointments	3 months	The IG demonstrated statistically significant improvement in all three measures of the methadone maintenance treatment program. Less drug-positive urine: 15.4% relative reduction. Fewer missed daily methadone doses: 2% relative reduction. Fewer missed appointments with the methadone physician: 40% relative reduction

(Continued)

TABLE 1 | **Continued**

Reference, country	Target population	Number of subjects	Control intervention	CM interventions/dose of CM	Outcome measures	Follow-up	Results
Prendergast et al. (28), USA	Correction population who were enrolled in a drug-treatment program within a correctional institution (prison, work release, community correctional facility) in four states	*N* = 812 (men and women) IG: *n* = 412; CG: *n* = 400	Standard referral/services (SR group)	TCM using the SBCM model: strengths assessment, conference call 1 month prior to release, community sessions. After release, weekly sessions for 3 months, followed by 3 monthly follow-up contacts for any client needing additional help	SUD treatment services, other social services, drug use, alcohol use, arrest, HIV risk behavior	3 and 9 months following release from prison	There were no significant differences between parolees in the TCM group and the SR group on outcomes related to participation in drug abuse treatment, receipt of social services, or drug use, crime, and HIV risk behaviors. For specific services (e.g., residential treatment, mental health), although significant differences were found for length of participation or for number of visits, the number of participants in these services was small and the direction of effect was not consistent
Rapp et al. (24), USA	Substance abusers seeking treatment; not psychotic and not only alcohol use disorder	*N* = 678. SBCM: *n* = 222 One session of MI: *n* = 226; CG: *n* = 230	Standard care at a centralized intake unit	SBCM: assessing, individual solution planning, referral, advocating, and conferencing. Up to five sessions of SBCM. MI: clarify motivation, reinforce treatment-seeking behaviors. One 1-h interview	Linkage with SUD treatment within 90 days	3 months	SBCM (*n* = 222) was more effective in improving linkage compared to CG (*n* = 230), 55.0 vs. 38.7%, respectively ($p < 0.01$). SBCM improved linkage more than MI did (55.0 vs. 44.7%, $p < 0.05$). MI (*n* = 226) was not significantly more effective in improving linkage than in CG (44.7 vs. 38.7%; $p > 0.05$). The three trial groups differed only slightly on the client characteristics that predicted linkage with treatment
Saleh et al. (34), USA Saleh et al. (35)	Alcohol or drug abuse	*N* = 627 IG: *n* = 437 (treatment agency: *n* = 167, social service agency: *n* = 160, telecom CM: *n* = 147); CG: *n* = 188	Usual care in treatment centers	12 months of CM services in community non-profit substance abuse treatment centers	Number of hospitalization days, number of ER visits, number of physician visits. Study 31: legal, employment, psychiatric improvements	3, 6, and 12 months	IGs showed decrease of the usage of mental health services. However, hospital usage, ER visits, and access to physicians were increased in IGs. The short duration of CM services was expected to increase the use of access outcomes. Study 32: legal, employment, and psychiatric improvements
Scott et al. (33), USA	Substance abuse clients who used alcohol or other drugs in the past 6 months and who were enrolled in one of nine community substance abuse treatment facilities	*N* = 692 IG: *n* = 344; CG: *n* = 348	Usual care in community	CM services over a 22-month period: assessment, referral services, client advocacy, counseling, and follow-up treatment	Treatment retention, show rates to treatment		IG was significantly more likely to show response to treatment than CG. No differences found in dose (amount or length of substance abuse treatment services) in both IG and CG

(Continued)

TABLE 1 | **Continued**

Reference, country	**Target population**	**Number of subjects**	**Control intervention**	**CM interventions/dose of CM**	**Outcome measures**	**Follow-up**	**Results**
Siegal et al. (25), USA	Veterans seeking treatment for substance abuse problems	$N = 632$ CM: $n = 313$; CG: $n = 319$	CG: no CM group	Veterans in the inpatient component participate in three phases lasting a total of 28 days. Outpatients attend 10 weeks of sessions involving education about substance abuse problems and group therapy sessions designed to assist in achieving abstinence. Both inpatient and outpatient clients are referred to an aftercare service upon completion of primary treatment. The clients in the IG received help for strengths assessment, identifying goals, and, if appropriate, accompaniment on job search	Substance use (ASI), psychosocial functioning, employment outcomes	6 months	All clients showed significant improvement in employment outcomes, an increase of 6 days worked ($p < 0.01$) in the last 30 days before the 3-month follow-up. SBCM reported 3.5 additional days worked compared to non-case-managed clients. There was a positive relationship between improved employment functioning and improvement in other life areas
Slesnick and Erdem (32), USA	Substance-abusing homeless mothers with a 2- to 6-year-old child	$N = 60$ IG: $n = 30$; CG: $n = 30$	Usual care in community	Ecologically based treatment with CM services. The mothers were housed in apartments of their choosing and received 3 months of utility and rental assistance. CM services for 6 months, focusing on basic needs (i.e., referrals to food pantries); assisting, obtaining government entitlements; employment; connecting to social services; providing referrals and/or transportation to appointments. Average of 23.1 sessions in 6 months	Substance use, retention rate, independent living days	3, 6, and 9 months	Mothers receiving ecologically based treatment showed a high retention rate on treatment, a faster decline in alcohol use ($p < 0.05$), and a faster increase in their independent living days ($p < 0.001$). Furthermore, with supportive services, two-thirds of women were successful in maintaining their apartments 6 months after rental assistance ended. However, no treatment effects were found in drug use ($p > 0.05$)
Strathdee et al. (26), USA	Clients of the Baltimore Needle Exchange Program who sought drug abuse treatment	$N = 245$ IG: $n = 128$; CG: $n = 117$	Passive referral [voucher printed with date, time, and location for intake appointment (of opioid agonist) at the drug-treatment program]	SBCM: engagement, strengths assessment, personal case planning, resource acquisition. The duration and frequency of CM contacts were client-driven, based on individual desires and needs	Intake appointment for opioid agonist therapy within 7 days	7 days	In a multivariate "intention-to-treat" model (i.e., ignoring the amount of CM actually received), those randomized to CM were more likely to enter treatment within 7 days (40 vs. control: 26%, $p = 0.03$). Additional "as-treated" analyses revealed that participants who received 30 min or more of CM within 7 days were 33% more likely to enter treatment. The active ingredient of CM activities was provision of transportation

CM, case management; SUD, substance use disorder; IG, intervention group; CG, control group; PCM, probation case management; TAU, treatment as usual; ASI, Addiction Severity Index; BDI, Beck Depression Inventory; BSI, Brief Symptom Inventory; AUDIT, Alcohol Use Disorders Identification Test; AUDRUG, Drug Use Identification Test; SIP, Short Index of Problems; ICM, intensive case management; CCM, coordinated care management; SR, standard referral; TCM, transitional case management; SBCM, strengths-based case management; MI, motivational interviewing; ER, emergency room.

other study with a negative outcome, by Prendergast et al. (28), showed no improvement in treatment participation for parolees with SUD who were receiving CM. However, this finding cannot be generalized, as the case manager's adherence to the protocol and the intervention was not standardized. Moreover, the case manager seemed to have limited contact with the parolee and the parolees did not enroll voluntarily in the project.

The studies are heterogeneous in their clinical approach, which limits our ability to generalize specific implications for practice. Different types of populations with different risk levels seem to account for the variation in readmission rates (36). For example, the study populations varied in illness severity (comorbidities and service use), which would most likely have an effect on the study outcome. Some comorbid populations were also excluded from surveys. The CM model is a specific intervention that seems more useful to specific subgroups who are unable to use existing health-care services. A large number of patients find adequate health care in the usual care programs, as shown in research on CM interventions that involve psychiatric patients with psychosis. Patients who benefit from CM have been shown to be those with greater social and psychosocial needs, more psychiatric symptoms, and higher service use (37), with others not needing this specific intensive care (38). If CM is applied to a large group, the effect on a smaller subgroup would likely be diluted and not as visible in the outcome measures. It will be important to further specify these subgroups in future in order to refer patients to the appropriate programs.

The intensity of application of CM differs in these studies, which also limits our ability to generalize the effects (39). These examples show the importance of face-to-face time with patients, which can be managed only with small caseloads. This seems to have been a limiting factor in the two studies (28, 30) mentioned above. In addition, the adherence to the model by the case manager and the voluntary participation of the patients seem to affect the outcome.

The majority of the studies were performed in the United States, which is a limiting factor in generalizing these findings to other countries such as those in Europe, where health systems differ in organization and funding. A further limitation of this research was that the data search was performed only on the PubMed database and possibly that unpublished negative studies were not taken into account. Furthermore, we did not differentiate between alcohol use disorder and other SUDs.

CONCLUSION

Most of the analyzed studies showed improvement in the chosen outcome measures, although these varied in different studies. Treatment adherence mostly improved, but substance use decreased in only a third of the studies. Overall functioning improved in about half of the studies. The differences in chosen outcome measures make it difficult to compare the results. The type of intervention and intensity of treatment also varied.

The heterogeneity of these results might be linked to the different types of populations studied. The specific CM intervention seems to be helpful only for specific subpopulations with SUDs. Further studies are necessary to determine inclusion criteria for CM treatment for patients with SUD in order to orientate those most likely to benefit from this approach to the specific CM programs.

Only a few studies on this intervention and SUD have been published. Further research is needed to examine the effect of treatment intensity of the CM intervention. Longitudinal studies are also needed in Europe to ensure the effectiveness of these treatments.

AUTHOR CONTRIBUTIONS

LP, AM, and YK designed the strategy for the present review and drafted the manuscript. AM and LP searched for the references and read the manuscripts. LP, AM, and YK discussed the results. All authors reviewed the manuscript and helped with the final writing.

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Linking Primary and Secondary Care after Psychiatric Hospitalization: Comparison between Transitional Case Management Setting and Routine Care for Common Mental Disorders

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Objectives: To improve engagement with care and prevent psychiatric readmission, a transitional case management intervention has been established to link with primary and secondary care. The intervention begins during hospitalization and ends 1 month after discharge. The goal of this study was to assess the effectiveness of this short intervention in terms of the level of engagement with outpatient care and the rate of readmissions during 1 year after discharge.

Methods: Individuals hospitalized with common mental disorders were randomly assigned to be discharged to routine follow-up by private psychiatrists or general practitioners with ($n = 51$) or without ($n = 51$) the addition of a transitional case management intervention. Main outcome measures were number of contacts with outpatient care and rate of readmission during 12 months after discharge.

Results: Transitional case management patients reported more contacts with care service in the period between 1 and 3 months after discharge ($p = 0.004$). Later after discharge (3–12 months), no significant differences of number of contacts remained. The transitional case management intervention had no statistically significant beneficial impact on the rate of readmission (hazard ratio = 0.585, $p = 0.114$).

Conclusion: The focus on follow-up after discharge during hospitalization leads to an increased short-term rate of engagement with ambulatory care despite no differences between the two groups after 3 months of follow-up. This short transitional intervention did, however, not significantly reduce the rate of readmissions during the first year following discharge.

Trial registration number: ClinicalTrials.gov Identifier NCT02258737.

Keywords: case management, discharge planning, mental health care, psychiatry, readmission

INTRODUCTION

The movement of deinstitutionalization transformed care provision in most Western Countries during last decades (1, 2). The number of psychiatric admissions has increased, whereas the number of psychiatric beds has decreased (3). Mental health teams are now faced with an increased number of discharges and have less time to prepare them. Aftercare provision is one of the most consistent predictors of rehospitalization (4) and attendance at outpatient appointments after discharge reduces early readmissions (5). In a recent study, among individuals who had been discharged from a hospital closest to their death by suicide, three-quarter died in the month following discharge, and the most consistent modifiable factor associated with death in the month following last contact was number of outpatient consultations following discharge (6). In this context, linking with primary and secondary care after psychiatric hospitalization is a particular challenge.

A literature review by Steffen and colleagues has shown that discharge planning intervention improved adherence to after care and reduced readmissions among people with a severe mental illness (7). The authors mentioned that most of the studies were conducted in the USA, Canada, and the UK and the findings were not generalized in other countries. Another concern was the heterogeneity of diagnosis and a broad variation in post-discharge problems. In another literature review, Vigod and colleagues reported, however, that only 7 out of 15 studies found a significant reduction of rehospitalizations (8). Previous studies demonstrated that around 50% of hospitalized psychiatric patients did not attend their scheduled or rescheduled outpatient appointment after discharge (9, 10). A pilot study showed that primary and secondary care hospitalized patients tend to have a less severe illness and a better social functioning than heavy users of acute psychiatric care but that their distress and needs tended to be underestimated during hospitalization (11). Moreover, their profile of mid age women with personality and mood disorder correspond to those patients most at risk of suicide during the weeks following discharge of psychiatric hospitalization (12). To improve the focus on establishing follow-up after discharge, a "transitional case management" intervention has been developed. This is a short, structured intervention which follows the same principles as critical time intervention (13). It is started during the hospitalization and continues for 1-month after discharge. The intervention is aimed at patients who return home after discharge and who are followed up by a general practitioner or a private psychiatrist. It aims to improve engagement with ambulatory care and reduce the risk of relapse and readmission (11).

Aim of the Study

This study tests whether transitional case management improves engagement with ambulatory care 1 year after psychiatric hospitalization and whether the intervention affects readmission rate during the year following discharge compared to routine treatment. The first outcome was defined as whether transitional case management intervention improved engagement with care, measured as number of contact with ambulatory care, during the follow-up after discharge. The second outcome was defined as whether transitional case management intervention had an impact on the rate of readmission during the 12 months following discharge.

MATERIALS AND METHODS

Participants

This study is a randomized controlled trial (ClinicalTrials.gov Identifier NCT02258737). Eligible patients were those hospitalized in the admission ward of the psychiatric hospital of Cery in Lausanne, returning home after discharge and followed up by a general practitioner or a private psychiatrist (primary or secondary outpatient care). They were aged between 18 and 65 years. Patients suffering an organic disorder or non-French speaking subjects and those followed up within the university psychiatric services were excluded (tertiary outpatient care). The study was approved by the Biology and Medicine faculty Ethics Committee of Lausanne University. Patients were informed about the confidentiality of data and their right to withdraw from participation at any time. Written informed consent was obtained from all patients.

Immediately after initial assessment, each patient was randomized and assigned to either treatment as usual or to transitional case management. Randomization was in blocks of eight, based on a computer-generated allocation placed in closed envelopes. Envelopes were generated and kept by a member of the administrative staff of the project. Initial and follow-up assessments were conducted by six research psychologists who had been trained prior to the study to ensure inter-rater reliability.

Procedures

Treatment as Usual

Patients allocated to treatment as usual were referred to a general practitioner or a private psychiatrist after discharge.

Transitional Case Management Intervention

In the transitional case management group, a case manager, a nurse, or a social worker was added to the treatment as usual procedure. Their role was not to replace the other care providers but to coordinate care provision and to represent the patient's viewpoint. Transitional case management followed the same nine target areas as critical time interventions to improve continuity of care: system coordination, engagement in psychiatric care, continuation of substance abuse treatment, medication adherence, family involvement and social support network, life skills training and support, integration of medical care, establishment of community linkage, and practical needs assistance (13). Intervention was structured in six steps (14). First, every patient who was to be followed by primary or secondary care was identified at admission. Second, a first contact with the patient was made during hospitalization to propose intervention and evaluate the demands. Third, an evaluation was done with two or three appointments, some of them with the patient alone, other with members of the patient's network, using specific clinical tools:

1. "Echelle lausannoise d'autoévaluation des besoins" (ELADEB), a self-administrated scale that determines patient's needs and expectations through visual cards classified by the patient (15).
2. "Carte réseau," a self-representation of the personal network through which the patient identified people, professional or not, that could provide help after discharge.
3. A "Joint crisis plan" constructed with the case manager (16).

Since discharge, most contacts took place in the community outside the office, up to twice a day if necessary. The fourth step was a home visit, which insured that the discharge plan was realistic and that the network was available. Joint crisis plan was readjusted if necessary. Fifth, during the month after discharge, the transitional case management is adapted according to the needs of patients: minimal was phone calls and being available on demand, standard was four contacts during the follow-up, intensive was more than four contacts with home visits up to twice a day. The case manager often attended appointments (e.g., medical, social work, welfare) with the patient. Sixth, the intervention ended with a meeting between the patient, the transitional case manager, and the medical doctor in charge. A written report was delivered.

Measures

Data on contact with ambulatory care and social functioning were provided by interviews during follow-up assessments (after 1, 3, 6, and 12 months). Social functioning was assessed using the Global Assessment of Functioning (GAF) (17) and clinical status at baseline using the symptom check-list (SCL-90R) global score (18, 19). Data on readmissions were provided by hospital records.

Analysis

The first outcome was defined as whether transitional case management intervention improved engagement with care during the follow-up after discharge. The dependant variable was the number of contact with ambulatory care between 0 and 1, 1 and 3, 3 and 6, and 6 and 12 months after discharge. Because of the count nature of the dependant variable, the comparison between groups was performed using a Poisson regression model. The potential influence of age, sex, level of education, initial level of social functioning, and familial situation was controlled for in an adjusted model. Only significant covariates were included in this additional model. Power calculations for the Poisson regression were based on estimated number of contact with ambulatory care. Given a base rate of 2 contacts with ambulatory care in the treatment as usual group, we could test a 50% increase of the number of contacts with a power of 0.80 with 48 patients per group.

The second outcome was defined as whether transitional case management intervention had an impact on the rate of readmission during the 12 months following discharge. The dependant variable was the duration before first psychiatric readmission. A continuous-time survival analysis was performed using the Cox regression model. The potential influence of age, sex, level of education, initial level of social functioning, and familial situation was controlled for in an adjusted model. Only significant covariates were included in this additional model. We anticipated an event rate of 0.4 and a SD of 0.5 for the group covariate, which would allow us to detect a hazard ratio of 1/3 with a power of 0.80 with 33 observations per group.

Comparisons in terms of demographic and baseline characteristics between the two groups were performed with independent *t*-tests for continuous variables. For categorical variables, analyses were performed using Pearson's Chi-Square tests. All statistical tests were two-tailed and significance was determined at the 0.05 level. All statistical analyses were performed with the Mplus statistical package version 7.4 and IBM SPSS version 22.

RESULTS

Figure 1 summarizes the participant flow. On 396 patients admitted to the "Admission, Orientation, Crise" service during the 17 months of recruitment, 223 (56.3%) were ineligible as they were followed up by the university clinics, were not aged between 18 and 65 years, presented an organic disorder or had significant difficulties in understanding French. One hundred seventy-three (43.7%) fulfilled inclusion criteria and were discharged to follow-up by a general practitioner or a private psychiatrist. Although eligible, 23 (13.29%) patients refused to participate to the study. The transitional case management team was not able to provide an intervention for 40 (23.12%) people: the admission time was too short for 24 patients, the case manager had no availability for 7 patients, and 9 did not live in a catchment area. One hundred ten patients completed the consent form and were randomized. Eight patients, four in each arm, did not attend the baseline interview after randomization. Two moved away in the intervention group and six others withdrew. One hundred two patients were randomly allocated to discharge with transitional case management intervention ($n = 51$) or with a treatment as usual ($n = 51$). Eighty-four (82.4%) patients were interviewed after 12 months of follow-up: research psychologists were not able to contact 8 patients in the transitional case management group and 10 in treatment as usual group. Data from the 51 patients from the transitional case management intervention arm and the 51 patients from the treatment as usual arm were analyzed in an intent to treat analysis. There were no differences between the two groups regarding patients' baseline and clinical characteristics (**Table 1**). Given the low rate of psychotic patients, this sample could be referred as patients suffering from common mental health disorders.

Concerning the first outcome, results of the Poisson regression models at 1, 3, 6, and 12 months are presented in **Table 2**. During the first month after discharge, the number of contact with ambulatory care was not significantly different between the two groups ($B = 0.098$, $p = 0.372$). Between 1 and 3 months after discharge, transitional case management patients reported more contacts with care service ($B = 0.371$, $p = 0.004$). The mean count of contact in the transitional case management group was 2.79 (SD = 1.42), while only 1.93 (SD = 1.29) in the treatment as usual

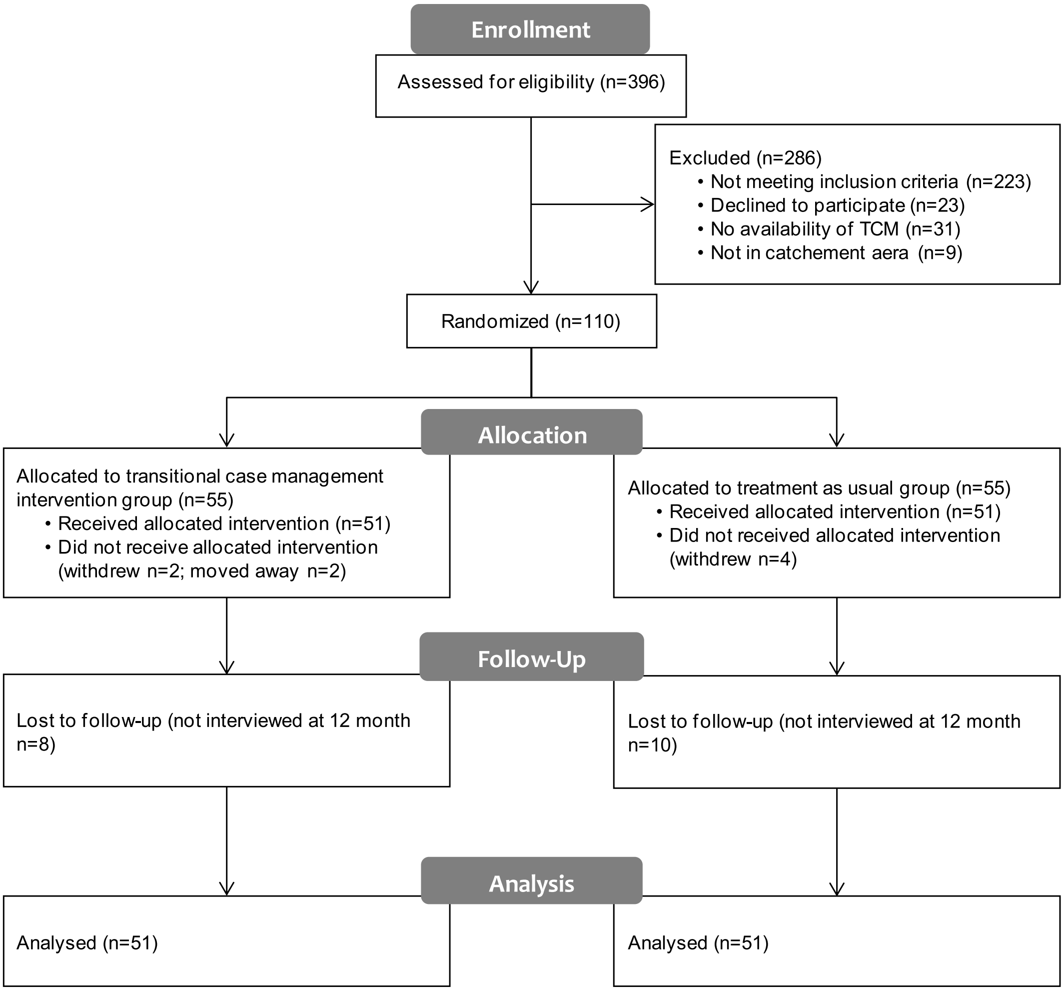

FIGURE 1 | **Participant flow**.

group (Cohen's $d = 0.64$; medium effect). Interestingly, the ratio of patients who reported at least one contact with ambulatory care during the same period was high in both groups (100 versus 87.5% in the control group). In the next 3 months of follow-up (3–6 months after discharge), no significant differences of number of contacts remained ($B = 0.076$, $p = 0.603$). Age favorably influenced the contact count ($B = 0.015$, $p = 0.016$) while male patients tended to report a greater number of contacts with ambulatory care ($B = 0.392$, $p = 0.005$).

Finally, during 6–12 months after discharge, no difference in the number of contact could be observed ($B = 0.108$, $p = 0.406$). However, the positive effect of male gender ($B = 0.423$, $p = 0.001$) and greater age ($B = 0.010$, $p = 0.035$) could still be observed. Overall, the intervention leaded to a moderately increased short-term rate of engagement with ambulatory care despite no differences between the two groups after 3 months of follow-up. In contrast to age and gender, the general level of social functioning at baseline and education were not related to the number of contacts with ambulatory care.

Results of the continuous-time survival analysis are reported in **Table 3**. The Cox regression model revealed no statistically significant beneficial impact of the transitional case management intervention on the rate of readmission (hazard ratio = 0.585, $p = 0.114$; **Figure 2**). The rate of readmission in the treatment as usual group (43.1%) was similar as those observed in the same hospital during the two previous years (respectively, 44.7 and 45.5%), whereas rate of readmission in the transitional case management group was 27.5% although this difference failed to reach statistical significance. A high level of education proved, however, to be a preventing factor against readmission (hazard ratio = 0.292, $p = 0.011$). It should also be noted that the general level of social functioning at baseline was not related to the probability of readmission.

DISCUSSION

Transitional case management leaded to a moderately increased short-term rate of engagement with ambulatory care

TABLE 1 | Patient characteristics at baseline.

Characteristics	Transitional case management group ($n = 51$)	Treatment as usual group ($n = 51$)	Statistic	*p*-Value
Demographics				
Age (years)	40.0 (11.9)	41.3 (10.6)	$t(100) = -0.555$	0.580
Sex, % female (*N*)	66.7 (34)	52.9 (27)	$\chi^2(1) = 1.998$	0.157
Education				
Low[a]	31.4 (16)	31.4 (16)		
Intermediate[b]	39.2 (20)	41.2 (21)	$\chi^2(2) = 0.059$	0.971
High[c]	29.4 (15)	27.5 (14)		
Familial situation				
Single	35.3 (18)	29.4 (15)		
Married	29.4 (15)	43.1 (22)	$\chi^2(2) = 2.097$	0.350
Other[d]	35.3 (18)	27.5 (14)		
Ethnicity				
Caucasian	84.3 (43)	92.2 (47)	$\chi^2(1) = 1.511$	0.219
Origin				
Swiss	62.7 (32)	52.9 (27)	$\chi^2(1) = 1.005$	0.316
Language				
Mother tongue French	78.4 (40)	70.6 (36)	$\chi^2(1) = 0.826$	0.363
Clinical status				
Global assessment of functioning	45.5 (5.9)	46.0 (7.0)	$t(100) = -0.426$	0.671
Symptom check-list global score (SCL-90R)[e]	1.1 (0.5)	1.2 (0.7)	$t(100) = -0.901$	0.370
Duration of illness				
Less than a year	35.3 (18)	33.3 (17)		
Between 1 and 5 years	33.3 (17)	27.5 (14)	$\chi^2(2) = 0.763$	0.683
More than 5 years	31.4 (16)	39.2 (20)		
Clinical history				
First psychiatric admission	84.3 (43)	76.5 (39)	$\chi^2(1) = 0.955$	0.318
Main disorder				
Affective disorder	52.9 (27)	70.6 (36)	$\chi^2(1) = 3.363$	0.067
Neurotic, stress-related or somatoform disorder	19.6 (10)	7.8 (4)	$\chi^2(1) = 2.981$	0.084
Personality disorder	11.8 (6)	5.9 (3)	$\chi^2(1) = 1.097$	0.295
Psychotic disorder	7.8 (4)	7.8 (4)	$\chi^2(1) = 0.000$	1.000
Substance use	7.8 (4)	7.8 (4)	$\chi^2(1) = 0.000$	1.000

[a] *No post school training.*
[b] *Post school training.*
[c] *College/University.*
[d] *Divorced/widowed/separated.*
[e] *Global Severity Index.*

despite no differences between the two groups after 3 months of follow-up. This may indicate that it is the focus on preparing for engagement, rather than the specifics of the transitional case management process that is particularly effective. Globally, the rate of engagement with care was, however, much higher than it was in the only previous study carried out in Lausanne which mostly included younger male patients with first episode psychosis (10). This rate was also considerably above the average rate of 50% identified in the wider literature for follow-up after acute hospitalization (9). These results suggest that linking with primary and secondary outpatient care is better for these patients than linking with tertiary care for more severe and persistent illness.

This short transitional intervention did, however, not reduce significantly the rate of readmissions during the first year following discharge. The rate of readmission in the transitional case management group was not significantly lower than in the treatment as usual group or those generally observed in the same hospital. This lack of important decrease may suggest that case management does not markedly reduces the rate of readmission during the year following discharge and is in accordance with the results of a systematic review about the effectiveness of transitional interventions to reduce psychiatric readmissions in adults (8). Three other studies recently tested a similar intervention and did not find a reduction in either rehospitalization rates (13, 20, 21). The Hengartner et al. study (21) focused on low-frequency users which could be comparable to our sample. The Puschner study included more highly impaired high-frequency users (20), whereas the Dixon study sample could be considered as "intermediate" (13).

Age and male gender showed to increase the number of contact with ambulatory care. A high level of education also showed to be a preventing factor against readmission. Finally, it should be noted that the general level of social functioning at baseline was neither related to the number of contact with ambulatory care nor the probability of psychiatric readmission. These findings may be explained by the focus on a population of higher functioning independent mid age patients who need more support to prevent losses (job, couple, housing) linked to the psychiatric episode.

In fact, most of the research concerning transitional interventions has focused on "revolving door" patients or on severe mentally ill patients suffering a psychosis or a bipolar disorder (22, 23). In this study, the profile of the population differed. The majority of the patients were women. They were married and employed at the moment of their baseline hospitalization. The main diagnosis was an affective, neurotic, stress related, or somatoform disorder in most of the situations. Few patients suffered from psychotic disorder. The duration of the illness was more than 1 year for two-thirds of the patients, but the baseline hospitalization was the first one for the majority of them. The transitional case management concerns itself with specific patients who go through a life crisis and may potentially lose their social situation. These patients may be neglected during their hospitalization, when ward teams are busy with more severe cases. This population is also at high risk to commit suicide in the first weeks after a psychiatric hospital discharge (12).

TABLE 2 | Poisson regression models for the number of contact with ambulatory care.

	B	95% CI	*p*-Value
0–1 months after discharge			
Bivariate model			
Intervention	0.098	−0.110 to 0.307	0.372
Intercept	0.907	0.728–1.086	<0.001
1–3 months after discharge			
Bivariate model			
Intervention	0.371	0.117–0.626	0.004
Intercept	0.655	0.450–0.860	<0.001
3–6 months after discharge			
Bivariate model			
Intervention	0.076	−0.210 to 0.362	0.603
Intercept	0.808	0.613–1.003	<0.001
Adjusted model			
Intervention	0.071	−0.189 to 0.331	0.593
Age	0.015	0.003–0.028	0.016
Sex	0.392	0.116–0.668	0.005
Intercept	−0.108	−0.741 to 0.525	0.739
6–12 months after discharge			
Bivariate model			
Intervention	0.108	−0.147 to 0.363	0.406
Intercept	0.840	0.644–1.037	<0.001
Adjusted model			
Intervention	0.097	−0.134 to 0.329	0.410
Age	0.010	0.001–0.020	0.035
Sex	0.423	0.183–0.664	0.001
Intercept	0.130	−0.334 to 0.594	0.740

CI, confidence interval.

TABLE 3 | Cox continuous-time survival analysis of the duration before first psychiatric readmission.

	B	Hazard ratio	95% CI hazard ratio	*p*-Value
Bivariate model				
Intervention	−0.537	0.585	0.301–1.137	0.114
Adjusted model				
Intervention	−0.540	0.583	0.300–1.132	0.111
Education (high)	−1.232	0.292	0.113–0.752	0.011
Education (low)	−0.429	0.651	0.350–1.362	0.255

CI, confidence interval.

Potential Shortcomings and Limitations

Limitations of this study are low sample size and unique site implementation: replication is therefore needed. The results also relied on a small subsample of all patients initially screened for eligibility. Generalizability of the results may thus be restricted.

CONCLUSION

This 1 month transitional intervention produced a moderately increased short-term rate of engagement with ambulatory care, but no significant reduction in the rate of readmissions during the first year following discharge. Its conception and effectiveness were comparable to the 9 months critical time intervention (24), while focusing on less severe common psychiatric disorders that link with primary or secondary outpatient care after discharge. This suggests that several forms of transitional case management may be necessary to meet the different needs of hospitalized psychiatric patients. Considering deinstitutionalization in psychiatry, more research is needed to study and improve the link between tertiary and primary care.

AUTHOR CONTRIBUTIONS

CB, SGM, PF, and JF contributed to the conception and design of the study. SGM, SG, PF, CB, and SM contributed to the acquisition of the data. PG, SGM, SG, SM, CB, and CBe contributed to data analysis and interpretation of the data. SM and CB drafted the manuscript. PG, SGM, SG, PF, CBe, and JF were involved in the critical revision of the manuscript. All authors have given final approval of the version to be published.

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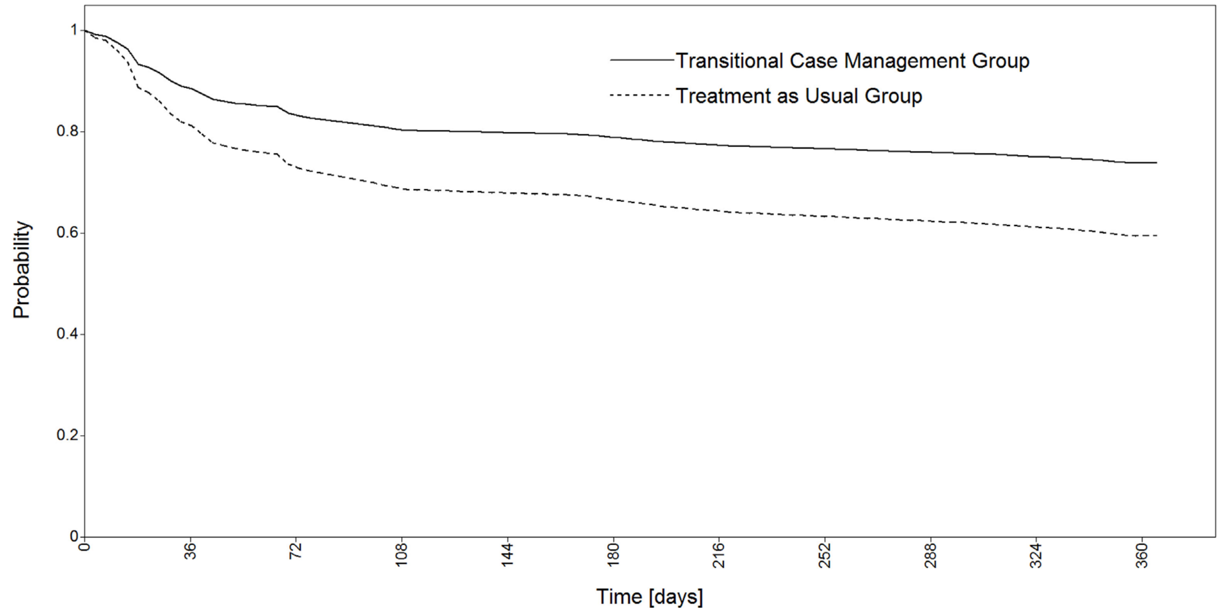

FIGURE 2 | **Cox regression survival curves for the duration before first psychiatric readmission**.

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CLINICAL TRIAL
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The Post-Discharge Network Coordination Programme: A Randomized Controlled Trial to Evaluate the Efficacy of an Intervention Aimed at Reducing Rehospitalizations and Improving Mental Health

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Purpose: To evaluate the efficacy of a post-discharge intervention for psychiatric inpatients aimed at preventing hospital readmissions and at improving patients' mental health and psychosocial functioning.

Methods: Randomized controlled trial using parallel group block randomization including 151 patients with ≤3 hospitalizations within the last 3 years, a GAF score ≤60, and aged 18–64 years, assessed at two psychiatric hospitals from the canton of Zurich, Switzerland, between September 2011 and February 2014. Primary outcomes were rate and duration of rehospitalization; secondary outcomes were mental health and functioning. Outcome measures were assessed before discharge from the index hospitalization (t_0), 3 months after discharge when the intervention terminated (t_1), and 12 months after discharge (t_2). Participants received either a brief case management post-discharge intervention or treatment as usual.

Results: In the short-term (i.e., t_0–t_1), no significant effect emerged in any outcome. In the long term (i.e., t_0–t_2), the two groups did not differ significantly with respect to the rate and duration of rehospitalization. Also, the intervention did not reduce psychiatric symptoms, did not improve social support, and did not improve quality of life. However, it did slightly increase assessor-rated general ($d = 0.30$) and social functioning ($d = 0.42$), although self-reports revealed a deteriorative effect on symptom remission ($d = -0.44$).

Conclusion: This psychosocial post-discharge intervention showed no efficacy in the primary outcome of rehospitalization. With respect to secondary outcomes, in the

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long term it might lead to slightly increased social functioning but revealed no significant effect on psychopathology, social support, and quality of life. By contrast, with respect to self-reported symptom remission, it was revealed to have a negative effect. In this high-resource catchment area with comprehensive community psychiatric and social services, the intervention thus cannot be recommended for implementation in routine care.

Keywords: randomized controlled trial, rehospitalization, discharge, community care, case management, social work

INTRODUCTION

The reduction of costly rehospitalization rates and duration of inpatient treatments constitutes a major objective of modern deinstitutionalized community mental health care in areas with high levels of resources (1). The time immediately after hospital discharge and the transition from inpatient to outpatient treatment is a pivotal time period for psychiatric patients, characterized by high risk of suicide and self-harm (2, 3). Rehospitalization is frequent because, unfortunately, many persons with mental disorders do not comply with appointments in outpatient services (4, 5), do not adhere to medication (6, 7), or disengage from outpatient care (8, 9). These findings emphasize the need for a rigorously planned and coordinated transition from inpatient to outpatient care and for continuity of care (10).

A systematic review of interventions aimed at reducing rates of readmission conducted by Vigod et al. (11) found a statistically significant effect of moderate to large magnitude in only 7 out of 15 studies. Steffen et al. (12), in their systematic review of 11 studies on discharge planning interventions after inpatient treatment, found a modest reduction in readmission rates and mental health problems as well as an increase of adherence to outpatient treatment, but not an improvement in quality of life. Moreover, the validity of those results was limited by the small number of trials and their small sample sizes and conclusions were mostly restricted to the USA. A recent multicentre randomized controlled trial (RCT) in Germany aimed at improving needs-oriented discharge planning [not included in Vigod et al. (11)] failed to find statistically and clinically significant effects (13). In line with this, meta-analyses of case management programs similarly produced mixed results and demonstrated that overall the effectiveness of case management is rather modest (14, 15). Thus, the questions as to whether there is any need for post-discharge interventions or whether a different approach should be adopted remain to be answered.

The aim of this RCT was to evaluate the effectiveness of a newly designed psychosocial post-discharge intervention named Post-Discharge Network Coordination Programme (PDNC-P). This intervention is in line with an emerging focus on resource-oriented therapeutic interventions that aim at fostering interpersonal relationships and social networks (16). As detailed in the study protocol (17), we specifically hypothesized that the PDNC-P would (a) reduce the rate and duration of rehospitalization, (b) reduce psychiatric symptoms, (c) improve social support, (d) improve quality of life, and (e) increase social functioning.

METHOD

Participants and Design

This study was conducted as part of the Zurich Programme for Sustainable Development of Mental Health Services (ZInEP; in German: "Zürcher Impulsprogramm zur nachhaltigen Entwicklung der Psychiatrie"), a research and health care program involving several psychiatric research divisions and mental health services from the canton of Zurich, Switzerland. This RCT initially included 167 participants from the Winterthur – Zurich Unterland psychiatric catchment area, an urban/suburban area of high level resources near the city of Zurich, Switzerland. The sample size was determined according to *a priori* calculations as detailed in von Wyl et al. (17), which assumed an expected medium effect size and a drop-out rate of 25%. The participants were enrolled at two different psychiatric hospitals, that is, the Psychiatrie-Zentrum Hard in Embrach and the Klinik Schlosstal in Winterthur, which are both part of the umbrella organization Integrierte Psychiatrie Winterthur – Zürcher Unterland (IPW). The inclusion criteria were as follows: (1) no more than three hospitalizations within the last 3 years (including the index hospitalization), (2) a Global Assessment of Functioning (GAF) score of 60 or lower, (3) cognitive ability to provide written informed consent, and (4) age between 18 and 64 years. Exclusion criteria were as follows: (1) insufficient German language proficiency, (2) simultaneous support by another case manager, and (3) patient living in supportive housing. Of the 167 randomized participants, 151 patients (90.4%) were included in the analysis. The 16 participants who were excluded from the analysis after the group allocation comprised cases that subsequently conflicted with the inclusion criteria (mainly because they received additional case management or were accommodated in supportive housing over the course of the study). Data analysis was conducted according to the logic of the intention-to-treat (18). The study was approved by the cantonal ethics committee of Zurich (reference number: KEK-ZH 2011-0175). The trial was registered in the International Standard Randomised Controlled Trial Number (ISRCTN) register (reference number: ISRCTN58280620) and the study protocol published and freely available online (17). This report was drafted according to the CONSORT statement (19).

Randomization and Procedure

Participants were allocated randomly to either the intervention or control group with a stratified block randomization for the psychiatric diagnoses according to ICD-10 (20). The random allocation sequence was generated with Microsoft Excel and was implemented by a research associate who was not part of the study group. The intervention, named Post-Discharge Network Coordination Programme (PDNC-P), was developed in collaboration between the IPW and the Zurich University of Applied Sciences (ZHAW). The intervention program aims to improve hospital discharge planning and to ease the transition from inpatient to outpatient care by coordinating a social support network (21). The intervention was provided by two experienced social workers, to one of whom each patient from the intervention group was assigned. Each patient met his social worker prior to discharge and collaboratively agreed upon a close network of social support, a crisis plan, and the terms of program termination. After discharge, a close person from the patient's social network was assigned to be network representative. Also, mostly after discharge, the social workers were instructed to organize an interdisciplinary care review meeting that included the most important persons from the network (in some cases, the meeting took place before discharge). The social worker then visited the patient within the first week after discharge to support and monitor the patient's adjustment to outpatient care and daily life. After the first-week home visit, the social worker scheduled subsequent visits. The program was tailored to meet the patient's personal needs and the frequency of the visits was based on the patient's personal progress. The intervention was directly targeted at promoting recovery through social relationships, which is a key element of resource-oriented therapies (16). The intervention concluded once the terms of termination were reached or after a maximum of 3 months post-discharge from inpatient care (i.e., at t_1). Afterwards the social support network continued to aid the patient without the social worker's assistance. For a detailed rationale of the intervention program, see Hengartner et al. (21).

The control group received treatment as usual, which in Switzerland comprises the patient receiving assistance from a social worker during his or her inpatient stay only if prescribed by the treating physician. Any support by the hospital's social worker ends when the patient is discharged from hospital. However, after discharge some patients still see social workers who are not affiliated with a psychiatric hospital, but instead with the social welfare office of a larger urban community or psychiatric outpatient services. Therefore, patients in the control group might also have seen a social worker during the intervention period, depending on their individual needs.

Both groups were assessed prior to discharge from the index hospitalization (t_0), 3 months after discharge when the intervention terminated (t_1), and 12 months after discharge (t_2). Participants and evaluators were blind to their group allocation at baseline measurement t_0 only, because masking was not feasible once the intervention had started. The recruitment began in September 2011 and the last follow-up assessment of t_2 was carried out in April 2015. The participants' flow is indicated in **Figure 1**.

Outcome Measures

All instruments and measures applied in this study are extensively researched and widely applied in clinical practice and have all shown good reliability and validity. Because of space limits imposed by the journal, we therefore refrain from providing detailed information here and refer to the scientific literature or to von Wyl et al. (17). In short:

Primary outcome: the frequency of readmissions and the duration of inpatient stays were assessed using the IPW clinical registry and the Client Socio-Demographic and Service Receipt Inventory – European Version (CSSRI-EU) (22).

Secondary outcomes: patients' social functioning was measured with the Social and Occupational Assessment Scale (SOFAS) (23). Global functioning was assessed using the GAF scale (24). Both GAF and SOFAS are administered by clinicians and range from 1 (extremely impaired functioning) to 100 (excellent functioning). Social support was measured with the Fragebogen zur sozialen Unterstützung – Kurzform 14 (F-SozU K-14) (25). The F-SozU K-14 is a German self-rating questionnaire, comprising items from the following three domains of perceived social support: emotional support, instrumental support, and social integration. Psychopathological distress and illness severity was assessed with an assessor-rated scale, the Health of the Nation Outcome Scales (HoNOS) (26), as well as with one self-rating instrument, the Outcome Questionnaire (OQ-45, German version) (27). Finally, quality of life was captured with the self-rating scale Manchester Short Assessment of Quality of Life (MANSA) (28).

Statistical Analysis

The group allocation variable (control vs. intervention) was included as the independent or predictor variable in all models. The distribution of various measures across groups at t_0 was analyzed with independent samples Mann–Whitney U tests for continuous variables and with contingency tables and χ^2 tests for categorical variables. Number of rehospitalizations and inpatient days were analyzed with generalized linear models using Poisson distribution and log-link function. For rehospitalization when defined as a dichotomous outcome (no vs. yes), we fitted a binomial logistic regression model. The repeated measures of all outcomes over time in relation to group were examined with a series of generalized estimating equations (GEE) (29). These models were introduced to fit regression analyses that account for within-subject correlation, which is an inherent part of longitudinal studies that rely on repeated measures. Owing to the probability density function of the dependent variables, a Gamma distribution with log-link function best fitted our data for all outcomes (i.e., HoNOS, GAF, SOFAS, F-SozU, MANSA, and OQ-45). Since the total score of the F-SozU was originally left skewed, it was inverted for statistical analysis in order to change its distribution from left skewed to right skewed. As a result, after transformation higher scores indicate less social support. The within-subject covariance was specified with the "unstructured" correlation type to avoid any constraints on the covariance structure. A robust estimator was used to reduce the effects of outliers and influential observations. The intercept and slope factor were included in all analyses, which is standard procedure in longitudinal data modeling (30). In longitudinal analyses, the intercept corresponds to the baseline value of the repeated measures and the slope corresponds to the linear growth rate of those measures (i.e., time-trend). In addition to adjust for the within-subject correlation, the slope factor was also modeled as an interaction effect with the group variable to examine changes in the outcomes over time in relation to group allocation (i.e.,

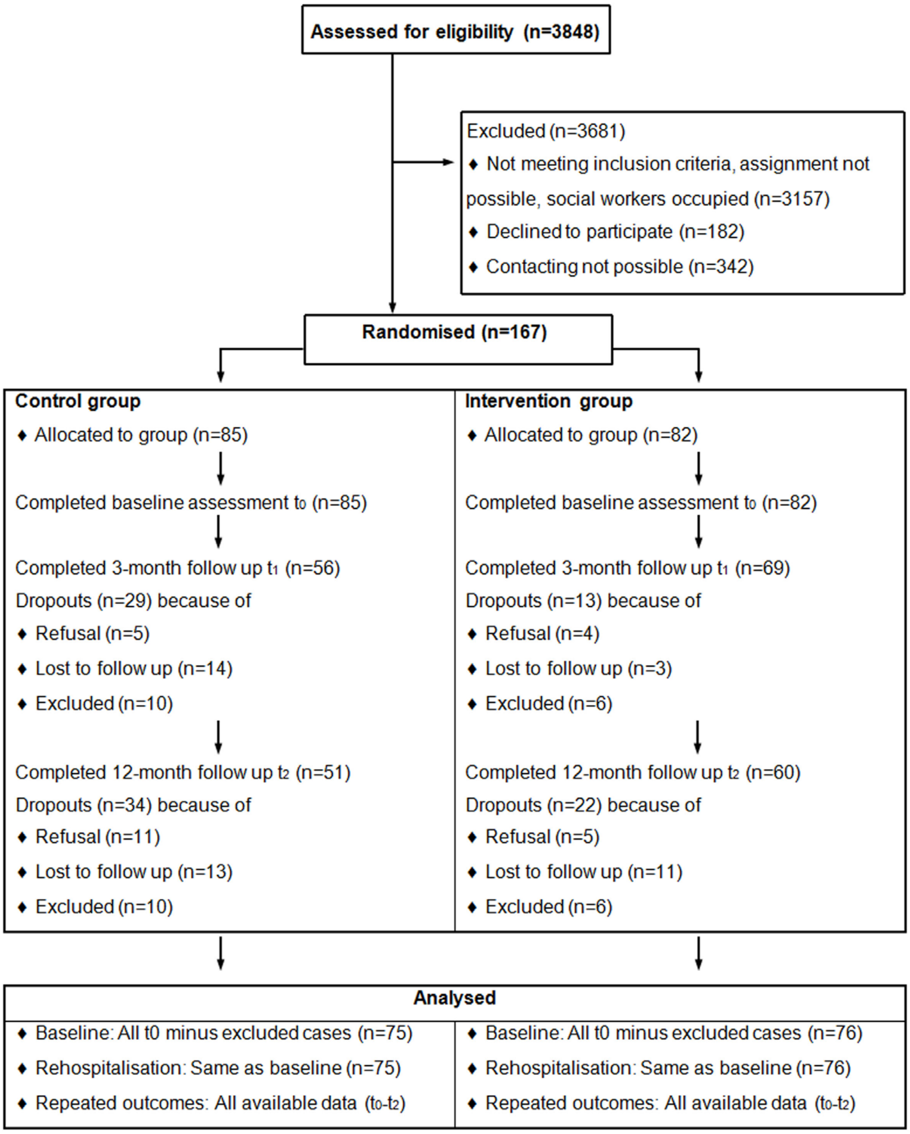

FIGURE 1 | **Participants flow-chart.**

intervention*time). The advantage of such a modeling approach is that its estimates are independent of group differences in baseline values (30). The interaction term was modeled in two different ways: once from t_0 to t_2 to examine group differences across study onset and 12-month follow-up (i.e., enduring effect) and once from t_0 to t_1 to examine group differences across study onset and termination of the intervention at 3-month follow-up (i.e., immediate effect). All analyses were conducted with SPSS 21 for Windows.

RESULTS

The baseline demographic and clinical characteristics at t_0 are shown in **Table 1**. Scores on the HoNOS were on average slightly higher in the intervention group ($p = 0.007$). However, the corresponding effect size was small (Cohen's $d < 0.3$). The distribution of all other variables did not vary significantly across groups (all $p > 0.05$).

Overall, the number of hospital readmissions at the 12-month follow-up ranged from 0 to maximally 6, with a mean number of 0.52 and a SD of 1.06. The total duration of rehospitalizations ranged from 0 to 191 days with a mean and SD of 12.99 and 29.41. The two measures did not differ significantly between groups (both $p > 0.65$ and $d < 0.2$) (see **Table 2**). Adjustment for sex and age did not alter the results; both covariates did not relate to rehospitalization rate and duration. We additionally examined the total number of outpatient visits according to self-reports from the CSSRI-EU. Those numbers did not differ significantly either (M intervention = 13.67; M control = 10.48; Wald $\chi^2 = 2.30$, df = 1, $p = 0.121$). Here, a main effect for sex

TABLE 1 | Baseline descriptive statistics (t_0).

		Group		Test statistic	*p*
		Control ($n = 75$)	Intervention ($n = 76$)		
Age	Years (SD)	41.0 (11.3)	42.1 (11.4)	$U = 2954.0$	0.699
Sex	Men (%)	39 (49.4)	40 (50.6)	$\chi^2 = 0.0$ (df = 1)	0.938
	Women (%)	36 (50.0)	36 (50.0)		
Marital status	Single (%)	31 (49.2)	32 (50.8)	$\chi^2 = 0.4$ (df = 2)	0.809
	Partnership/married (%)	18 (46.2)	21 (53.8)		
	Sep./div./widowed (%)	26 (53.1)	23 (46.9)		
Education level	Low (%)	16 (47.1)	18 (52.9)	$\chi^2 = 0.1$ (df = 2)	0.933
	Moderate (%)	41 (50.0)	41 (50.0)		
	High (%)	18 (51.4)	17 (48.6)		
Present hospitalization[a]	First (%)	43 (50.6)	42 (49.4)	$\chi^2 = 4.1$ (df = 2)	0.126
	Second (%)	18 (40.0)	27 (60.0)		
	Third (%)	14 (66.7)	7 (33.3)		
Primary diagnosis	SUD (%)	19 (51.4)	18 (48.6)	$\chi^2 = 0.7$ (df = 3)	0.862
	Psychosis (%)	22 (53.7)	19 (46.3)		
	Mood disorder (%)	25 (48.1)	27 (51.9)		
	Others (%)	9 (42.9)	12 (57.1)		
HoNOS	Mean (SD)	16.03 (5.49)	18.64 (6.34)	$U = 3578.5$	0.007
GAF	Mean (SD)	36.84 (11.10)	34.30 (10.32)	$U = 2438.5$	0.125
SOFAS	Mean (SD)	43.24 (11.61)	40.26 (11.75)	$U = 2401.0$	0.094
F-SozU (inv.)	Mean (SD)	2.29 (0.91)	2.43 (0.91)	$U = 3058.0$	0.282
MANSA	Mean (SD)	4.43 (1.02)	4.19 (1.13)	$U = 2462.5$	0.189
OQ-45	Mean (SD)	74.02 (24.08)	73.66 (30.43)	$U = 2389.5$	0.918

HoNOS, Health of the Nation Outcome Scales; GAF, Global Assessment of Functioning; SOFAS, Social and Occupational Assessment Scale; F-SozU (inv.), Fragebogen zur sozialen Unterstützung (inverted) [Social Support Questionnaire]; MANSA, Manchester Short Assessment of Quality of Life; OQ-45, Outcome Questionnaire 45.

[a] *Refers to the past 3 years.*

TABLE 2 | Number of rehospitalizations and total inpatient days at 12-month follow-up according to clinical registry records (primary outcomes).

	Group	Mean	95% CI	Test statistic	*p*
Rehospitalizations	Intervention	0.55	0.37; 0.84	$\chi^2 = 0.17$ (df = 1)	0.677
	Control	0.48	0.29; 0.81		
Inpatient days	Intervention	12.96	8.44; 19.91	$\chi^2 = 0.00$ (df = 1)	0.991
	Control	13.01	7.29; 23.22		

was found, with women reporting significantly more outpatient visits (women: mean visits [95% CI] = 15.26 [12.67–18.39]; men: mean visits = 8.90 [6.60–12.99]; $p = 0.001$). However, there was no interaction effect between treatment arm and sex ($p = 0.522$).

All other outcome measures were examined longitudinally with repeated measures. Their means and 95% confidence intervals are depicted graphically in **Figure 2**. The corresponding statistical significance testing of the regression coefficients using a series of GEE is shown in **Table 3**. We found no significant interaction between groups and trajectories from baseline to 3-month follow-up with respect to all outcomes (intervention*time t_0, t_1). However, values differed significantly from baseline to 12-month follow-up between groups (intervention*time t_0, t_2) with respect to GAF, SOFAS, and OQ-45. As measured with both GAF and SOFAS, patients in the intervention group showed slightly better functioning over time compared to those in the control group (Cohen's $d = 0.30$ and 0.42, respectively). As for the OQ-45, participants in the control group had a steeper decline, indicating that their subjective distress improved more than those in the intervention group (Cohen's $d = -0.44$).

DISCUSSION

General Discussion

This RCT was conducted to evaluate a newly designed psychosocial intervention named Post-Discharge Network Coordination Programme (PDNC-P), which is a brief form of transitional case management. For more information, see Hengartner et al. (21). The PDNC-P was primarily conceived to reduce instant readmission after psychiatric hospitalization and secondarily to improve patients' mental health, social support, quality of life, and social functioning. This intervention was designed according to the emerging recovery approach and its focus on the personal needs of the service user (31). As recently reviewed by Priebe et al. (16), social relationships form a key element in resource-oriented therapeutic interventions. Nevertheless, the intervention yielded no significant immediate short-term effect at all (i.e., 3-month follow-up). In the long term (i.e., 12-month follow-up) and with respect to both primary outcomes and most secondary outcomes, our program yielded no effect either. That is, the PDNC-P did (a) not reduce the rate and duration of rehospitalization, (b) did

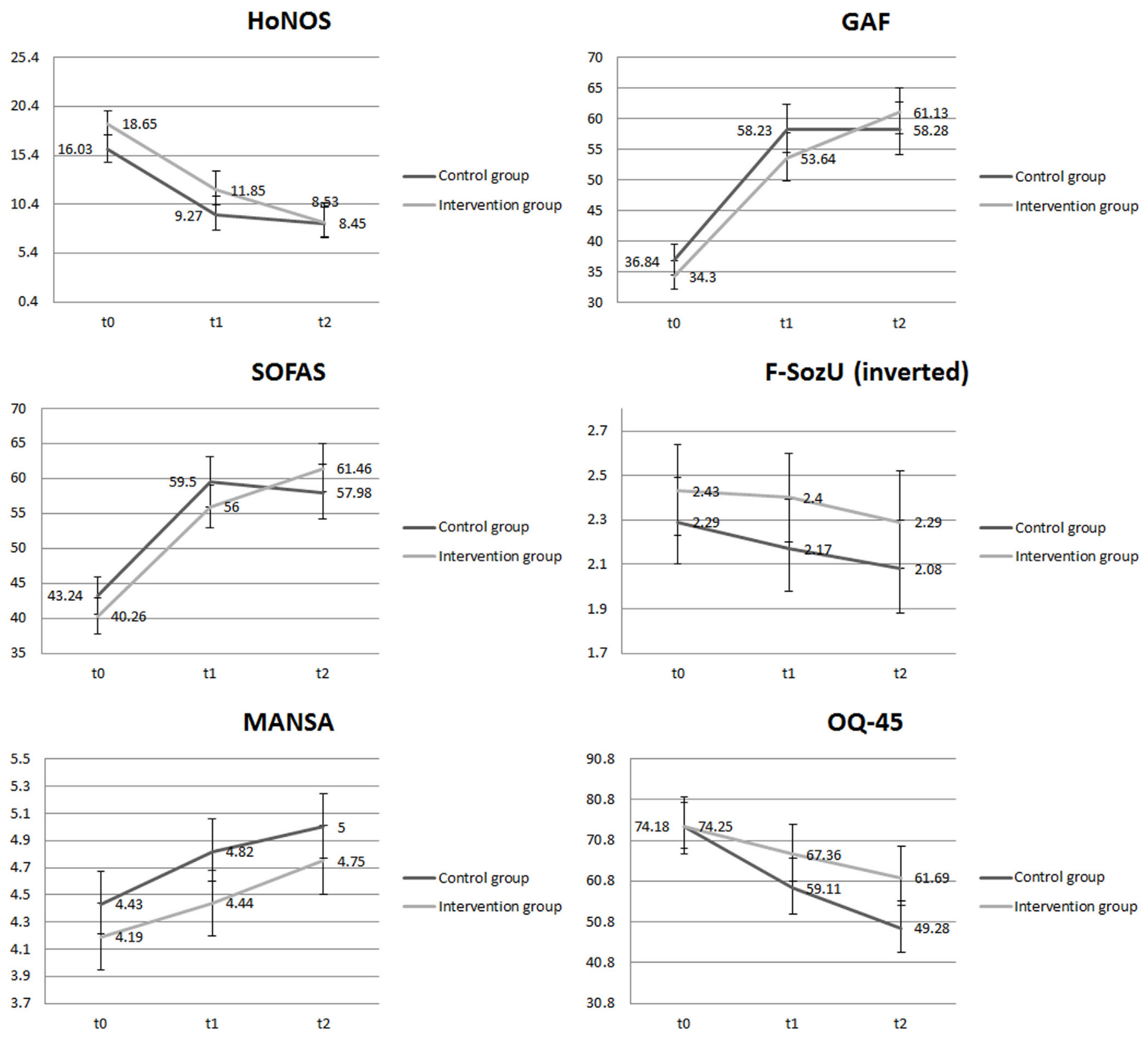

FIGURE 2 | Results of repeated outcome measures (secondary outcomes). HoNOS, Health of the Nation Outcome Scales; GAF, Global Assessment of Functioning; SOFAS, Social and Occupational Assessment Scale; F-SozU (inv.), Fragebogen zur sozialen Unterstützung (inverted) [Social Support Questionnaire]; MANSA, Manchester Short Assessment of Quality of Life; OQ-45, Outcome Questionnaire 45.

not reduce psychiatric symptoms, (c) did not improve social support, and (d) did not improve quality of life. However, (e) it slightly increased social functioning in the long term according to GAF and SOFAS, but on the other hand (f) with respect to self-reported illness severity (i.e., OQ-45), we found that the intervention had a moderate negative effect. That is, participants in the intervention group indicated significantly less symptom remission in the long term than participants in the control group. This is an unexpected finding that needs careful examination in further studies. Although it has been shown that some psychosocial interventions may cause harm in certain patients (32, 33), it would be premature to draw any conclusions on this issue here without additional analyses. Our main objective in future research will, thus, certainly be to conduct comprehensive in-depth analyses with respect to the OQ-45.

For the time being, in an attempt to integrate the findings of the present study with the literature, we conclude that they are mainly in line with the lack of association and inconsistent results of previous studies. For instance, a needs-oriented discharge planning across multiple sites in Germany evaluated by Puschner et al. (13) did not reveal any positive effect on the patients' psychopathology and hospital readmission rates. Neither did, for instance, another well-known RCT (34) nor a matched case-control study (35) from the US. A recently conducted systematic review showed mixed

TABLE 3 | Results of a series of GEE. Control group is the reference (secondary outcomes).

		b	95% CI	Test statistic	*p*
HoNOS	Intervention * Time t_0, t_2	−0.14	−0.40; 0.11	$\chi^2 = 1.2$ (df = 1)	0.278
	Intervention * Time t_0, t_1	0.10	−0.14; 0.33	$\chi^2 = 0.6$ (df = 1)	0.426
GAF	Intervention * Time t_0, t_2	0.12	0.01; 0.23	$\chi^2 = 4.3$ (df = 1)	0.040
	Intervention * Time t_0, t_1	−0.01	−0.14; 0.12	$\chi^2 = 0.0$ (df = 1)	0.869
SOFAS	Intervention * Time t_0, t_2	0.13	0.02; 0.24	$\chi^2 = 5.1$ (df = 1)	0.024
	Intervention * Time t_0, t_1	0.01	−0.10; 0.12	$\chi^2 = 0.0$ (df = 1)	0.843
F-SozU (inv)	Intervention * Time t_0, t_2	0.04	−0.09; 0.17	$\chi^2 = 0.4$ (df = 1)	0.543
	Intervention * Time t_0, t_1	0.04	−0.06; 0.15	$\chi^2 = 0.6$ (df = 1)	0.432
MANSA	Intervention * Time t_0, t_2	0.01	−0.06; 0.07	$\chi^2 = 0.0$ (df = 1)	0.891
	Intervention * Time t_0, t_1	−0.03	−0.11; 0.05	$\chi^2 = 0.4$ (df = 1)	0.507
OQ-45	Intervention * Time t_0, t_2	0.23	0.08; 0.37	$\chi^2 = 8.9$ (df = 1)	0.003
	Intervention * Time t_0, t_1	0.13	0.00; 0.26	$\chi^2 = 3.8$ (df = 1)	0.050

HoNOS, Health of the Nation Outcome Scales; GAF, Global Assessment of Functioning; SOFAS, Social and Occupational Assessment Scale; F-SozU (inv.), Fragebogen zur sozialen Unterstützung (inverted) [Social Support Questionnaire]; MANSA, Manchester Short Assessment of Quality of Life; OQ-45, Outcome Questionnaire 45.

and inconclusive results as well, pointing out that only seven of 15 studies (that is, less than half) found a significant reduction in readmission rates (11). In an earlier systematic review, Steffen et al. (12) showed that discharge planning interventions had only a small effect on mental health outcomes and no effect on quality of life. Finally, meta-analyses of psychiatric case management also yielded rather modest beneficial outcomes overall, especially in patients who are not high-frequency users (14, 15). Hitherto, engagement with health services proved to be the only consistently replicated positive outcome in intensive case management programs (36). Therefore, a conservative interpretation of the literature would be that to date there is no compelling evidence of a reliable and sustainable (post-) discharge intervention with unequivocal and substantial long-term benefits, especially in care settings that have already achieved low rates of hospitalizations and in patients with rather low use of inpatient treatments (14).

Since case management programs appear to be effective only in severely impaired "revolving-door" patients (14, 15), it could be that our sample was not impaired enough. The rather low rehospitalization rates point toward such an explanation. In addition, as discussed previously (21), a social network intervention, such as the PDNC-P, builds on the premise that patients possess an adequately robust social network, an assumption that is certainly violated in many patients. Finally, the PDNC-P is not targeted at stable internal patient characteristics; it aims at altering external structures, that is, the patient's social environment. Hence, a patient's personality, in particular trait neuroticism, which is a major predictor of service use (37–40), remains mostly unaffected by such an intervention and may, thus, undermine its effectivity. More specifically, persons scoring high on neuroticism are less resilient to the effects of stressful life events (41, 42), respond inadequately to psychosocial treatments (43, 44), and have, which is crucial for a social network intervention, often disruptive relationships and poor interpersonal resources (45, 46). That is, for these patients the social network is not a resource, but rather a problem area. As, for instance, detailed in Hengartner (37) and Tyrer (47), we therefore suggest that future interventions should opt to consider patients' personality traits to improve sustainability and effectivity of psychiatric interventions. Finally, in Switzerland, a comprehensive care system that offers support and consulting to persons with mental health and social problems is provided not only by inpatient psychiatric services but also by social welfare departments and outpatient community services in larger urban communities. Those regulatory community services provide, among others, socio-legal support for tenancy issues, occupational resettlement programs upon unemployment, and psychiatric nursing. In particular in the urban region of Zurich, a comprehensive and highly specialized network of mental health services and care providers has been established, which also includes many private offices of psychotherapists and psychiatrists. However, in suburban and rural communities, outpatient mental health services are less frequent. In those parts of the catchment area, only social assistance and home care exist, but no specialized services. Nevertheless, in communities with high mental health resources, for initially low-frequency users with minor treatment needs, it is possible that additional post-discharge interventions do not provide a benefit to the established psychosocial care and support services.

Limitations and Generalizability

The generalizability of the results is limited insofar as only low-frequency users were included (i.e., patients with no more than three hospitalizations within the last 3 years). We felt obliged to conceive the study in this way because we had experienced that chronic high-frequency users were not suitable for this kind of intervention. Moreover, only 151 patients out of 3848 persons (4.0%) who were initially assessed for eligibility were eventually included in the analysis. As a consequence, the representativity and generalizability of the study may be restricted. However, this is a general limitation inherent to most, if not all, research in this field. The systematic exclusion of most patients in RCT-research poses a serious problem to the relevance and validity of RCT-findings for general mental health practice in the community (48). Another limitation is that blinding was feasible only at t_0. Afterwards, the patients, the social workers, and the assessors were aware of which group each patient was allocated to (open-label trial). In an attempt to minimize bias, we ensured that participants were not always rated by the same assessor. It is also important to note that self- and assessor-ratings capture differential aspects of the same person, which is why they are commonly only moderately correlated (49). Another limitation that needs to be addressed is the drop-out rate of 33.5%. No measure of mental health and functioning at baseline (t_0) predicted subsequent drop-out at t_1 or t_2. However, the analysis showed that the drop-out rate differed considerably between groups (40.0% in the control group vs. 26.8% in the intervention group). This is relevant insofar as it has been argued that both harmful and successful interventions may yield higher drop-out rates (33). Therefore, we cannot exclude a respective potential bias.

In conclusion, in this RCT, a post-discharge intervention comprising a brief case management and network coordination provided by a social worker did not yield a statistically and practically significant effect on rates and duration of rehospitalizations (primary outcomes). In respect to secondary outcomes, the intervention did neither relate to quality of life and social support at 12-month follow-up after hospital discharge. The intervention did slightly increase global and social functioning, though. However, with respect to enduring self-reported mental health, the intervention even exerted a deteriorative effect on patients' recovery. As a consequence, we feel compelled to state that in contrast to the assessor-rated social functioning, the intervention demonstrated a negative effect on the patients' self-reported mental health in the long term. Taken together, without modifications this intervention, thus, cannot be considered appropriate and helpful for patients without a preceding history of frequent hospitalizations in a setting with high resources and diverse mental health and social services as implemented in the region of Zurich, Switzerland. We, therefore, contend that the development and implementation of further psychosocial post-discharge interventions should be subject to close scrutiny.

ETHICS STATEMENT

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The study was approved by the ethics committee of the canton of Zurich (KEK).

AUTHOR CONTRIBUTIONS

MH drafted the manuscript and conducted all statistical analyses. SP and GH participated in data collection and writing of the manuscript. AA and AW designed the study and participated in writing. WR designed the complete research program (ZInEP) and participated in writing of the manuscript. All authors critically revised the manuscript and approved the final version.

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Challenges and Perspectives in Bridging In- and Outpatient Sectors: The Implementation of Two Alternative Models of Care and Their Effect on the Average Length of Stay

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New models of care aimed at reinforcing the outpatient sector have been introduced in Germany over the last few years. Initially, a subscription-based model ("integrated care") was introduced in 2012 in the Immanuel Klinik Rüdersdorf, wherein patients had to actively subscribe to the integrated care program. This integrated care model was replaced after 2 years by a subscription-free "model project," in which all patients insured by the contracting insurance company took part in the program. Data showed that the introduction of the integrated care program in the inpatient setting led to an increase of the average length of stay in this group. The switch to the model project corrected this unwanted effect but failed in significantly decreasing the average length of stay when compared to standard care. However, both the integrated care program and model project succeeded in reducing the length of stay in the day care setting. When adjusting for the sex and diagnosis proportions of each year, it was shown that diagnosis strongly influenced the average length of stay in both settings, whereas sex only slightly influenced the duration of stay in the inpatient setting. Thus, in spite of strong financial and clinical incentives, the introduction of the model project couldn't fulfill its primary purpose of shifting resources from the inpatient to the outpatient setting in the initial years. Possible explanations, including struggle against long-established traditions and reluctance to change, are discussed.

Keywords: integrated care, psychiatric care, outpatient treatment, care models, duration of stay

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INTRODUCTION

In the past few years, Germany has experimented with new models of care in order to repair the known deficits of the German psychiatric care system. Namely, it sought to counter the unbalanced allocation of resources, and the lack of interface management between the in- and outpatient sectors. These deficits have already been described in depth in previous studies and reports (1, 2).

The first initiative took the form of regional budgets. Regional budgets are financing models that are based on the cooperation between regional health care providers and all health insurance companies involved. In this model, a global annual budget is allocated to hospitals by the insurance companies to finance psychiatric care. The use of in- and outpatient resources is financed by this budget under the sole responsibility of the care providers, who make all decisions regarding their allocation. This annual budget creates a strong financial incentive to reduce the use of inpatient care and develop more comprehensive offerings in the outpatient sector. Such a project was established for the first time 10 years ago in the region of Steinburg. Meanwhile, other projects emerged, particularly in Schleswig-Holstein, but also in Nordhausen/Thüringen. However, the legal basis of the regional budgets [§26 of the "Bundespflegesatzverordnung" (German National Hospital Rate Ordinance)], set important barriers to their implementation, notably that all health insurance companies must agree to the regional budget.

The so-called integrated care (legally governed by the §140 a SGB V), presents itself as an alternative to regional budgets. In this model, the care provider receives annually a fix amount of money per patient subscribing to the program. It can be implemented in the community as well as in hospitals without the participation of all insurance companies, since it is based on cooperation agreements between a care provider and a single insurance company. Examples of integrated care models are the projects located at the University Hospital Hamburg/Eppendorf, in Munich (Klinikum München-Ost) as well as home treatment models in Krefeld und Frankfurt (3).

Data regarding the effects of integrated care projects and regional budgets on clinical and financial outcomes are, to date, scarce. Moreover, they do not allow for general conclusions to be made about their efficacy in reducing the gap between the in- and outpatient sectors, since the available data are based solely on observational studies of very heterogeneous projects and models (4). After 5 years, the accompanying research of the University of Leipzig showed that the use of inpatient resources within the regional budget in Steinburg was considerably reduced. The rates of day- and outpatient care were concomitantly increased (5–8). In Munich, the average length of stay decreased since the implementation of the new integrated care model and patients reported a high level of satisfaction, although the implementation process was not free of difficulties (9). In Hamburg, a new model that focused on severely ill patients (F2x und F3x ICD-10 diagnostic codes) contributed to an increase in the outpatient contacts, a decrease of the average inpatient length of stay, and higher patient satisfaction by maintaining cost-effectiveness (10–12). In Krefeld, a new home treatment-based implemented model proved to be effective in increasing the satisfaction of patients and their next of kin, while preserving a constant quality of care when compared to standard inpatient care (13, 14). Finally, the integrated care project of the public insurance provider DAK-Krankenkasse has been implemented in four regions in Germany. It is based on a close cooperation with psychiatrists in private practices and has led to a significant reduction of inpatient length of stay, as an observational evaluation study showed (15).

The new patient-linked remuneration system of the integrated care models should offer a more flexible form of care. In this model, the service providers carry the responsibility for the allocation of resources and hence bear all the financial risks. As in the case of regional budgets, this should be a powerful financial incentive to reduce the costs of the inpatient sector and to develop more comprehensive outpatient care including assertive community treatment (ACT) and home treatment (16). A stronger and more dynamic cooperation with the outpatient sector should allow patients to be discharged earlier and thus decrease the average inpatient length of stay.

A potential problem of the integrated care model is that patients must actively subscribe to it, with the risk that many severely ill patients, who should primarily benefit from such a program, do not get to subscribe to it. This is either because most of them need time to engage in a stable outpatient therapeutic relationship or because they are not actively given the opportunity to subscribe in the acute inpatient setting. Data regarding this issue are controversial: in a previous work, we confirmed this hypothesis by showing low subscription rate by patients with a F2 diagnosis (17), whereas another study showed higher subscription rates of patients with a F2/F31 diagnosis when compared to other diagnostic groups (18).

To avoid this potential negative effect, the legislator introduced another legal basis governing the development of new models of integrated care. The §64b SGB V stipulates that at least one so-called "model project" consisting in an agreement between care providers (e.g., hospitals) and an insurance company should be implemented in every federal state. All patients insured by the contracting insurance company benefit from the program without active subscription, thus allowing the most severely ill patients to be part of such a program. This should help to reduce the duration of their hospital stays and to transfer them effectively in the outpatient care.

An integrated care model was implemented in the Immanuel Klinik Rüdersdorf in 2012 on the basis of the described subscription model (§140a) in cooperation with one, and later two, insurance providers (Techniker Krankenkasse and Barmer GEK). After 2 years, the model switched to the new subscription-free model project (§64b) to counter the described negative effects of the subscription model as well as the increase of the lengths of stay observed in our hospital in 2013.

The present study aims at evaluating if the switch to the model project led to a shortening of the average length of stay when compared to the integrated care program and to standard care.

We thus here analyze and compare the average lengths of stay of patients of these three groups (integrated care, model project, standard care).

MATERIALS AND METHODS

The data analysis is based on patient's data available in the hospital information system (here SAP) that have been analyzed using the associated software. Patients admitted to the hospital over the course of 2013 and 2014 were divided in three groups: standard care (2013 and 2014), integrated care after §140a (2013), and model project after §64b (2014). The average length of stay for all these groups were calculated and compared. Patients insured by the cooperating insurance company actively subscribed to the integrated care model in 2013. In 2014, all patients insured by both cooperating companies were included in the model project, without the need to subscribe. Patients admitted at the end of 2013 remained under the regime of integrated care (§140a). Their calculated length of stay has been taken into account for 2013. Length of stay of patients admitted in the end of 2014 and discharged in 2015 has been taken into account for 2014. No change from one model to another occurred.

To describe and analyze the influence of confounding factors, a multifactorial analysis of the length of stay was made including sex, age, and diagnosis (after ICD-10) as potential explaining factors.

The statistical analysis was carried out using the SAS 9.4, TS1M319 package (19). For checking the equality of proportions, the asymptotic χ^2 test ($n \geq 1{,}000$) or Fisher's exact test ($n < 1{,}000$) was used. Mean lengths of stay were compared by Student's t test. For estimating the model effect on the length of stay while adjusting for effects of sex, age, or diagnosis group, a backward analysis of variance (ANOVA) was carried out. Starting model in all cases was in symbolic form: length of stay = model + year + diagnosis group + sex + age group + diagnosis group * model. The factor "model" has two values: standard treatment and non-standard treatment, where the latter means treatment within the integrated care program (in 2013) or treatment within the model project (in 2014). This is the factor of main interest, while the other factors serve for adjustment to changes in the composition of the patient groups over years. Type III sum of squares were used to assess the importance of factors. For all tests a p value ≤ 0.05 ($\alpha = 5\%$) was considered to signal a significant difference.

The present study was conducted solely on the basis of anonymized data retrieved from the hospital information system and didn't imply the direct involvement of patients. Hence, it did not require the approbation of the local ethics committee.

TABLE 1 | Patient counts by sex and age group.

Inpatient setting		2013		2014	
		Integrated	**Standard**	**Model**	**Standard**
	Total	119	1,514	375	1,179
	Women (%)	56 (47.0%)	693 (45.7%)	180 (48.0%)	477 (40.4%)
Age groups (%)	<18 years	–	1 (0.07%)	1 (0.3%)	–
	18–35 years	25 (21.0%)	389 (25.7%)	92 (24.5%)	253 (21.5%)
	36–55 years	62 (52.1%)	645 (42.6%)	189 (50.4%)	532 (45.1%)
	56–65 years	14 (11.7%)	249 (16.4%)	41 (10.9%)	189 (16.0%)
	>65 years	18 (15.1%)	230 (15.2%)	52 (13.9%)	205 (17.4%)
Day care setting		**2013**		**2014**	
		Integrated	**Standard**	**Model**	**Standard**
	Total	60	304	161	249
	Women (%)	38 (63.3%)	202 (66.4%)	105 (65.2%)	159 (63.8%)
Age groups (%)	<18 years	–	–	–	1 (0.4%)
	18–35 years	19 (31.7%)	111 (36.5%)	58 (36.0%)	80 (32.1%)
	36–55 years	29 (48.3%)	153 (50.3%)	80 (49.7%)	118 (47.4%)
	56–65 years	10 (16.7%)	38 (12.5%)	19 (11.8%)	42 (16.9%)
	>65 years	2 (3.3%)	2 (0.7%)	4 (2.5%)	8 (3.2%)

RESULTS

Demographic Characteristics of the Patients Sample

The patients' demographic characteristics are summarized in **Table 1**.

Average Length of Stay

In 2013, the average length of stay of patients in inpatient setting who subscribed to the integrated care model was 26.8 days ($n = 119$). The length of stay of patients who did not take part in this program was 20.0 days ($n = 1{,}514$). This difference was shown to be statistically significant ($p = 0.003$). In 2014, the average length of stay of patients in the model project was 20.7 days ($n = 375$). Patients in the standard care group stayed in the hospital 19.5 days in average ($n = 1{,}179$, $p = 0.397$), thus showing no statistically significant difference. The comparison of the average lengths of stay between the integrated care group (2013) and the model project group (2014) showed a statistically significant reduction of the average length of stay ($p = 0.017$). These results are summarized in **Table 2**.

In day care setting, the average duration of stay of patients who subscribed to the integrated care program in 2013 was 30.4 days ($n = 60$), whereas patients in the standard care group showed a significantly longer average length of stay [36.6 days ($n = 304$)] ($p = 0.017$). A similar difference could be shown for 2014 after the transition to the model project: patients in the model project showed shorter lengths of stay when compared to the standard care group [31.6 days ($n = 161$) vs. 35.9 days ($n = 249$)] ($p = 0.008$). No significant difference in the length of stay between the integrated care and model project could be shown ($p = 0.901$). These results are summarized in **Table 3**.

Diagnosis and Length of Stay

The average lengths of stay in each diagnostic group (after ICD-10) in both inpatient and day care setting are summarized in **Tables 2** and **3**. No statistically significant difference regarding diagnostic groups could be shown between 2013 and 2014 for patients in the integrated care and model project in both inpatient and day care setting.

Analysis of Variance

In the inpatient setting, the ANOVA for the factors potentially influencing the average length of stay in both standard and integrated care/model project groups (type of model, age, sex, diagnosis, and year) showed that it strongly depends on diagnosis and sex. Patients of the F2 and F3 groups showed significantly longer lengths of stay compared with the other diagnosis groups. Male patients stayed on average 2.6 days shorter than female patients. Participation to the integrated care program or model project only slightly influenced ($p = 0.594$) the length of stay. No influence of age could be shown. The integrated care program and model project showed no diagnosis-specific effect compared to the subscription program on the average length of stay. These results are shown in **Table 4**. Estimated durations of stay for the various subgroups are shown in **Figure 1**, together with their 95% confidence intervals.

In day care setting, the ANOVA showed that the average length of stay strongly and significantly depended on the diagnosis and on participation to the integrated care/model project, with patients in this group staying 5.7 days shorter on average. No specific effect of age, sex, or an interaction of diagnosis and

TABLE 2 | Mean length of stay of inpatients by diagnosis group and sex.

Inpatient setting		2013		2014		*p* Value (integrated care vs. model project)
		Integrated	Standard	Model	Standard	
All diagnoses	*n*	119	1,514	375	1,179	
	L. of stay (d)	26.8	20.0	20.7	19.5	0.017
Male	*n*	63	821	195	702	
	L. of stay (d)	23.2	15.7	17.1	17.5	0.069
Female	*n*	56	693	180	477	
	L. of stay (d)	30.9	25.2	24.6	22.4	0.087
F00–F09	*n* (%)	1 (0.8%)	78 (5.2%)	16 (4.3%)	70 (5.9%)	
	L. of stay (d)	11.0	16.3	17.6	14.9	–
F10–F19	*n* (%)	28 (23.5%)	602 (39.8%)	135 (36.0%)	456 (38.7%)	
	L. of stay (d)	12.9	10.6	10.3	11.0	0.17
F20–F29	*n* (%)	17 (14.3%)	220 (14.5%)	46 (12.3%)	159 (13.5%)	
	L. of stay (d)	26.9	31.4	43.6	34.2	0.14
F30–F39	*n* (%)	67 (56.3%)	439 (29.0%)	129 (34.4%)	326 (27.7%)	
	L. of stay (d)	33.8	32.4	27.6	28.4	0.095
F40–F49	*n* (%)	5 (4.2%)	125 (8.3%)	42 (11.2%)	131 (11.1%)	
	L. of stay (d)	15.0	9.1	11.3	12.1	0.59
F60–F69	*n* (%)	–	28 (1.8%)	7 (1.9%)	19 (1.6%)	
	L. of stay (d)	–	9.3	6.7	15.1	–

Indicated p values refer to t test results for comparing the mean lengths of stay under the integrated care program (2013) with the model project (2014).

TABLE 3 | Mean length of stay of day care patients by diagnosis group.

Day care setting		2013		2014		*p* Value (integrated care vs. model project)
		Integrated	Standard	Model	Standard	
All diagnoses	*n*	60	304	161	249	
	L. of stay (d)	30.4	36.8	31.6	35.9	0.90
F10–F19	*n* (%)	–	1 (0.3%)	4 (2.5%)	7 (2.8%)	
	L. of stay (d)	–	10.0	6.8	21.7	–
F20–F29	*n* (%)	4 (6.7%)	15 (4.9%)	11 (6.8%)	17 (6.8%)	
	L. of stay (d)	26.0	36.9	27.6	40.2	0.88
F30–F39	*n* (%)	53 (88.3%)	251 (82.6%)	119 (73.9%)	189 (75.9%)	
	L. of stay (d)	31.0	37.1	32.3	37.7	0.97
F40–F48	*n* (%)	1 (1.7%)	24 (7.9%)	16 (9.9%)	25 (10.0%)	
	L. of stay (d)	12.0	30.8	29.9	28.8	–
F60–F69	*n* (%)	2 (3.3%)	13 (4.3%)	11 (6.8%)	11 (4.4%)	
	L. of stay (d)	33.0	40.2	39.8	23.9	0.74

p Values refer to t test results for comparing the mean lengths of stay under the integrated care program (2013) with the model project (2014).

TABLE 4 | Final results of backward analysis of variance for inpatients.

Source	DF	Type III SS	Mean square	F value	Pr > F
Type of treatment (standard or inscription/model)	1	135.5	135.5	0.28	0.5944
Diagnosis group	6	285,842	47,640	99.67	<0.0001
Sex	1	4,576	4,576	9.57	0.0020

*Estimated durations of stay for the various subgroups are shown in **Figure 1**.*

type of model could be shown. These results are shown in **Table 5**. Estimated durations of stay for all relevant subgroups are shown in **Figure 2**, together with their 95% confidence intervals.

DISCUSSION

The introduction of a subscription-based integrated care model was supposed to lead to shorter average lengths of stay. Such an effect in an inpatient setting could not be observed in the present study. On the contrary, the average length of stay in this setting rose, against expectations, whereas they decreased as expected in day care setting.

This result was obviously linked to the negative effect of the subscription model and the repartition of diagnoses it led to, as shown in a previous work in which possible explanations are discussed (17). These include a stronger desire for more comprehensive and intensive treatments by patients with affective disorders; a difficulty to reach many patients who stay only a few days in the hospital, thus making an active subscription to the program difficult; and the fact that many patients with an addictive disorder only completed short treatment courses without being willing to engage in longer and comprehensive outpatient treatments. Thus we expected to counter this effect after switching to the newly introduced subscription-free model project. The hypothesis was that this switch would correct the observed shift in the distribution of diagnostic groups in the

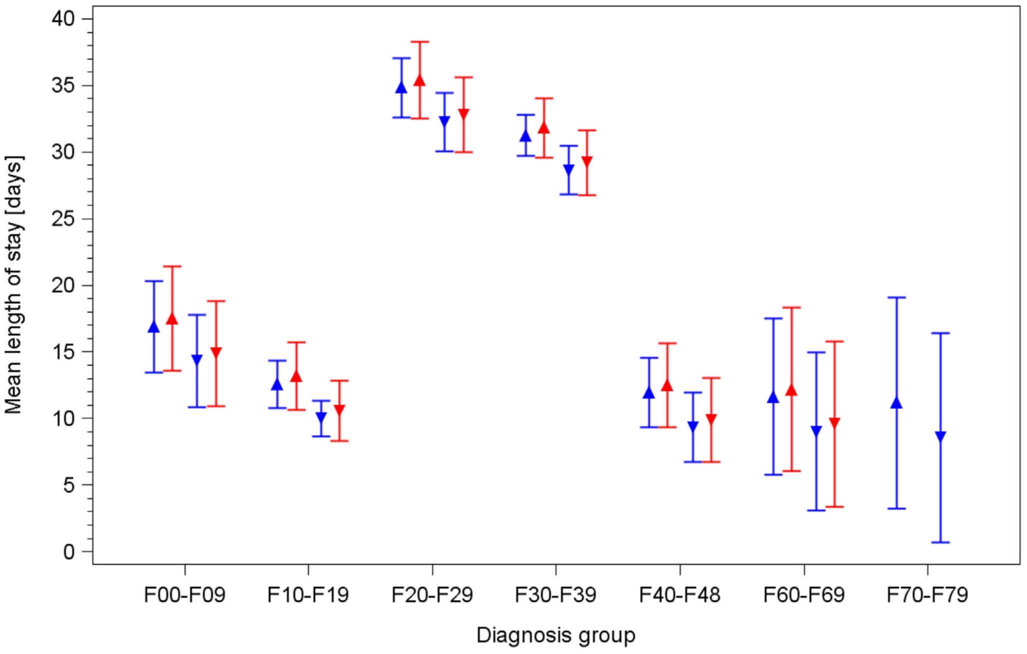

FIGURE 1 | Mean duration of stay for inpatients in both standard care and integrated care/model project groups, by diagnosis and sex, estimated by the final model of backward analysis of variance. Upward triangles: females; downward triangles: males. Blue lines/symbols: standard care; red lines/symbols: integrated care/model project.

TABLE 5 | Final results of backward analysis of variance for day care patients.

Source	DF	Type III SS	Mean square	*F* value	Pr > *F*
Type of treatment (standard or inscription/model)	1	5,052	5,052	14.52	0.0001
Diagnosis group	4	6,495	1,624	4.67	0.0010

Estimated durations of stay for the various subgroups are shown in ***Figure 2****.*

integrated care program and thus lead to a shortening of the average length of stay when compared to the integrated care program. Furthermore, we hoped that the model project could show its expected effect on the duration of inpatient stay compared to standard care.

The results partly confirmed our hypothesis in the inpatient setting. There, the switch to the subscription-free model project led to a statistically significant shortening of the average length of stay when compared to the old integrated care program but not when compared to the standard care group. ANOVA results showed that the mix of diagnoses plays a central role in the average length of stay with patients of the F2 and F3 group showing longer duration of stay. An analysis of the repartition of the diagnostic groups in both the integrated care program and the model project showed that patients with a F3 diagnosis were overrepresented and patients with a F1 diagnosis underrepresented in the integrated care program. The overrepresentation of patients of the F3 group led to an increase in the average length of stay that could then be countered with the new model project. ANOVA results for the inpatient setting showed age did not affect the average length of stay. Surprisingly, however, sex was shown to influence the average length of stay, with male patients having a slightly shorter stay in the hospital than women. This is explained by the higher rate of substance abuse disorders among male patients (2013: 481 male patients vs. 149 female patients; 2014: 452 male patients vs. 139 female patients), which, in our experience, often leads to early discharge due to reluctance to engage in long-term treatment.

In contrast to this, the results for the day care setting showed no difference in the average lengths of stay between the integrated care program and the model project. In this setting, ANOVA showed an effect of diagnosis on the length of stay in a similar way as in the inpatient setting. It also showed that both new models of care also played a role for the length of stay, but neither age nor sex. A possible explanation for the lack of effect from the switch to the model project in the day care setting can be found when analyzing the diagnostic repartition of patients in both groups: the introduction of the subscription-free program did not lead to a shift in the diagnostic repartition, as was the case in the inpatient setting. The longer duration of stay, the traditional greater focus on long-term rehabilitation in a day care setting, and the persistent overrepresentation of affective disorders also explain that needing to subscribe to the integrated care program did not represent an obstacle in this setting.

However, when compared to standard care, both new models of care led to a reduction in the average length of stay that could not be shown in the inpatient setting. A possible

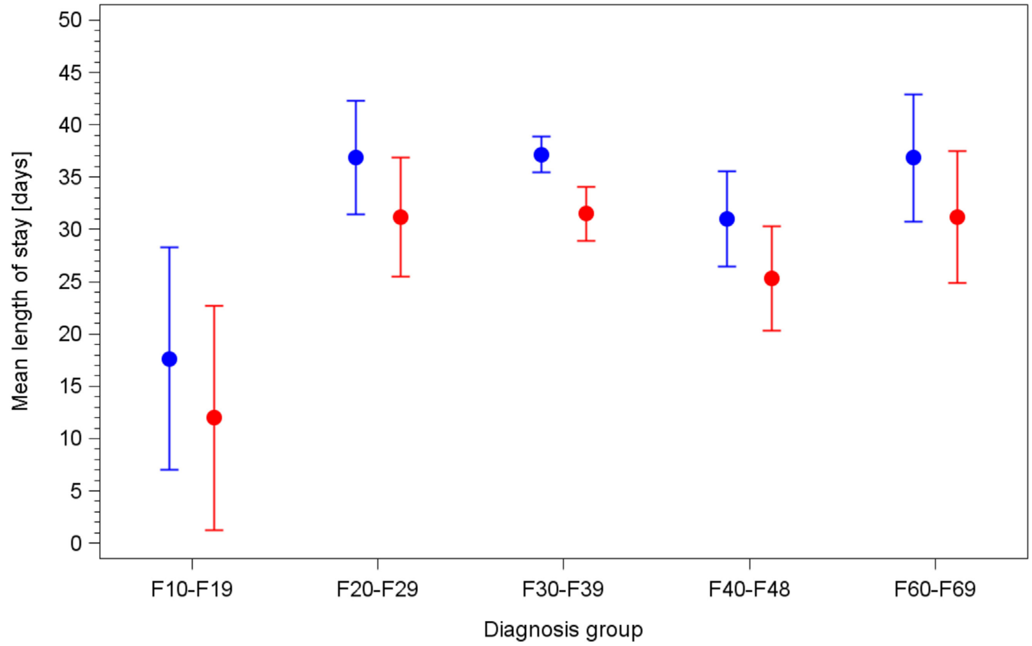

FIGURE 2 | Mean duration of stay for day care patients in both standard care and integrated care/model project groups, by diagnosis group, estimated by the final model of backwards analysis of variance. Blue lines/circles: standard care; red lines/circles: integrated care/model project.

explanation could lie in the particular configuration of our hospital. The day care department is located in the same buildings as the outpatient department, and both are located outside of the main hospital building where the inpatient sector is located. This proximity surely reinforces the cooperation and synergies between day care and outpatient sectors and thus promotes a faster transition in the outpatient care. This reduction of the average length of stay in the integrated care program and model project is in line with the results of previous studies evaluating the effect of such programs on the average duration of stay (9, 15).

The shift of psychiatric care resources from the in- to the outpatient sector, and the reduction of average length of stay are crucial and have been addressed in many countries over the last years. The newly introduced model projects could represent a great opportunity to deal with this issue. The shift of the financial risk from the insurance companies to the service providers requires the development of more comprehensive outpatient care, including home treatment, ACT, and a reinforced cooperation between the in- and outpatient sectors in order to reduce the use of inpatient resources and efficiently reduce the average length of stay. This would be in line with orientations wished by service providers, patients and their relatives. In spite of these strong incentives, in the year following the introduction of the new model project the expected effect could only be marginally observed in our study.

Surely the aforementioned geographical specificities of the hospital or the lack of a proper mobile home treatment/ACT unit combined with the great distances between clients in the region played a role in preventing the model project from having its full impact on the duration of stay. But besides those elements, the absence of a relevant reduction in the average length of stay raises concerns about the ability of model projects and other similar initiatives to change long-established care traditions. To date, the organization of psychiatric hospitals and wards has been directed at offering comprehensive inpatient care, which was also the main financial resource of institutions. In many places, the development of new models of outpatient treatment, such as ACT/home treatment, has been neglected. Staff members are often reluctant to engage in new models of care that imply such a profound change in the definition and practice of inpatient psychiatric care. Inpatient treatment devolves into intensive crisis management, often leaving symptoms remission and recovery to the outpatient sector. Such a change is often seen by staff members as a challenge to their ability to take care of acutely ill patients and to offer them comprehensive treatment. Such difficulties have already been described in the implementation process of new models of care (20). Hence, the introduction of such a model should be seen as a long-term process involving profound changes in traditions and routines.

Also, staff members in public institutions are often not used to consider economic factors in their everyday practice, what represents in case of new initiatives such as model projects an obstacle to their full implementation. Model projects require the full commitment of all staff members in managing the limited financial resources allowed by the insurance company and allocating them preferentially to the outpatient sector.

In conclusion, model projects constitute a possible way of bridging in- and outpatient care for all patient categories, particularly the most severely ill. However, their ability to efficiently reduce the average length of stay and hence to strengthen and develop outpatient care still needs to be proven. The discussed obstacles to their full implementation should be addressed by reinforcing the commitment of all staff members and by supporting the profound changes of structures and practices they imply. Only then can reluctance and long-established routines be overcome.

One of the most important limitations of the present study is the lack of outpatient data. Unfortunately, these are not available through the hospital information system, thus rendering their analysis impossible. Such data would however be of great interest and should be taken into consideration in further studies aimed at evaluating the implementation of new models of care and their effect on the average duration of stay.

AUTHOR CONTRIBUTIONS

AW contributed to the conception of the research article, data collection and processing, results discussion and manuscript redaction. WW and JT contributed to the statistical analysis of the data and their presentation. MH contributed to the conception of the article, discussion of the results, and manuscript redaction and supervised the whole process.

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An Integrated Care Initiative to Improve Patient Outcome in Schizophrenia

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The optimal treatment of schizophrenia patients requires integration of medical and psychosocial inputs. In Germany, various health-care service providers and institutions are involved in the treatment process. Early and continuous treatment is important but often not possible because of the fragmented medical care system in Germany. The Integrated Care Initiative Schizophrenia has implemented a networked care concept in the German federal state of Lower Saxony that integrates various stakeholders of the health care system. In this initiative, office-based psychiatrists, specialized nursing staff, psychologists, social workers, hospitals, psychiatric institutional outpatient's departments, and other community-based mental health services work together in an interdisciplinary approach. Much emphasis is placed on psychoeducation. Additional efforts cover socio-therapy, visiting care, and family support. During the period from October 2010 (start of the initiative) to December 2012, first experiences and results of quality indicators were collected of 713 registered patients and summarized in a quality monitoring report. In addition, standardized patient interviews were conducted, and duration of hospital days was recorded in 2013. By the end of 2012, patients had been enrolled for an average of 18.7 months. The overall patient satisfaction measured in a patient survey in June 2013 was high and the duration of hospital days measured in a pre–post analysis in July 2013 was reduced by 44%. Two years earlier than planned, the insurance fund will continue the successfully implemented Integrated Care Initiative and adopt it in the regular care setting. This initiative can serve as a learning case for how to set up and measure integrated care systems that may improve outcomes for patients suffering from schizophrenia.

Keywords: schizophrenia, integrated care, patient-centered, quality indicators, duration of hospital stays, psychoeducation, outpatient health care services

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INTRODUCTION

Schizophrenia is a mental disorder that affects ~0.3–0.7% of people at some point in their lives (1). The chronic and disabling course of the illness may have a major impact on daily routine, quality of life, and life planning. Thus, patients need intensive and long-term support in order to be able to cope with everyday life and to lead a life as close to normal as possible.

The optimal treatment of schizophrenia patients requires integration of medical and psychosocial inputs and has to be tailored to the individual needs of the patients and their families. The patient-centered care should be provided in an outpatient setting by a multidisciplinary team and should comprise medical, social, psychological, and psychotherapeutic support (2). In Germany, various health-care service providers and institutions are involved in the process of treatment of schizophrenia. However, continuous treatment is often not possible because of the fragmented medical care system in Germany (e.g., no short-term appointments with the physician who is to provide continued treatment after discharge from hospital or no outpatient medical contact if a crisis situation sets in the evening or during the weekend) (3). To overcome these difficulties, patient outcome-oriented solutions are needed that follow an intensified, integrative approach that exceeds the provided standard care in Germany. We hypothesized that this implies the coordination of treatment options offered by different service providers to increase therapy efficiency.

About the Integrated Care Initiative Schizophrenia

After a tender procedure, in July 2010 AOK Lower Saxony, the largest statutory sick fund in Lower Saxony, closed a contract on integrated care for schizophrenia sufferers with the Institute for Innovation and Integration in Healthcare (I3G GmbH), according to § 140 b Abs. 1 SGV V (German law on social welfare). The I3G is an independent subsidiary of the researching pharmaceutical company Janssen-Cilag GmbH. I3G bore the responsibility for the process and budget, as well as the economic risk. I3G assigned parts of the on-site operative implementation to the company Care4S GmbH. Their task was to locally build, expand, and support networks with the Integrated Care parties involved – taking up on existing structures wherever possible.

In addition, an independent multidisciplinary expert committee, composed of key stakeholders involved in schizophrenia care, such as medical specialists from hospitals and practices, experts in the areas of health care and health care research, specialist nurses, and relatives' representatives, was established. The expert committee gave advice on the implementation, advancement, and evaluation.

Objectives and Strategy of the Integrated Care Initiative Schizophrenia

The Integrated Care Initiative Schizophrenia pursued the goal of optimizing patient-centered care for patients suffering from schizophrenia. The initiative is based on a networked care concept that integrates various stakeholders of the health care system. Medical attention is closely linked to psychosocial support in this network. Office-based psychiatrists, specialized nursing staff, psychologists, social workers/pedagogues, hospitals, psychiatric institutional outpatient's departments, and other community-based mental health services collaborate in an interdisciplinary approach.

In this initiative, local specialized physicians and psychiatric care services organize the outpatient treatment. However, superabundance and shortage of medical care are both to be avoided. A focus is on assisting the patients in coping with their illness in their domestic surroundings whenever possible (e.g., by home treatment). This requires close cooperation between all care providers across professional groups and institutions.

Apart from establishing and improving networks, this initiative gives patients access to an augmented range of ambulatory treatment options that are not offered or not offered to that extent in standard care in Germany. While the drug treatment options are the same as in standard care, this initiative has much more psychosocial care options. Much emphasis is placed on psychoeducation. Further efforts cover the areas of socio-therapy, visiting care, and family support. As an example, specialist nursing is available for all patients according to the needs of the patient. Home treatment is provided by psychiatric nurses directed by an office-based psychiatrist. In case of hospitalization, cooperation with clinicians is intended to ensure that inpatient treatment can be evolved into intensive outpatient treatment. Here, an expert team supports the patient. Furthermore, a 24/7 crisis service is available for patients and their families.

The pivotal contact for the patients is the psychiatrist – he or she is in charge of the therapy. The psychiatrists are independent in their patient-oriented therapeutic decision making, as well as being committed to the current status of understanding in medical science. Therapy decisions comprise all drugs that are approved and available in the German market for the treatment of schizophrenia. Together with the other members of the care team, but above all in consultation with the patient ("shared decision-making"), the psychiatrist defines therapy modules meeting the patient's needs. These modules correspond to the latest scientific insights by the WHO and DGPPN (German Society of Psychiatry, Psychotherapy and Neurology). They form the multilevel and modular treatment path of the Integrated Care Initiative Schizophrenia, which shall allow tailoring care to patients' needs and personal preferences (**Figure 1**).

Here, we present the first experiences and results of descriptive analyses from the quality monitoring report of the Integrated Care Initiative Schizophrenia Lower Saxony during the period from October 2010 (start of the initiative) to December 2012.

MATERIALS AND METHODS

Participation in the Integrated Care Initiative was open for AOK insurees above 18 years of age with registered residence in Lower Saxony according to their health insurance card upon presentation of a confirmed diagnosis of schizophrenia (ICD-10: F20, correlating with the international statistic classification of diseases and related health problems, version 2010). The participation was voluntary. The patient had to contact a psychiatrist who was a contract partner of the Integrated Care Initiative, then he was informed about the integrated care provision and had to sign a declaration of participation. There were no exclusions regarding schizophrenia severity, comorbidities, or previous hospitalizations. In order to meet data privacy requirements, a system for data transfer was implemented.

The Integrated Care Initiative was implemented by office-based psychiatrists in cooperation with specialized psychiatric nursing staff. They introduced the patients to the various care services

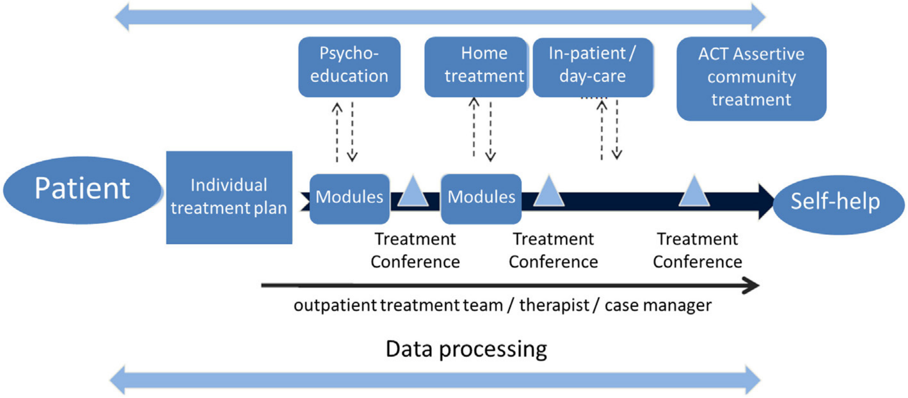

FIGURE 1 | Patient-centered approach in the integrated care initiative schizophrenia.

and types of support. Psychoeducational groups for patients and their family members were set up by the network partner, aiming at improving knowledge about the disease, which in turn enables improved compliance and early detection of relapses (4).

Routine records from the Integrated Care Initiative and accounting data of the AOK Lower Saxony as well as qualitative and quantitative effects of care recorded in an IT-documentation system served as basis for the descriptive analyses.

Educational Materials and Training Concept

The Integrated Care Initiative provided a range of materials and documents specifically developed for conducting outpatient psychoeducation. The standardized training followed the APES manual (Arbeitsbuch PsychoEdukation bei Schizophrenie, published by Schattauer Verlag) and could be supplemented with further contents as needed.

An initiative coordinator organized workshops that provide the network partners with strategies for the implementation of psychoeducation in the individual regions. In these train-the-trainer sessions, local specialists and the outpatient psychiatric care team were educated in the theory and practice of psychoeducation based on the APES manual. Among others, the content addressed the symptoms and course of the disease, stress coping models, issues of salutogenesis and empowerment, early warning symptoms, and crisis management. Participants were qualified to conduct future psychoeducation as trainers.

The workshops on how to conduct psychoeducation took place in 1-day blocks. Didactics of knowledge transfer, visualization methods, and interactive conversation were central learning units. Role-playing exercises consolidated the theoretical knowledge.

Quality Indicators

When establishing a new form of health care, it is essential to verifiably ensure and transparently document the quality of care. In contrast to the somatic area, in the psychiatric field quality indicators are not standard practice in Germany yet. The subjective perception of disease and concomitant personal assessment of the treatment results make valid and reliable quality measurement based on objective criteria an extremely challenging task. To face this challenge, in 2009, the Federal Association of the AOK initiated a project to develop quality indicators for patient-centered care of people affected by schizophrenia (5). The following indicators derived from this are aimed not simply at individual care areas, but rather at an integrated cross-sector treatment approach. They were used to monitor the *status quo* of the initiative:

(A) *Continuity of outpatient treatment after discharge from hospital*: the percentage of patients who received further outpatient treatment within 7 days after being discharged.
(B) *Hospital readmission rate*: the percentage of patients who were readmitted to hospital within 30 days after an inpatient psychiatric treatment.
(C) *Antipsychotic polypharmacy*: the number of patients who took at least two antipsychotics simultaneously over a timespan of at least 4 weeks during the reference period.
(D) *Compulsory treatment*: this indicator describes how many patients in the Integrated Care Initiative Schizophrenia were hospitalized due to legal requirements.
(E) *Discontinuation of treatment for more than 90 days*: the percentage of patients who had no contact with health care providers within the Integrated Care Initiative Schizophrenia for more than 90 days.
(F) *Case management*: the percentage of severely ill patients [defined by a global assessment of functioning (GAF) scale value below 50] who were in contact with a case manager during the last 6 months of the reference period.
(G) *Inclusion of relatives into the treatment*: the proportion of patients whose relatives were included in the treatment support during the reference period.
(H) *Availability of a disease self-education program*: the proportion of patients who participated in psychoeducational training during the reference period.
(I) *Number of suicides and suicide attempts*: all documented suicides and suicide attempts per 1,000 patients.

Patient Satisfaction

In addition to analysis of the quality indicators, qualitative and quantitative effects of care from the patients' points of view were recorded. In 2013, patients were retrospectively interviewed concerning their experience with this initiative. The patient interviews were conducted from May 1 to June 15, 2013 using a standardized eight-item questionnaire (modified ZUF-8) (6). Every answer was graded from 1 (lowest satisfaction) to 4 (highest satisfaction). Scores from all of the eight answers on the patient questionnaire were summed up to form an overall rating so that 32 was the highest rating and 8 was the lowest rating for minimum participant satisfaction.[1]

Duration of Hospital Stays

The time that patients spent in the hospital was routinely monitored in the quality assurance review. All patients who participated in the Integrated Care Initiative for more than a year were included into a pre–post analysis of this parameter in July 2013, regardless of schizophrenia severity. The analysis compared the total number of days spent in hospital during the year before enrollment with the total number of days spent in hospital within the first year after enrollment.

RESULTS

By the end of 2012, 713 out of ~6,800 eligible patients were enrolled in the regions where the program was activated. The observed patient group (*N* = 713) consisted of 51% male patients and 49% female patients. The mean ages in the male and female group were 44.2 (±12.2) years and 50.3 (±12.0) years, respectively.

By the end of 2012, patients were enrolled in the Integrated Care Initiative for an average of 18.7 months. Ninety-five out of 713 patients (13.0%) had at least one hospitalization.

Data on comorbidities were available from 499 patients who participated during the period from July 2011 to June 2012. In all, 51.0 and 85.0% of the patients were diagnosed with at least one secondary psychiatric disease and at least one somatic disorder, respectively. This correlates with other epidemiological data obtained for Germany (7, 8).

Quality Indicators

Continuity of Outpatient Treatment after Discharge from Hospital

More than half of the hospitalized patients (57.5%) received further outpatient treatment timely, i.e., within 7 days after being discharged.

Hospital Readmission Rate

In the Integrated Care Initiative Schizophrenia, a total of 18.4% of patients were readmitted to hospital within 30 days after discharge from an inpatient psychiatric treatment. International literature reports readmission rates between 20.7 and 34.5% (9).

Antipsychotic Polypharmacy

In the Integrated Care Initiative Schizophrenia, 21.6% of patients received two or more different antipsychotics for at least 28 days. By comparison, international literature reports 40.0% of patients with antipsychotic polypharmacy (10, 11).

Compulsory Treatment

Out of 95 patients who had a temporary stay at an inpatient facility, 6.3% experienced compulsory treatment.

Discontinuation of Treatment for over 90 Days

In the Integrated Care Initiative Schizophrenia, 15.0% of patients had no contact to a key carer for at least 90 days. Weinmann et al. give a reference value of 15.0% for this indicator (5).

Case Management

As no rating by GAF value was available, the analysis included not only severely ill persons but all the patients enrolled in the reference period.

In the Integrated Care Initiative Schizophrenia, 80.0% of the patients were individually looked after by the key carer system. International literature reports values between 38.0 (12) and 65.0% (severely ill patients) (13).

Inclusion of Relatives into the Treatment

In the Integrated Care Initiative Schizophrenia, the percentage of patients whose relatives were included into the treatment support was 17.1% (14).

Availability of a Disease Self-Education Program

By the end of 2012, 2.7% of the patients in the Integrated Care Initiative Schizophrenia participated in outpatient psychoeducational training. Since the launch of the initiative in autumn 2010, the model was tested in pilot regions in Lower Saxony until the first quarter of 2012. The rollout in Lower Saxony was started in April 2012. Thus, the analysis of 2012 data included only the startphase of outpatient psychoeducation, which was in the phase of implementation.

One of the first (October 2010) activated regions within the Integrated Care Initiative was Hildesheim in Lower Saxony. In this area, 8.6% of the enrolled patients took part in psychoeducational trainings by the end of 2012.

Number of Suicides and Suicide Attempts

As per Hor et al., the suicide rate (life-time risk) among schizophrenia patients is about 5.0% (15). In the Integrated Care Initiative Schizophrenia, the documented suicide rate amounted to 0.4% during the year 2012.

Patient Satisfaction

A total of 344 patients could be identified who were registered after the start of the initiative in October 2010 and participated for at least 12 months. After a period of 1 year, patients can be expected to be fully integrated in the integrated care program and therefore be able to give a valid rating. In June 2013, 121 of the 344 patients (males: 67 and females: 54) from 25 specialist practices

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[1] One patient did not answer question 6 of the ZUF-8 questionnaire (*N* for question 6 = 120).

took part in interviews. At the time of the survey, the participating patients were enrolled in the initiative on average for almost 2 years (23.9 ± 5.5 months) and had a mean age of 47 (±12) years. **Figure 2** shows the gender-specific age pattern of this population.

The findings from the interview analyses showed high patient satisfaction scores for each of the eight items of the questionnaire (**Table 1**). The mean total score was 27.9 (±3.2) out of a maximum of 32 points achievable.

Duration of Hospital Stay

Of the 713 patients enrolled in the Integrated Care Schizophrenia at the end of 2012, 13.3% were treated in hospital. On average, the length of hospital stays for all enrolled patients was 5.6 days. In comparison, the accumulated length of stay in 2011 for all schizophrenia patients insured by AOK Lower Saxony was 11 days.

This positive trend was confirmed by a pre–post analysis performed in 2013, which compared the sum of days spent in hospital in the year before and the year after enrollment in the Integrated Care Schizophrenia. Statistical analysis was performed in July 2013 and evaluated the data of 458 patients. The quality monitoring covered an observation period of about 2 years for the entire group.

In the year before enrolling in this initiative, the patients spent a total of 6,977 days in hospital due to schizophrenia (F20 diagnosis). During the first year of enrollment, they spent a total of 3,906 days in hospital due to an F20 diagnosis. This means a reduction of 44.0% in the number of inpatient days during the Integrated Care Schizophrenia reference period (**Figure 3**).

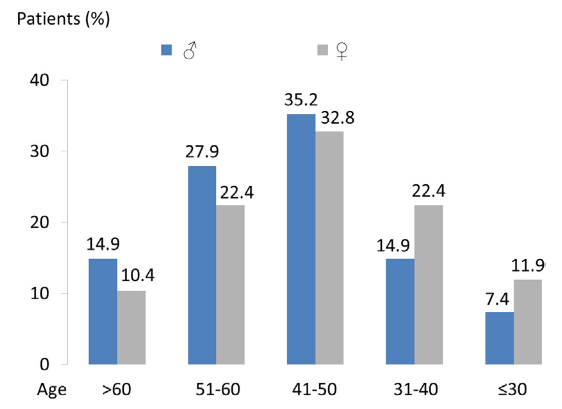

FIGURE 2 | Age and gender distribution of the 121 patients who completed the modified ZUF-8 questionnaire.

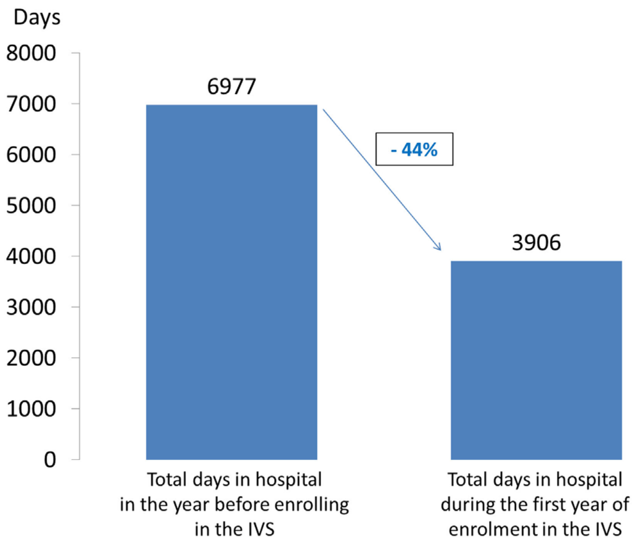

FIGURE 3 | Pre/post analysis of days in hospital due to an ICD-10-CM F20 diagnosis (*N* = 458; July 2013).

TABLE 1 | Patient responses to the eight items of the modified ZUF-8 questionnaire.

Item	Question	Response, *N* = 121; patients (%)			
1	Please rate the quality of the care you have received	Very good 35%	Good 62%	Fair 1%	Poor 2%
2	Has the treatment that you have received met your expectations?	Clearly yes 46%	Generally yes 48%	Rather not 3%	Clearly not 3%
3	To what extent did the treatment by the physician/specialist nurse service fulfill your needs?	Almost completely 51%	By and large 44%	Only partially 5%	Not at all 0%
4	Would you recommend Integrated Care to a friend if he/she needed similar help?	Clearly yes 65%	Probably yes 26%	Probably not 6%	Clearly not 3%
5	Please rate your satisfaction with the level of help you received from the physician/specialist nurse service within Integrated Care	Very satisfied 50%	Satisfied 47%	Somewhat satisfied 3%	Dissatisfied 0%
6	Did the care by the physician and/or specialist nurse service help you to cope with your problems better?*	Yes, helped a lot 66%	Yes, helped a little 29%	No, did not help 4%	No, has made things worse 0%
7	Please rate your general satisfaction with the integrated care you have received	Very satisfied 55%	Satisfied 43%	Somewhat satisfied 2%	Dissatisfied 0%
8	Will you continue your treatment within Integrated Care?	Definitely 71%	Probably 26%	Probably not 2%	Definitely not 1%

**One patient did not answer question 6 of the ZUF-8 questionnaire (N for question 6 = 120).*

DISCUSSION

Today, the routine care setting of mental ill patients remains fragmented (3). By offering more patient-centered care, the patient outcomes regarding primary, secondary, and health system parameters can be improved (16).

The Special Role of Psychoeducation in Schizophrenia

In our opinion, a key driver was the actual implementation of psychoeducation. The Integrated Care network partners often report that the biggest obstacle is motivating the patients to participate. However, in our experience, once the patients are convinced and take part, they are enthusiastic about the psychoeducational spectrum.

Psychoeducation is defined as systematic, structured, and didactic provision of information on the disorder and its treatment. This educational method allows the afflicted and their relatives to obtain information about schizophrenia, to receive support with coping strategies, and thus to be empowered to make informed decisions concerning relapse prevention (17). There is a body of evidence supporting the fact that psychoeducation of patients with schizophrenia improves understanding of mental illness, increases quality of life, enhances compliance with antipsychotics, and can reduce relapse rates (17, 18). National and international guidelines classify the psychoeducation as a highly effective intervention in order to reduce hospital readmission rates, the resultant costs, and substantial human suffering (17).

Clinical practice shows, however, that there still exists an enormous gap between scientific findings and clinical reality. Although the benefit of psychoeducation for the empowerment of patients and the effectiveness of the therapy are proven, to date, it is provided only for every fifth inpatient with schizophrenia and only for one family member of every 50th patient (17). In the outpatient sector, psychoeducation is barely part of standard care so far. It therefore seems to be essential to offer structured psychoeducation for more patients with schizophrenia and their families than is the case today.

In the Integrated Care Initiative, the network partner himself or herself organized the training for the patients. This may be of importance because the patients confided in their caregiver. This mutual trust was essential in convincing the patients to participate.

The Integrated Care Initiative as a Learning Case

Since the initiative started, the Integrated Care Initiative continuously developed new regions in the federal state of Lower Saxony, and, from the beginning of 2013, is now available area-wide. The first experiences with the Integrated Care Initiative in a federal state of Germany are encouraging. The introduction of the initiative improved communication between all carers. As a consequence, patients benefited from shorter waiting times, reduced bureaucracy, shorter distances, and an unchanging point of contact. The closer integration of relatives into the initiative may additionally help to better manage crisis situations. Correspondingly, patient interviews showed high patient satisfaction with the treatment path selected by the initiative.

This concept paves a way for optimizing health-care systems. Efforts and strengths of all participants who are involved in patient care could be joined successfully beyond existing structures. Linking and integrating of all the participants in the health-care system, including health-care providers, funding bodies, and health-care industry, may further improve quality of care in a sustainable manner. A health care company, in particular, can make essential contributions to achieving this goal by participating in the development and implementation of comprehensive solutions, as shown in the present Integrated Care Initiative.

Two years earlier than planned, the AOK continued the successfully implemented Integrated Care Initiative and adopted it in the regular care setting starting from January 2015. The AOK carried on ensuring optimum treatment for the insurees. The established procedures for participating physicians and psychiatric nursing services remained in place. Parallel to this, the pharmaceutical company Janssen continues to work on optimizing modular health-care concepts to increase outcomes for patients who are suffering from mental health disorders.

Limitations and Outlook

It is important to note that the present paper is not a research study but a quality monitoring report of a novel care setting initiative. Quality monitoring of health-care performance is mandatory in the German health system (§ 140 b Abs. 1 SGV V – German law on social welfare).The data presented here were collected in the framework of the quality assurance of the integrated care project.

An evaluation designed as a prospective, observational cohort study with two independent control groups was originally planned but could not be finalized by the independent contractor due to minor recruitment numbers.

In our view, the Integrated Care Initiative can serve as a learning case for how to set up and measure integrated care systems that may improve outcomes for schizophrenic patients. Such real-world quality monitoring data are as yet rare and can make an important contribution to reflection on appropriate ways to optimize patient health-care services for mental health reasons. A further evaluation of routine data is ongoing to determine how the findings of the initiatives' quality monitoring report will develop compared against standard care.

ETHICS

Please note: This is not a research study but a quality monitoring report of a novel care setting initiative. Quality monitoring of health-care performance is mandatory according to the German Law. The data were collected in the framework of the quality assurance of the integrated care project. Those data are rare and are often seen as an important real-life contribution to the mental health-care issue. An evaluation designed as a prospective, observational cohort study with two independent control groups was originally planned but could not be finalized by the independent contractor due to minor recruitment numbers. Further routine data analyses will compare the integrated care schizophrenia against standard care.

AUTHOR CONTRIBUTIONS

NM-A: significant contribution during IVS program conduction and analyses, especially on the psychoeducational content: substantial intellectual contribution to concept, revising this article critically for important intellectual content, final approval of the version to be published. RW: significant contribution to contents that refer to the independent multidisciplinary expert committee for the Integrated Care Initiative Schizophrenia: substantial intellectual contribution to concept, revising this article critically for important intellectual content, final approval of the version to be published. SW: significant contribution to all parts of the manuscript: substantial intellectual contribution to concept and analyses, writing this article, final approval of the version to be published.

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