PSYCHOSOCIAL INTERVENTIONS IN PSYCHOTIC ILLNESSES

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PSYCHOSOCIAL INTERVENTIONS IN PSYCHOTIC ILLNESSES

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STUDY PROTOCOL
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UP'S: A Cohort Study on Recovery in Psychotic Disorder Patients: Design Protocol

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Recovery is a multidimensional concept, including symptomatic, functional, social, as well as personal recovery. The present study aims at exploring psychosocial and biological determinants of personal recovery, and disentangling time-dependent relationships between personal recovery and the other domains of recovery in a sample of people with a psychotic disorder. A cohort study is conducted with a 10-year follow-up. Personal recovery is assessed using the Recovering Quality of Life Questionnaire (ReQoL) and the Individual Recovery Outcomes Counter (I.ROC). Other domains of recovery are assessed by the Positive and Negative Symptom Scale Remission (PANSS-R), the BRIEF-A and the Social Role Participation Questionnaire—Short version (SRPQ) to assess symptomatic, functional and societal recovery, respectively. In addition, multiple biological, psychological, and social determinants are assessed. This study aims to assess the course of personal recovery, and to find determinants and time-dependent relationships with symptomatic, functional and societal recovery in people with a psychotic disorder. Strengths of the study are the large number of participants, long duration of follow-up, multiple assessments over time, extending beyond the treatment trajectory, and the use of a broad range of biological, psychological, and social determinants.

Keywords: recovery, personal recovery, psychosis, psychotic disorders, cohort study

INTRODUCTION

The course of personal recovery among people with a psychotic disorder is largely unknown since this a relatively new concept not included in long-term cohort studies. The present study aims to find determinants of personal recovery, and disentangle time-dependent relationships among personal and other dimensions of recovery and its determinants over a 10-year period. Based on

Dutch Mental Health Care reports (1–4), recovery can be defined as a four-dimensional framework. This framework consists of personal, symptomatic, societal, and functional recovery, with personal recovery at the center (**Figure 1**). The dimensions of recovery are thought to be related to one another, but could also be independently achieved (2).

Personal Recovery

Personal recovery from mental illness is a construct that has gained increased attention over the past thirty years (5). Since the early nineties, participants in the debate on recovery from serious mental illnesses have underlined the notion that personal recovery from a psychotic disorder can occur, either with (6–8) or without psychiatric symptoms being present (9). This is in line with the narratives of people who have experienced mental health issues and used mental health care services (8). It is now acknowledged in mainstream parts of mental health care that mental illnesses should be seen as vulnerabilities, not as a disease that can be cured (10). However, in many studies, those who have remaining symptoms are still considered to be non-recovered (11). Due to the different definitions and ideas used in research and the new line of thought in mental health care, there remains confusion about the concept of personal recovery among clients, their families, clinicians, policy makers and researchers (12). Furthermore, it remains unclear how different factors influence both short- and long-term personal recovery in schizophrenia and other psychotic disorders after treatment (13). There is, however, some consensus on what elements the concept of personal recovery consists of. Publications show that personal recovery should be person-centered, re-authoring, based on exchange, and within the community (14). In line with this analysis, the Slade group stated that (15) personal recovery refers to an individual process of adaptation and development where one does not simply return to, but rather grows beyond the premorbid self.

Slade et al. developed the CHIME conceptual framework for recovery, which identifies five processes that constitute personal recovery: Connectedness, Hope and Optimism, Identity, Meaning in life, and Empowerment (16). However, the CHIME framework has been criticized for being overly optimistic. The difficulties that arise during personal recovery are neglected, as is the influence of therapeutic input. Therefore, the more extensive framework CHIME-D, with the D for "difficulties" (17), has been proposed. However, the specific content of personal recovery, the process is dynamic and non-linear with both gains and relapses (6). A dimension of recovery which should therefore be exclusively client-rated (18).

Symptomatic Recovery

Symptomatic recovery from psychosis is one of the secondary outcomes in this study, alongside functional and societal recovery. Symptomatic recovery in psychotic illnesses is about reducing positive and negative symptoms (19) using objective, reliable measures (20). A recent analysis showed that symptomatic recovery is constructed from both client-rated and staff-rated factors (18, 21, 22), with health care professionals being leading when deciding which path to take.

Functional Recovery

Functional recovery focuses on whether someone is capable to recover or compensate for the loss of skills (23). People with schizophrenia may score lower on several dimensions of cognition, like memory, concentration and attention, compared to healthy controls (24, 25), either due to deterioration or impaired development. Especially impairment in executive functions like planning, self-control, and other self-regulating functions (26) can have a major negative impact on one's daily functioning, career, education or social life.

Societal Recovery

Lastly, societal recovery focuses on counteracting the public stigma on mental illness and improve the position and rights of (ex-)clients within society (20). In this study, we focus on the position of clients in their own social environment by studying how important they find the different social roles and the difficulties they encounter in performing these roles. Furthermore, societal recovery also includes measures on quality of housing, work, education, and social relationships (2). People with SMI often experience difficulties in finding employment and

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Abbreviations: ACE, Adverse Childhood Experience; BACS, Brief Assessment of Cognition in Schizophrenia; BCIS, Birchwood Cognitive Insight Scale; BRIEF-A, Behavior Rating Inventory of Executive Function—Adult version; BRS, Brief Resilience Scale; BT, Blood Test; CISS, Coping in Stressful Situations; EPD, Electronic Patient Dossier; GAD-7, Generalized Anxiety Disorder—7-item Anxiety Scale; GGZ KIT, Mental Health—Cluster Index Test (In Dutch: GGZ Kluster Indicatoren Toets); IC, Informed Consent; I.ROC, Individual Recovery Outcome Counter; IHL, Integrated Recovery List; ISMI, Internalized Stigma of Mental Illness; LKV, Bodily Complaints Questionnaire; MATE, Measurements in the Addiction Triage and Evaluation; NEL, Netherlands Empowerment List; NEO—FFI, NEO Five Factor Inventory; PAM, Psychosis Attachment Measure; PANSS—R, Positive and Negative Symptoms Scale—Remission; PHQ-9, Patients Health Questionnaire—Depression Scale; PIF, Patient Information Form; PSQI, Pittburgh Sleep Quality Index; ReQOL, Recovering Quality of Life; ROM, Routine Outcome Monitoring; SCIL, Screener for Intelligence and Mental Challenge (in Dutch: Screener voor Intelligentie en Licht verstandelijke beperking); SCT, Social Cognitive Tasks; SEL, Service Engagement Scale; SRPQ—SF, Social Role Participation Questionnaire—Short Form; TiC-P, Questionnaire on healthcare utilization and productivity losses in patients with a psychiatric disorder; TSQ, Trauma Screening Questionnaire; WHO-DAS, World Health Organization—Disability Assessment Schedule; ACE, Adverse Childhood Experience; BACS, Brief Assessment of Cognition in Schizophrenia; BCIS, Birchwood Cognitive Insight Scale; BRIEF-A, Behavior Rating Inventory of Executive Function—Adult version; BRS, Brief Resilience Scale; BT, Blood Test; CISS, Coping in Stressful Situations; EPD, Electronic Patient Dossier; GAD-7, Generalized Anxiety Disorder—7-item Anxiety Scale; GGZ KIT, Mental Health—Cluster Index Test (In Dutch: GGZ Kluster Indicatoren Toets); IC, Informed Consent; I.ROC, Individual Recovery Outcome Counter; IHL, Integrated Recovery List; ISMI, Internalized Stigma of Mental Illness; LKV, Bodily Complaints Questionnaire; MATE, Measurements in the Addiction Triage and Evaluation; NEL, Netherlands Empowerment List; NEO—FFI, NEO Five Factor Inventory; PAM, Psychosis Attachment Measure; PANSS—R, Positive and Negative Symptoms Scale—Remission; PHQ-9, Patients Health Questionnaire—Depression Scale; PIF, Patient Information Form; PSQI, Pittburgh Sleep Quality Index; ReQOL, Recovering Quality of Life; ROM, Routine Outcome Monitoring; SCIL, Screener for Intelligence and Mental Challenge (in Dutch: Screener voor Intelligentie en Licht verstandelijke beperking); SCT, Social Cognitive Tasks; SEL, Service Engagement Scale; SRPQ—SF, Social Role Participation Questionnaire—Short Form; TiC-P, Questionnaire on healthcare utilization and productivity losses in patients with a psychiatric disorder; TSQ, Trauma Screening Questionnaire; WHO-DAS, World Health Organization—Disability Assessment Schedule.

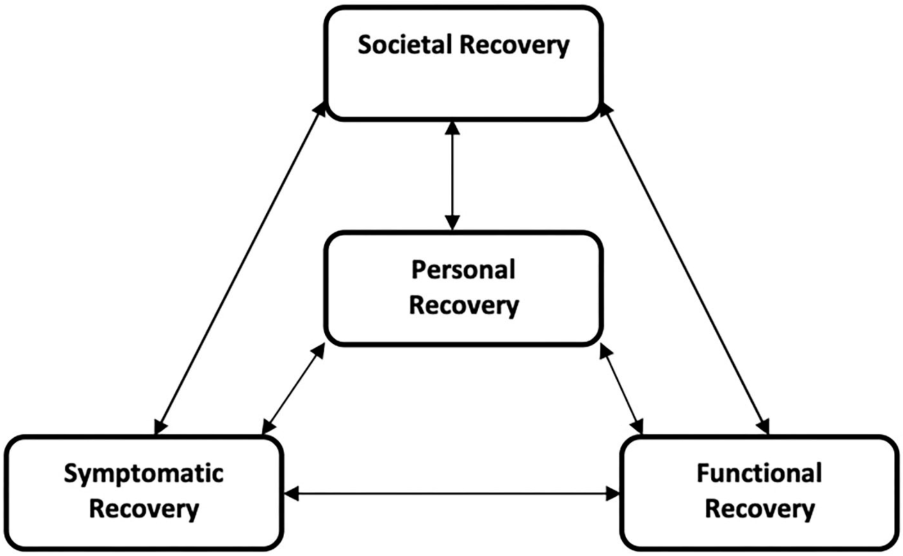

FIGURE 1 | Four dimensional framework of Recovery (2).

report some form of social exclusion and broken relations with family and friends (27) often due to the stigma of being perceived as dangerous (28–30).

In this four-dimensional framework of recovery, every domain has its own course and characteristics as well as interactions with other domains. Personal recovery is positioned at the center, given it's close connection to the client's own narrative of their own life-course (2). In the present study this multidimensional concept of recovery will be used to try to disentangle the determinants of (the course of) personal recovery.

Determinants of (Personal) Recovery

Although personal recovery is thought to be the most central and important, the four dimensions may be determined by similar factors. Therefore, we will discuss groups of determinants (i.e., biological, psychological, and social) that may be related to all four dimensions of recovery.

Biological Determinants

Age, genetic factors (12, 31), poor physical health, sleep dysfunction, (32) and drug and alcohol use during illness (33) may have an effect on all dimensions of recovery (34–36). These dysfunctions have been linked to poor quality of life (31) and to severity of symptoms (37). The hypothesis is that poor physical health and sleep dysfunction or delay negatively affect the dimensions of recovery. How, and to what extent, these biological factors influence recovery, is dependent on the specific determinant and dimension of recovery.

Psychological Determinants

Trauma

People with a severe mental illness (SMI) have a higher risk of being traumatized, or become a crime victim (38, 39). For example, both physical and emotional neglect and complex PTSD are highly prevalent in this group (40, 41), especially if a person is also intellectually disabled (42). Furthermore, trauma is thought to have both a direct and indirect negative effect on the onset and symptomatic course of psychotic disorders (43). Therefore, early childhood trauma, recent victimization, and traumatic experiences of the illness itself and during the course of the illness are expected to have a negative impact on all dimensions of recovery.

Cognitive Function

Cognition is an umbrella term used to describe multiple mental skills, including learning, memory, problem solving, reasoning, attention, and decision making (44). It is known that impaired cognition is both a predictor for poor outcome in schizophrenia as well as a consequence (45). More specifically, having poor memory is a risk factor for the development of schizophrenia, whereas having a higher verbal IQ is a protective factor (46). During the illness, general cognitive functioning is lower for people with schizophrenia compared to healthy controls (25). Approximately 40% of People with a SMI are suspected to have an intellectual disability (42, 47), with a decreased cognitive flexibility (i.e., mentally switching between, or adapting to different tasks or stimuli) as a consequence. This negatively influences the course of recovery (48). Likewise, illness-insight–partly predicted by cognitive abilities (49)–and treatment compliance (50) are predictors of the course of the illness (50). It is therefore expected that overall cognitive functioning not only predicts better functional recovery, but also better symptomatic and societal recovery.

Personality Traits

Psychopathological personality traits can be identified in people with proneness to psychosis (51). These traits are related to the five major categories of personality (i.e., openness, extraversion, conscientiousness, agreeableness, and neuroticism) (52), which are found to influence well-being (53). This goes especially for neuroticism, since adolescents with higher neuroticism scores are at higher risk for developing psychotic symptoms (54, 55). Therefore, it is hypothesized that traits of neuroticism will also negatively affect the process of personal recovery.

Empowerment and attachment

Self-esteem, resilience, hopelessness and empowerment (16) are all shown to correlate with Quality of Life measures (56). Furthermore, spirituality, self-esteem (57), attachment (58, 59) and positive social support are thought to contribute to all dimensions of recovery (60). Due to these findings, along with the prominent place empowerment has in the CHIME framework (16), it is believed that the more empowered participants are, the more likely they are to further their personal recovery. Furthermore, the ability to securely attach and thus build personal bonds with those around, is hypothesized to influence personal, functional, symptomatic and societal recovery in a positive manner.

Social Determinants

Social capital is thought to be a (health) resource (61), which has cognitive and structural components (62). Cognitive components of social capital are associated with mental health (63) and levels of experienced discrimination (64). The structural part of social capital is derived from social contacts and social participation (65). Social participation thus has an influence on individual health (61), self-reported health (66), and social functioning (67), and is likewise expected to contribute positively to (societal) recovery.

Social Factors

Many people with a psychotic disorder suffer from stigmatization and social exclusion (68). For example, public and internalized stigma have been associated with lower levels of perceived social support, recovery, and quality of life (57, 69) and stigma in general is associated with harmed self-esteem (57). Other social factors, including employment and income, contribute to the size of social networks, and the number of social relationships (70), as does living with a partner or as part of a family (71). Clients often define their problems not only in terms of pathology, but also in social terms such as failed friendships, careers, or loneliness (72). Furthermore, employment is positively linked to a health-related quality of life (73). Mental health difficulties like low income, unemployment (74) or poor housing (75) may on the other end act as barriers to social inclusion (76, 77). There is also evidence that suggests migration or ethnic minority status is associated with an inferior social position, which may add to the risk of developing a psychotic disorder (78). Participation and social functioning can thus all influence dimensions of recovery in a positive manner (26), since having one or more social relationships and a wider social network is thought to be critical for achieving recovery (79).

Given all these findings we expect that when high internalized stigma is present, empowerment will be low. Likewise, when there is high internal stigma, recovery—especially personal and societal recovery—will be slower and with more downs. Furthermore, it is hypothesized that when someone is employed, this will positively contribute to societal and personal recovery, as do high(er) income and no debts.

Treatment Related Determinants

Evidence-based mental health care with treatment related factors including pharmacological and psychosocial treatments, aim at improving outcome. Therefore, (adherence to) treatment may be an important determinant of outcome. In addition, the number of psychotic relapses and hospitalisations have been associated with outcome.

Study Objectives

The primary aim of this cohort study is to investigate the proportion of clients who increase on the primary outcome measure of personal recovery over time. Secondary objectives include investigating the proportion of clients who increase on measures of symptomatic, functional and societal recovery over time. Other aims include exploring interactions and time-dependent relationships between the four dimensions of recovery. Furthermore, to explore different effects of determinants, we measure biological (somatic functioning, sleep, drug abuse), psychological (diagnosis, personality traits, anxiety, depression, adverse childhood experiences, trauma, attachment, cognition, social cognition, illness insight, empowerment, resilience), social parameters (internalized stigma and disability in functioning), and treatment related factors (psychosocial treatments and medication). Another secondary objective is identifying how these determinants and their interactions may influence the four dimensions of recovery over time.

Whereas, most studies have focused on only a few episodes of recovery (80), the relatively extensive follow-up period of the current study will make it possible to observe more episodes of recovery over time. Furthermore, most previous research only focused on one aspect or dimension of recovery (81), undermining the complex and multidimensional nature of recovery.

By including all the above-mentioned aspects of a participant's life, this study eventually aims to identify mechanisms which in the end can be translated into (the adaptation of existing) interventions which support clients in their recovery processes.

METHODS/DESIGN

Study Design

The current study is a multicentre, longitudinal cohort study on recovery from psychotic disorders. The study has a 10-year follow-up period for participants diagnosed with a psychotic disorder.

Setting

In order to test 600 participants every year, multiple centers in the Netherlands are participating in this study. Every center has multiple facilities, which give care to people with early psychosis and/or reoccurring psychosis. These facilities can either be outreaching or a clinical setting.

Data Collection

To test all participants, student-researchers will participate in each team and/or facility involved in this study. These student-researchers are MSc student in psychology, medicine or health sciences for whom this study is part of their research internship. They will be trained beforehand and are tasked with informing clients about the study, asking them to participate, including them in the study, interviewing them, processing the data and writing a report for the practitioners. As part of this team, they will sign a confidentially agreement, as is standard in Dutch mental health care. Furthermore, they receive access to the Electronic Patient Files (EPF).

Recruitment and Consent

Clients will be selected through a search in the EPF of the participating Mental Health Care Institutions. An anonymised list of all clients within a team will be made by the institution. All those not eligible to participate in this study based on the inclusion criteria, will be filtered out. Of the remaining list, 30 clients will be randomly selected. The student-researcher and the team will then receive this list of clients to ask them to participate. Their primary practitioner within the mental health care team is thus aware which clients will be asked to participate and is able to identify those still in active psychosis who are thus unable to participate at that moment. Furthermore, the practitioner can already prepare the client on the visit of the student-researcher, who will be responsible for data collection.

After student-researchers and participants are introduced to one another by the primary practitioner, the first appointment will be made in which the client will be fully informed on the study by the student, and the client will receive the subject information sheet. When all questions are answered, participants are given 2 weeks to consider their participation. If they like to participate, they will be asked to sign an informed consent (IC), of which they will receive a copy. The IC involves consent for feedback to the practitioner, access to the EFP files and using the collected data for research. These are mandatory to participate in the study. Furthermore, the participant is given the option to consent to the study using contacts of choice and using the municipal address database (in Dutch: GBA) when contact through available personal information fails. After the IC is signed, the main health care practitioner will be informed, after which an appointment will be made to include the participant in the cohort. For follow-up assessments, participants are contacted via personal details listed in the EPF. These entail name, surname, maiden name if applicable, date of birth, initials, address, e-mail address and, if consented to, the contact details of two contacts given by the participant. As mentioned earlier, these contact details will only be used if researchers fail to establish contact during follow up, which will most likely be the case when participants are no longer in mental health care or have moved to a different region. Given the aim of the study, those recovering over time are still asked to participate, even though they are referred back to their general practitioner. Likewise, some participants who are worsening over time might lose touch with mental health care. These participants will also be followed-up for the duration of the study. If at any follow-up measurement the participant is unable to participate, e.g., due to active psychosis or incarceration, the measurement will be postponed. However, if a measurement has not been carried out within 9 months, the measurement will fall through and the next measurement will become the objective.

Moreover, measures will be taken to minimize drop-out rates and to increase participant motivation to take part in follow-up interviews. These include sending participants optional birthday cards and regular updates via newsletters and social media channels. Researchers will also regularly visit the cooperating mental health care facilities and participate in any relevant events. Lastly, researchers will regularly evaluate reasons why clients decline participation in order to adjust recruitment strategies accordingly.

Participants

The research population will consist of clients who receive treatment for a first episode psychosis or have a diagnosis of schizophrenia or another psychotic disorder (schizoaffective disorder, delusional disorder, psychosis not otherwise specified) and who are between 18 and 65 years old. They will be recruited at different Mental Health Care centers in various teams specialized in in- and outpatient care for severe mental illnesses. Furthermore, they all should be able to give informed consent (IC). The aim is to include both clients diagnosed with early psychosis and chronic psychosis. Early psychosis patients are those who have had psychotic symptoms no longer than 5 years. Psychoses are considered chronic, when the psychotic symptoms are present for 5 or more years. Clients who have insufficient proficiency of the Dutch language, will be excluded from participation.

Measures

Primary Outcome Measures

Main study parameter will be scores on two scales assessing personal recovery, measured by the 10-item ReQOL (82) and the I.ROC (83). An overall index score for the ReQOL can be calculated by summing the numbers for the 10 questions where 0 indicates poorest and 40 indicates the highest quality of life. The reliability (internal consistency) in patient samples for the ReQoL-10 is shown to be high ($\alpha = 0.85$) (82). The I.ROC consists of four dimensions. Three questions are asked on the dimensions of empowerment, home, people and opportunity. The scores range from 0 to 6 per question. The internal consistency is shown to be high ($\alpha = 0.86$).

Additionally, the Dutch ReQoL-10 will be validated during the course of the study, allowing the construction of normal distribution tables on which cut-off scores for personal recovery will be based.

Secondary Outcome Measures

Secondary outcome measures include symptomatic recovery as assessed by the Positive and Negative Symptom Scale–Remission (PANSS-R; $\alpha = 0.80$) (84). Level of functional recovery will be assessed using the BRIEF-A (self-rated; functional recovery; α = 0.96) (85), and level of social recovery will be assessed using the Social Role Participation Questionnaire [SRPQ; self-rated; social recovery; (86)] over time. The SRPQ has not yet been tested in a psychiatric population, but has been shown to be valid and reliable among patients with Ankylosing Spondylitis (AS) (87). To distinguish levels of symptomatic recovery, the Andreasen remission criterium (88) will be used for the PANSS-R, which states that symptoms are in remission when a score of "mild"/"three" is observed for all eight items, for 6 months. The PANSS-R will only be administered every year, so it will be necessary to deviate from the time threshold of 6 months. Cut-off scores for functional and social recovery will be based on normal distribution tables from the BRIEF-A (89) and the SRPQ, respectively, in which (sub)clinical levels of functional and social recovery can be identified. Psychiatric history and psychiatric diagnosis will be assessed using the OPCRIT+ electronic tool (90).

Determinants

Biological Determinants

Somatic health will be assessed using the Physical Complaints Questionnaire (in Dutch: *Lichamelijke Klachten Vragenlijst*-51) (91) and the Treatment Inventory of Costs in Patients with psychiatric disorders (TIC-P; α = 0.83) (92). Subsequently, sleep (patterns) will be measured through the Pittsburgh Sleep Quality Index (PSQI; α = 0.83) (93). Furthermore, substance abuse will be assessed using the Addictions for Triage and Evaluations questionnaire (MATE; α = 0.75–0.92) (94). A standard physical examination (PE) is done every year in people with both early and chronic psychosis. During these physical checks, length, weight, abdominal girth and blood pressure are measured. Furthermore, a case report form containing questions about age, gender, medication, lifetime psychiatric illness diagnosis and psychiatric history (including number of compulsory admissions) will be filled in as well.

Psychological Determinants

Intellectual disability will be screened using the *Screener for Intelligence and Learning Disabilities (SCIL)*, which has been shown to have good internal consistency (Cronbach's α = 0.83) (95). Depression and anxiety will be screened using the Patient Health Questionnaire-9 (PHQ-9; α = 0.89) (96) and Generalized Anxiety Disorder-7 (GAD-7; α = 0.92) (97) screening scales. Impaired cognition will be assessed using the Brief Assessments Cognition in Schizophrenia (BACS; α > 0.79 for all subtests) (24) and the social cognitive tasks will be the Picture Arrangements (98, 99) and the Hinting Task (100). Furthermore, personality traits, trauma, early childhood trauma and attachment will be assessed using the NEO-Five Factor Inventory (NEO-FFI; α = .88) (101), Trauma Screening Questionnaire (TSQ; AUC = 0.85) (41), Adverse Childhood Experience questionnaire (ACE; α = 0.76) (102, 103)and the Psychosis Attachment Measure (PAM; attachment anxiety α = 0.82 and attachment avoidance α = 0.76) (104), respectively.

Psychological processes like coping, resilience, empowerment, insight and therapy compliance will be assessed over time with the Coping Inventory in Stressful Situations (CISS; α = 0.86) (105, 106), Brief Resilience Scale (BRS; α = 0.83) (107, 108), Dutch Empowerment List (NEL; α = 0.94) (89), Brief Cognitive Insight Scale (BCIS; α = 0.60–0.68) (109) and Therapy adherence Scale (SES; α = 0.91) (110). Internalized stigma will be assessed using the ISMI-10 (α = 0.94) (111, 112).

Social Determinants

Social factors like education, work and work-history will be registered, along with administering the World Health Organization—Disability Assessment Schedule 2.0 (WHO-DAS 2.0; α = 0.95) over time (113). Basic social capital demographics, family history, socio-economic status, living situation, family composition, working situation, and income will also be enquired.

Assessment of Treatment Related Factors

Prescribed medication and psychosocial treatments will be assessed form the electronic patient files.

Questionnaires and Instruments

An overview of all the measurements is given in **Table 1**. The time for each questionnaire is also listed. When questionnaires are filled in afterwards by the researcher, and thus does not involve the participants involvement, the time is listed between brackets. All primary and secondary outcome measures will be assessed every year. All other questionnaires and procedures will be repeated every 2 years, with the last measurement 10 years after baseline. **Table 2** shows which questionnaires will be assessed over time. All questionnaires and procedures baseline will be assessed through a face-to-face interview at the participants home or at the health-care institution. Follow-up measurements can be done either face-to-face, over the phone, or via a combination of both. In both instances, the questionnaires can be spread out over multiple appointments in order to make sure the participant is able to answer all questions as is, without weariness or diminished attention getting in the way. Furthermore, this set-up also decreases the burden of the long and vast interview. Both the number of appointments and the location of the appointments are dependent on the preference of the participant. In some cases, face-to-face interviews in which the questionnaires will be read out loud and explained will be necessary and mandatory. This can be the case for e.g., participants with a possible learning disability. Student-researchers are trained to do so without changing the content of the questionnaires and without nudging participants to a certain answer.

Furthermore, a yearly physical examination (length, weight, abdominal circumference and blood pressure) and blood test (Hemoglobin, leukocytes and differentiation, renal function, liver function, triglycerides, HDL-cholesterol, prolactin, glucose) are gathered from the EPF. Since these are standardized care in this patient population in the Netherlands, and participants consent to gathering this information via their general practitioner while they are still receiving care. Participants receive a compensation of 25 euros for each completed measurement.

TABLE 1 | Questionnaires and instruments.

Parameters		Test	Time (min)
Primary	Personal	Recovering quality of life, short version 10 items (self-rated).	5
outcome	recovery	Individual recovery outcome counter (self-rated)	10
Secondary	Symptomatic recovery	Positive and negative symptoms scale—remission (observer-rated)	10
Outcomes	Functional recovery	Behavior rating inventory of executive function—adult version (self-rated)	15
	Societal recovery	Social role participation questionnaire—short form (self-rated)	10
Determinants	Biological	Physical complaints questionnaire 51 (in Dutch: Lichamelijke klachtenvragenlijst 51; self-rated)	[30] 15
		Questionnaire on healthcare utilization and productivity losses in patients with a psychiatric disorder (self-rated)	10
		Pittsburgh sleep quality index (self-rated)	5
	Psychological	Opcrit+	[45]
		Screener for Intelligence and mental challenge (in Dutch: screener voor intelligentie en licht verstandelijke beperking, SCIL; observer-rated)	10
		NEO—five factor inventory (self-rated)	10
		Patients Health Questionnaire—Depression Scale (self-rated)	5
		Generalized anxiety disorder—anxiety scale (self-rated)	3
		Adverse childhood experience (observer rated)	3
		Trauma screening questionnaire (self-rated)	5
		Measurements in the addictions for triage and evaluations part 1 & 4 (observer rated)	10
		Psychosis attachment measure (self-rated)	10
		Brief assessment of cognition in schizophrenia (observer-rated)	35
		Social cognitive tests (observer-rated)	21
		- Picture arrangements	10
		- Hinting task	11
		Coping inventory for stressful situations (self-rated)	10
		Beck cognitive insight scale (self-rated)	10
		Netherlands empowerment list—short version (in Dutch: Nederlandse empowerment lijst; self-rated)	10
		Brief resilience scale (self-rated)	3
		Internalized stigma of mental illness, short version (self-rated)	10
	Social	WHO-DAS 2.0 (observer-rated)	20
Other		Routine monitoring outcome (self-rated)	[15]
		Mental health—cluster index test (In Dutch: GGZ kluster indicatoren toets; observer rated)	[15]
		Integrated recovery list (in Dutch: Integrale herstel lijst; observer/self- rated)	[15]
		Service engagement scale	[15]
		Treatment overview (including medication)	[30]

Observations and Assessment Results

Observations and/or assessment results might be relevant for current care. Furthermore, some topics might reveal thoughts or actions which can be harmful to the participant or their environment, but which are not known by the practitioner. Therefore, all results are reported back to the mental health care team which gives care to the participant.

Patient Involvement

Service users/experience experts are involved in the design of the study, development and implementation of study protocols, and monitoring the study process. A group of peer-experts has been consulted during the process of creating this cohort. They made sure the interest and the vision of the process of recovery from clients would be valued and integrated in this cohort. Additionally, a small pilot study has been done with five peer-expert students to test the length and order of the interview and get their feedback on the questionnaires themselves. The results have been discussed with the original group of peer-experts, and changes to the organization of the interview were made in cooperation with these peer-experts. Furthermore, experience experts are present during the training of the student-researchers, guiding them through the meaning of recovery and letting them experience the concept, but also helping them streamline the interview in a way that is least demanding for the participants but without changing the validity of any of the questionnaires.

Furthermore, service users/experience experts attached to participating teams will support the student-researchers in

TABLE 2 | Overview of the procedures per time point.

Year	0	1	2	3	4	5	6	7	8	9	10
ReQOL	X	X	X	X	X	X	X	X	X	X	X
I.ROC	X	X	X	X	X	X	X	X	X	X	X
PANSS	X	X	X	X	X	X	X	X	X	X	X
BRIEF-A	X	X	X	X	X	X	X	X	X	X	X
SRPQ - SF	X	X	X	X	X	X	X	X	X	X	X
LKV-51	X		X		X		X		X		X
TiC-P	X		X		X		X		X		X
PSQI	X		X		X		X		X		X
OPCRIT+	X										
SCIL	X										
NEO-FFI	X										
PHQ-9	X		X		X		X		X		X
GAD-7	X		X		X		X		X		X
ACE	X										
TSQ	X		X		X		X		X		X
MATE	X		X		X		X		X		X
PAM	X		X		X		X		X		X
BACS	X		X		X		X		X		X
SCT	X		X		X		X		X		X
CISS	X		X		X		X		X		X
BCIS	X		X		X		X		X		X
NEL	X		X		X		X		X		X
BRS	X		X		X		X		X		X
ISMI-10	X		X		X		X		X		X
WHO-DAS	X		X		X		X		X		X
ROM	X	X	X	X	X	X	X	X	X	X	X
GGZ KIT	X	X	X	X	X	X	X	X	X	X	X
IHL	X	X	X	X	X	X	X	X	X	X	X
SES	X		X		X		X		X		X
PE	X	X	X	X	X	X	X	X	X	X	X
BT	X	X	X	X	X	X	X	X	X	X	X

ReQOL, Recovering Quality of Life; I.ROC, Individual Recovery Outcome Counter; PANSS-R, Positive and Negative Symptom Scale—Remission; BRIEF-A, Behavior Rating Inventory of Executive Function—Adult Version; SRPQ—SF, Social Role Participation Questionnaire—Short Form; LKV-51—Physical Complaints Questionnaire; TiC-P, Questionnaire on healthcare utilization and productivity losses in patients with a psychiatric disorder; SCIL, Screener for Intelligence and Mentally Challenged; PHQ-9, Patients Health Questionnaire—Depression Scale; GAD-7, Generalized Anxiety Disorder—Anxiety Scale; NEO-FFI, NEO Five Factor Inventory; ACE, Adverse Childhood Experiences; TSQ, Trauma Screening Questionnaire; MATE, Measurement in the Addictions for Triage and Evaluations; PAM, Psychosis Attachment Measure; BACS, Brief Assessment of Cognition in Schizophrenia; SCT, Social Cognitive Tasks; CISS, Coping Inventory for Stressful Situations; BCIS, Beck Cognitive Insight Scale; NEL, Netherlands Empowerment List; BRS, Brief Resilience Scale; ISMI-10, Internalized Stigma of Mental Illness, short version; WHO-DAS 2, World Health Organization—Disability Assessment Schedule 2.0; SES, Service Engagement Scale; ROM, Routine Outcome Monitoring; GGZ KIT, Mental Health—Cluster Index Test; IHL, Integrated Recovery List; PE, Physical Examination; BT, Blood Test; Medication, overview of taken medication in the last year; Treatment, overview of received treatment in the last year.

developing a good rapport and giving the feedback to the participants.

Sample Size Calculation

Personal recovery rates in schizophrenia and other psychotic disorders are estimated to be about 14% (80). We expect to observe recovery over time in a minimum of 10% of all subjects over a period of 10 years and opt for a desired precision of 5%. Precision-based sample size calculation using the formula: $n = (Z^2 \times P(1–P))/e^2$ (where $Z = 1.96$ for 95% CI, P is expected true proportion, and e is half the desired precision), results in 553 participants. Expected loss to follow-up is estimated at about 15% which gives a total of 651 participants to include.

Statistical Analysis

Primary analysis is to estimate the proportion of patients achieving personal recovery over a period of 10 years. The main focus will be on the interrelation of domains of recovery and impacts of different factors on the course of recovery. Using generalized linear mixed models, repeated measures of ReQOL and I-ROC will be the dependent variables, time will be the within-subjects factor and the biological, psychological and social determinants will be independent variables. All parameters will be checked for outliers; data will be transformed when necessary. Missing values will be dealt with accordingly. All (114), detailed descriptions will be given of participants included in each analysis.

RESULTS

Primary Outcome

For our primary analysis, we will calculate the proportion of clients who reach personal recovery as measured by the ReQOL and I-ROC questionnaires. Initial analysis will be based on dichotomized scores without covariates. In additional analyses, we model personal recovery over time. Using generalized linear mixed models, repeated measures of ReQOL and I-ROC will be the dependent variables, time will be the within-subjects factor and the biological, psychological, and social determinants will be independent variables.

Secondary Outcome

To investigate the associations between personal, clinical, societal and functional recovery, analyses will focus on changes in PANSS, BRIEF-A and SRPQ scores over time, respectively. Generalized linear mixed models will be fit to explore the course of recovery in relation to other recovery dimensions as time-dependent co-variates.

DISCUSSION

This study aims to assess the course of personal recovery, and to find determinants and time-dependent relationships with symptomatic, functional, and social recovery in persons with a psychotic disorder.

Participants with a psychotic disorder, from multiple healthcare centers in The Netherlands, will be interviewed every year for 10 years. Furthermore, biological, psychological and social determinants that in previous research have been associated with the four dimensions of recovery will be measured over time. Ultimately, this study hopes to contribute to the understanding of the complexity of recovery. In this study we hope to unfold time-dependent relationships between different forms of recovery and its determinants. Thus, (new) interventions can be tailored to better fit the needs of people who suffer from a psychotic disorder, so that recovery will be possible for many more of these people.

Strengths and Limitations

Strengths of the study are the large number of participants, long duration of follow-up, multiple assessments over time (also when participants are not in mental health care anymore), and the use of a broad range of biological, psychological, and social determinants. The entire study has been excogitated with the help of both a scientific board, consisting of established researchers from the different participating mental health care institutions, and a group of service users/experience experts.

Limitations are that, since this is an observational study, it is not intended to study intervention effects. However, the relatively long follow-up period is expected to provide information on time-dependent relationships. Secondly, two-yearly assessments of secondary measures will not capture all variation details over time. In add-on studies we hope to zoom in on the course of these outcomes in selected sub-samples. Thirdly, despite random selection of clients meeting the criteria, care avoiding or less motivated clients may not be willing to participate, possibly skewing our study population toward a more positive picture of the process of recovery. Fourth, the inability to include people not fluent in Dutch will limit the generalisability of this study. As mentioned, those with a migration status might have major social disadvantage, possibly causing the process of recovery to be very different and more difficult. By excluding those not able to answer the questionnaires due to language, we are unable to get the full picture of the process for that group. Fifth, this cohort does not take the recovery orientation per institution or team into account. We are therefore unable to control for the degree of recovery orientation. However, participants will be clustered within teams. Team-level might thus reflect whether team differences—like recovery orientation or other team-related or organizational differences—are of influence on the process of recovery for participants.

Lastly, all assessments mentioned above are assessments on topics which are known to be important in the course of the illness. Therefore, it is believed that a lot of these topics have been discussed to some extent with the practitioner, but have not (always) been objectified in a formal, numerical manner. Thus, although these interviews are observational, practitioners may influence some clinical decisions on the information gathered from the study.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Medisch Ethische Toetsingscommissie Erasmus MC Rotterdam. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

BA and ABa have written this protocol, under the direct guidance of AW and CM. All authors have commented on multiple versions of this manuscript. All authors have read and approved the final manuscript.

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Animal-Assisted Therapy in Middle-Aged and Older Patients With Schizophrenia: A Randomized Controlled Trial

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Objective: Animal-assisted therapy (AAT) has the potential to improve the symptomology, negative emotions, and level of well-being in older adults, as well as patients with mental illness. However, there remains limited evidence supporting the treatment efficacy of AAT in middle-aged and older adults with schizophrenia. Therefore, this study implemented a randomized controlled trial to assess the efficacy of a 12-week AAT psychological intervention with dogs for middle-aged and older patients with chronic schizophrenia in a clinical setting.

Method: Patients, age $\geq$ 40 years, with chronic schizophrenia were allocated randomly to either the AAT group or control group. Patients in the AAT group received an additional hour -long AAT session every week for 12 weeks. Patients in the control group received the usual treatment plus an hour long non-animal related intervention. All patients were assessed based on primary outcome measures before and after the 12-week intervention, including the Positive and Negative Syndrome Scale (PANSS), Depression Anxiety Stress Scales Assessment (DASS), and Chinese Happiness Inventory (CHI).

Results: Patients who received AAT had greater improvements in the PANSS and DASS-stress subscale scores than the control group ($p < 0.05$). The effect was small (success ratio different, SRD = 0.25) for the PANSS and the DASS-stress subscale (SRD = 0.15). There were no significant differences in the change scores of the CHI between the AAT and control groups ($p = 0.461$).

Conclusions: AAT seemed to be effective in reducing psychiatric symptoms and stress levels of middle-aged and older patients with schizophrenia. AAT could be considered as a useful adjunctive therapy to the usual treatment programs.

Keywords: animal assisted therapy (AAT), aging, schizophrenia, negative symptom, Adjunct therapy

INTRODUCTION

Schizophrenia is a mental disability characterized by positive symptoms (e.g., delusions and hallucinations), negative symptoms (e.g., apathy and anhedonia) (1), and general psychopathology (e.g., depression and anxiety) (2–5). Schizophrenia has adverse impacts on major areas of life, such as work and interpersonal relations (1). Approximately 1% of population are affected by schizophrenia (6), of which 25% or more will soon be middle-aged and older individuals (7, 8). Schizophrenia is particularly challenging for this age group because these individuals tend to have more severe psychotic symptoms and poorer psychosocial function (9). About 60% of patients with schizophrenia living in the hospital are middle-aged and older (10), dying 10–15 years earlier than the general population (11). Their negative symptoms and cognitive impairment are significantly more severe than those in younger patients (12) and pose a significant challenge to psychiatric treatment (7).

Treatments for schizophrenia typically involve antipsychotic drugs and psychotherapy (13). However, the effectiveness of these treatment is questionable (14–17) because negative and cognitive symptoms often remain problematic (11, 18). Therefore, it is important to seek alternative psychosocial treatments to improve the psychotic symptoms of patients with schizophrenia.

Animal-Assisted Therapy (AAT) has recently garnered increased attention and been used as an adjunct to typical treatments and interventions for patients with mental illness, including schizophrenia (19, 20). AAT is a structured, planned, and goal-oriented therapeutic intervention involving interactions between a patient and an animal (typically a dog), along with a therapist and an animal handler (21, 22). Example AAT activities include taking care of a dog and playing with a dog (19, 20, 23–25). AAT is typically used to improve the symptoms, functioning (emotional, social, and cognitive), and quality of life for patients with mental illness (19, 20, 23, 26–30), In addition, it may be particularly helpful in the treatment of schizophrenia (22). Interacting with animals can also increase oxytocin levels, which has been shown to improve psychiatric symptoms (31, 32). Relaxing human–animal relations may help dampen negative emotions (20, 29). Therapy dogs can serve as emotional mediators to provide support and company (20, 33), and may increase patient quality of life and well-being (29).

Previous studies have used AAT to improve psychiatric symptoms, emotion, and quality of life in patient with schizophrenia, but there still remains insufficient significant evidence demonstrating its effectiveness. Some studies have revealed positive results, with improvements in positive symptoms, negative symptoms, and general psychopathology symptoms (including stress, anxiety, and depression) (20, 23, 25, 29, 34). However, other studies found no significant improvements in motivation (25), general psychopathology symptoms (23), and quality of life (20). Moreover, there were several methodological limitations in previous studies, including the lack of structural AAT programs, small sample sizes, lack of control groups, short durations of intervention, and limited professionals and animals involved in AAT sessions (20, 21). Few studies have targeted middle-aged and older patients with schizophrenia (21). Therefore, the evidence regarding the effectiveness of AAT in middle-aged and older patients with schizophrenia remains inconclusive and insufficient (20, 21). As such, this study sought to evaluate the effects of AAT for middle-aged and older schizophrenia patients on psychotic symptoms, negative emotions, and well-being.

METHOD

Participants

Participants were recruited from a psychiatric rehabilitation ward and the day-care ward of a medical center in Taiwan. Participants met the following criteria: (1) diagnosis of schizophrenia according to the fifth edition of Diagnostic and Statistical Manual of Mental Disorders, (2) age≥40 years, and (3) stable physical and psychological health conditions based on clinician assessment. Participants with the following criteria were excluded: (1) severe cognitive impairment (e.g., aphasia or inability to follow three-step directions), (2) animal allergies, (3) history of asthma, (4) coagulation disorders, (5) presenting symptoms of dog-related specific phobia, anxiety disorder, and obsessive-compulsive disorder, and (6) had participated in other clinical trials in the past 6 months.

Design

This study implemented a randomized controlled trial (RCT) with parallel-group design and pre-post measurements. Because of the different functional characteristics of patients in day-care and rehabilitation wards, stratification was performed in order to control for confounding variables. Forty patients who met the inclusion criteria were recruited and randomly assigned to the AAT group (intervention group) and control group, with 20 participants in each group (**Figure 1**). To ensure allocation concealment, participants were randomized by an external clinic using sequentially numbered, opaque sealed envelopes. Stratified randomization was carried out with an online randomizer (www.randomiser.com). Previous studies suggested that group size was best kept small for AAT sessions to ensure quality and safety of treatment; accordingly, participants in the AAT group were further divided into two small groups (groups A and B) to attend the AAT session at the same time. There were no differences in treatment between groups A and B.

Procedure

Participants in both groups received their usual treatment programs, consisting of nursing interventions, pharmacotherapy, occupational therapy, psychotherapy, sociotherapy, and recreational activities. The AAT group received an additional hour of AAT session for 12 weeks. The control group received a non-animal-related nursing intervention and occupational therapy session of usual treatment programs instead. All participants were assessed 1 week prior to and after the 12-week program by one psychiatric physician and one occupational therapist.

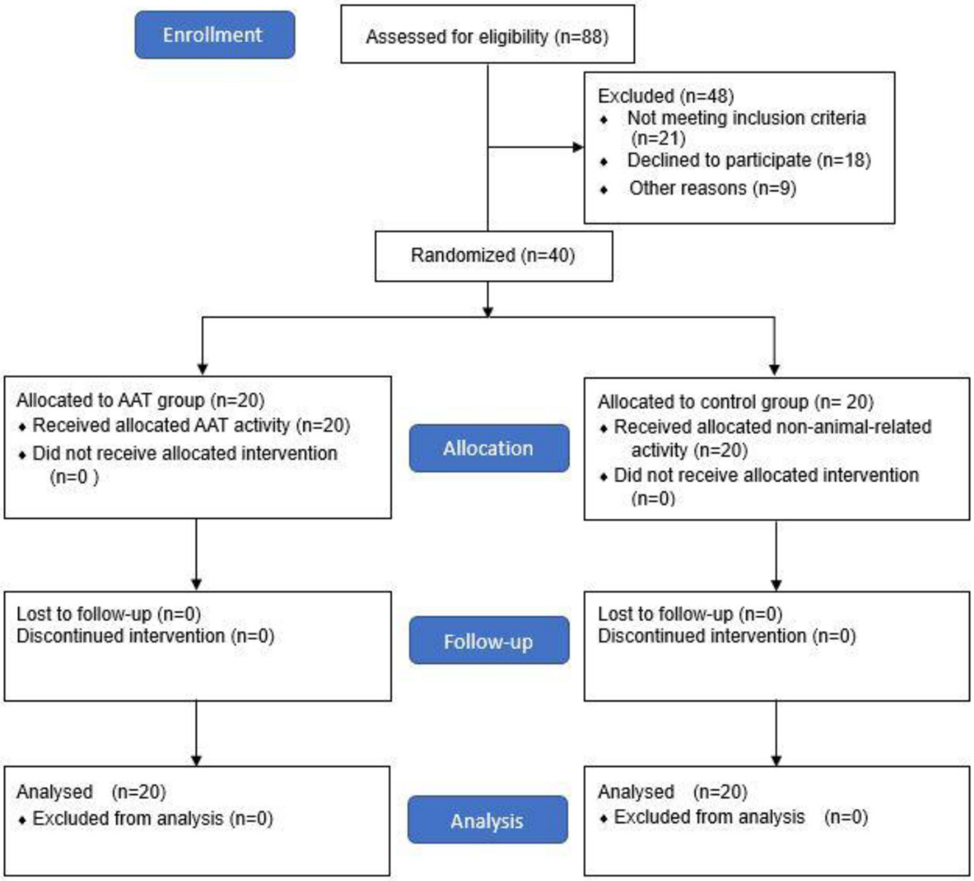

FIGURE 1 | Flow Diagram.

Measures

Positive and Negative Syndrome Scale (PANSS)

The PANSS is widely used to assess the symptom severity of patients with schizophrenia in clinical trials (2–4). The scale comprises 30 items across 3 subscales: the positive subscale (seven items), negative subscale (seven items), and general psychopathology subscale (16 items). Each item is scored on a 7-point scale based on the level of psychopathology present, from 1 (absent) to 7 (extreme). The total score ranges from 30 to 210, with higher scores indicating greater overall symptom severity (35). The validity and reliability of the Chinese Mandarin version of the PANSS has been established in a previous study (36). A minimum total change score of 10.4 was accepted as having responded to treatment (37). The minimum change score for each subscale was assessed based on the total score percentage of each subscale (positive: 2.4, negative: 2.4, general psychopathology: 5.6).

Chinese Happiness Inventory (CHI)

The 20-item version of the CHI is a self-report measure of subjective wellbeing for those following the Chinese culture (38, 39). The CHI comprises items with relation to achievement at work, downward social comparisons, peace of mind, optimism, social commitment, positive affect, sense of control, physical fitness, and satisfaction with self in the Chinese society (39, 40). Each item is scored on a 4-point scale from 1 to 4, corresponding to a different level of happiness (37). The total score ranges from 20 to 80, with higher scores indicating greater happiness (37). The CHI has high reliability (41).

Depression, Anxiety Stress Scales-21 (DASS-21)

The DASS-21 is a self-report questionnaire used to assess symptoms of depression, anxiety, and stress (42). The DASS-21 comprises 21 items, each describing a negative emotional symptom the participant experienced in the past week (42). Each item is scored on a 4-point scale from 0 (never) to 3 (almost always). Scores of depression, anxiety, and stress are calculated by summing the relevant items. Higher scores indicate more severe negative emotional symptoms. The DASS-21 is a well-established instrument with sufficient reliability and validity (42). The minimal detectable change of total score and each subscale of anxiety, depression, and stress were 7.8, 2.4, 2.2, and 3.2 respectively (43).

Interventions

Personnel

Each AAT session was conducted by an animal-assisted therapist, an occupational therapist, and a dog-handler pair (breeder). Prior to the commencement of the study, the animal-assisted therapist and occupational therapist cooperated to design the intervention protocol to match the needs of the patients. The AAT sessions were primarily led by the animal-assisted therapist, with the help of the occupational therapist as the co-leader, who helped encourage patients to participate. The breeder's job was to instruct their therapy dog to follow the directions of the therapist. All members were sufficiently qualified to effectively carry out the session.

The animal-assisted therapists, therapy dogs, and breeders have been certified by the Professional Animal-Assisted Therapy Association of Taiwan; and the therapy dogs, including Corgi, Labrador Retriever, Maltese, and Shiba Inu, passed the therapy dog test to ensures that they could remain calm in difficult, distracting, and stressful situations. The occupational therapists specialized in psychiatric rehabilitation and were familiar with the global functions of the patients.

Animal-Assisted Therapy

The primary goal of the AAT was to improve the negative symptoms (blunted affect, emotional withdrawal, social withdrawal, lack of spontaneity, and flow of conversation) and general psychopathology symptoms (anxiety, depression, uncooperativeness, disorientation, and poor attention) of patients. Secondary goals were aimed at improving positive symptoms (conceptual disorganization, suspiciousness, persecution, and hostility) and patient well-being.

The AAT sessions were conduct in a spacious and quiet classroom, with the participants seated in a semicircle. The animal assisted therapist, occupational therapist, and therapy dog were positioned in front of the participants. The dog approached the participants in turn, and each participant walked the dog around the classroom.

Each AAT session was carried out according to a similar overall structure: 15-min warm-up, 45-min therapeutic activities, and 5-min feedback. In the warm-up, the animal assisted therapist started by greeting each participant, introduced the therapy dog, reviewed the contents of the last session, and oriented participants to the therapeutic activities.

There were four types of therapeutic activities carried out to achieve the therapeutic goal: activity for positive emotion, social activity, cognitive activity, and physical activity. Activities aimed at positive emotion included touching the dog, singing a song, massaging the dog, playing with the dog (ball, loop, game), and artistic creation (dot art). Social activity involved introducing, greeting, praising, thanking, helping, talking, making appropriate physical and eye contact, and cooperating in the games with each other and the dog. Cognitive activity included questions and answers, training the dog, orienting the content of activity, playing a cognitive game (puzzle, triangle, and memory card), and writing a worksheet. Physical activity involved walking, handling, feeding, grooming, dressing, and doing exercises with the dog. Each activity was performed for three sessions with gradually increasing levels of difficulty.

Therapists gave feedback on what the group did during the therapeutic activities, asked how they felt with the dog, and previewed the content of the next session.

Data Analysis

Statistical analyses were conducted using Statistical Package for Social Sciences (SPSS, version 25.0; Chicago, IL, USA). Data from groups A and B of the AAT condition were analyzed collectively. Categorical variables (e.g., sex and level of education) were converted to percentages and compared using the chi-square test. Given the small sample size, the Shapiro–Wilk test was used to test the normality of the data. As the data fit a non-normal distribution, we used the non-parametric statistics. The continuous variables of the outcome measures (PANSS, DASS, and CHI scores) are presented as the median and interquartile range (IQR) and compared with the Mann-Whitney *U*-test. All tests were two-tailed with a probability ≤ 0.05 ($p \leq 0.05$) considered reflective of significance. Additionally, the effect size of success rate difference (SRD) (e.g., treatment group success rate–control group success rate) were calculated for all significant findings (44), with values of 0.11–0.27, 0.28–0.43, and >0.43 categorized as small, moderate, and large effect size, respectively (45).

Ethics

The study was approved by the local ethics committee of the Chang Gung Medical Foundation Institutional Review Board (No. 202000549B0C601). All participants provided written informed consent. The study was registered at ClinicalTrials.gov (Identifier: NCT04476836).

RESULTS

Sample Characteristics

A final sample of 40 participants (20 per group) was analyzed (**Figure 1**). No participants dropped out. There were no significant differences between the groups at baseline regarding age, sex, language, level of education, marital status, and living condition (**Table 1**). At pre-test, there were no significant differences between the AAT and control groups in the PANSS scores ($p = 0.340$), DASS ($p = 0.659$), and CHI ($p = 0.659$).

PANSS Scores

The change in the total PANSS score of the AAT group revealed a significant improvement compared to control group ($p = 0.001$). Moreover, the positive, negative, and general psychopathology subscale revealed a significant between-group difference ($p < 0.001$). The AAT group had less psychotic symptoms after the intervention than the control group. The change score in negative subscale presented a large effect size (SRD = 0.5), and the change score for total score, positive subscale, and general psychopathology subscale revealed a small effect size (SRD = 0.15–0.25).

TABLE 1 | Sample characteristics.

	AAT (*n* = 20) f (%)	TAU (*n* = 20) f (%)	*P* value
Gender			0.057
Male	6	12	
Female	14	8	
Age median (IQR)	55.3 (16.0)	54.1 (18.5)	0.445
40–49	7	7	
50–59	5	8	
60–71	8	5	
Language			0.633
Chinese	17	18	
Taiwanese	3	2	
Education			0.690
Uneducated	1	0	
Elementary school	3	3	
Junior high school	3	6	
Senior high school	9	7	
University/college	4	4	
Condition of marriage			0.327
Single	10	14	
Married	5	2	
Divorced	5	3	
Widowed	0	1	
Condition of living			0.598
live alone	1	1	
not alone	18	19	
Other	1	0	
Defined Daily Dose	1.1 (1.0)	1.3 (0.8)	0.289

DASS Scores

The change scores of stress subscale in DASS revealed a significant between-group difference ($p = 0.012$), subjects in AAT group had less stress after the intervention compared to the control group. The change score for stress subscale revealed a small effect size (SRD = 0.15). Moreover, a decreasing trend in anxiety and depression were observed in the AAT group.

CHI Scores

There were no statistically significant differences in the change score of CHI between the AAT and control groups ($p = 0.461$). However, there was an increasing trend of change scores in the AAT group, with higher well-being in the posttest (see **Table 2**).

DISCUSSION

Compared to the control group, the AAT group showed more significant improvements in negative symptoms, with a large effect size between the two groups. A previous study reported that participants given AAT showed a greater improvement in hedonic tone than the controls, with no significant effect on avolition. However, there was a trend toward improvement in avolition (25). Other studies demonstrated that participants received AAT showed significant improvements in negative symptoms after the intervention, but there were no significant differences than control groups (20, 23). It might be possibly due to the small sample size in previous studies (21 and 24, respectively) (20, 23). Besides, no study assessed the effect size between groups, and only one study has found a large effect size within the AAT group (20). Our study recruited relatively larger sample size, and the results revealed that AAT may improve the negative symptom of patients with schizophrenia.

Improvements in negative symptoms for the AAT group may be underpinned by three core mechanisms. First, therapy dogs acted as social catalysts or mediators to increase social interactions with therapist and patients (20, 46). Therapy dogs have been shown to increase verbal interactions (47), initiation, and participation in longer conversations in the older adults (48). Therefore, AAT improved negative symptoms including poor rapport, lack of spontaneity, and flow of conversation. Second, therapy dogs provided companionship and emotional support in the context of the AAT activities (49), leading to improvements in the apathetic social and emotional withdrawal, and blunted affect. Third, animals are known to help people release oxytocin (31, 32, 50), thereby reducing negative symptoms for patients with schizophrenia (51, 52). However, current evidence remains insufficient and these mechanisms warrant further investigation.

The other core finding was that of the significant effects on positive symptoms and general psychopathology with small effect size between the two groups. A previous study has revealed similar results and supports our finding (53). However, another study presented different results, wherein AAT showed no significant improvements in positive symptom and general psychopathology compared to controls (20, 23). As such, compared to previous results (20, 23), in our study, the AAT group improved more substantially in positive symptoms and general psychopathology. This may be due to our therapist ensured that participants felt well-oriented and that the sessions were realistic during the AAT sessions, clarifying participant conversations. This was not clearly mentioned in previous work. Thus, our study showed that AAT has more significant effects on positive symptoms (such as hallucinations, and conceptual disorganization). In addition, our activities included exercise in AAT, possibly helping to improve general psychiatric symptoms (such as tension, posturing, motor retardation, and impulse control).

Furthermore, as number of samples in past studies was small (20, 23), it remains difficult to determine the effects on positive and general psychopathology symptoms. The benefit of AAT on general positive symptoms and the psychopathology of schizophrenia is worth further investigating. Finally, our study provides initial evidence that AAT may slightly improve positive and general psychopathology symptoms of patients with schizophrenia.

Our findings revealed a significant decrease of stress in the AAT group than in the control group, alongside a small effect size between the two groups. A previous study demonstrated that their AAT group revealed a significant decrease in cortisol, considered as a decrease in stress, but mentioned no comparison between groups (20). Other AAT studies demonstrated stress

TABLE 2 | Median and interquartile range of PANSS, DASS, and CHI change scores between pre-test and post-test for the AAT group and control group.

		AAT group ($n = 20$)		**Control group ($n = 20$)**		***P* value**	**SRD**
PANSS		Median	IQR	Median	IQR		
total score	Pre	11.5	56.8–79.0	11.5	56.3–66.8	0.314	
	Post	11.0	50.5–69.8	11.5	53.8–72.5	0.925	
	Change	−1.0	−12.5–−3.0	0	−1.0–4.8	0.001	0.25
positive subscale	Pre	19.0	9.0–20.3	20.5	8.0–13.8	0.565	
	Post	16.5	8.3–17.0	20.5	8.0–14.8	0.211	
	Change	−3.0	−2.0–0	0	0–1.0	<0.001	0.15
negative subscale	Pre	33.0	16.3–26.8	30.0	16.0–23.8	0.211	
	Post	29.5	14.0–21.5	29.5	14.3–24.0	0.461	
	Change	−3.0	−5.0–−1.3	0	−0.8–0.8	<0.001	0.50
general psychopathology subscale	Pre	66.5	28.3–40.3	60.5	27.0–34.0	0.211	
	Post	57.5	23.3–33.8	60.0	27.0–33.0	0.383	
	Change	−7	−6.3–−1.0	0	−0.8–2.0	<0.001	0.20
DASSstress	Pre	6.0	2.3–11.3	5.5	1.3–10.8	0.659	
	Post	7.0	0.3–9.8	7.5	5.0–12.8	0.341	
	Change	−1.0	−2.0–1.0	1.5	−0.8–4.0	0.012	0.15
DASS anxiety	Pre	4.5	2.3–7.0	5.0	0.3–7.8	0.904	
	Post	4.5	2.0–7.0	5.5	2.3–10.0	0.512	
	Change	0	−1.8–1.0	1.0	−1.0–1.8	0.289	
DASS depression	Pre	5.0	2.3–8.8	4.5	1.0–7.0	0.620	
	Post	6.0	0.5–7.0	7.0	2.0–11.5	0.289	
	Change	0	−0.8–1.8	0.5	−0.8–5.0	0.265	
DASS total	Pre	15.0	6.8–26.8	15.0	3.3–24.0	0.659	
	Post	18.0	2.8–27.0	22.5	9.8–30.5	0.301	
	Change	−0.5	−3.8–3.3	2.5	−2.0–10.8	0.114	
CHI	Pre	42.0	35.8–50.0	41.0	32.8–54.5	0.659	
	Post	43.0	35.8–64.3	41.0	34.0–55.8	0.512	
	Change	1.5	−0.8–8.8	0	−3.5–6.5	0.461	

reduction in patients with post-traumatic stress disorder (54, 55) and dementia (56). Reduced stress-related hormonal responses in patients after AAT may be explained by three core mechanisms. First, the relaxing human–animal bond acted via the adrenal gland and other corticosteroids, the release of oxytocin, dopamine, and endorphins, which may reduce arterial pressure and cardiorespiratory rates, thus leading to decrease stress (20, 29). Second, our AAT session incorporated singing, massaging, artistic creation, and exercises which may help patients reduce stress, as confirmed by previous studies (57–60). As such, our study provided initial evidence that AAT may slightly decrease stress in patients with schizophrenia.

Our study revealed no significant difference between the two groups, although there was a trend toward decreased anxiety and depression in the AAT group. Some previous studies demonstrated similar results. In these studies, reduced anxiety was twice as great (34) and there was a significant decrease in depression in patients with schizophrenia after AAT (29), but no significant difference between the two groups (29, 34), consistent with our finding. However, another study found that neither the AAT nor the control group showed significant improvements in anxiety and depression (20). This study provided limited information regarding anxiety and depression scores because some patients could not fully understand all items' meanings (20). Therefore, it is difficult to compare the difference in results to ours.

Our study revealed that AAT had limited effectiveness in anxiety and depression, possibly because the pre-test levels of depression and anxiety subscales in our participants were mild to normal (61). As such, they had less depression and anxiety, meaning that the AAT had limited effectiveness. In the future, schizophrenic patients with moderate to extremely severe depression and anxiety can be recruited to further assess the effectiveness of AAT on depression and anxiety.

An increasing trend in well-being could be observed for the AAT group, but there was no significant difference between the two groups. Our study is the first to present the effects on well-being among patients with schizophrenia. A previous study showed that participants with mental illness reported the experience as enjoyable and interesting at the end of the AAT (29), partially supporting our findings. A few studies showed indirect evidence that participants with schizophrenia and dementia experienced a better quality of life after the AAT (19, 20, 62), which may further improve their sense of well-being (63). One reason for the improvement in their well-being may be that in company of dogs, participants experienced more love and support (64, 65), sharing feeling with the dogs. However, the effect and mechanism of AAT on well-being warrant further investigation.

There are three strengths to our study. First, our study used the trans-disciplinary approach enlisting both of animal-assisted therapist and occupational therapist, based on their unique knowledge and skills, together determine the therapy that would most benefit patients. Second, the AAT activity was structured and diversified, including activity for positive emotions, social activity, cognitive activity, and physical activity to achieve therapeutic goals. Lastly, there had been few controlled studies of AAT in the community other than in a hospital setting, and in our study no participants dropped out, thereby ensuring the feasibility and high adherence to the AAT for hospitalized psychiatric patients.

There are also a number of limitations that should be mentioned. Owing to the nature of the intervention, it was not possible to blind the participants and therapist to the allocations. Moreover, our study presented only short-term effects; and future research could extend the time of follow-up to ensure the long-term effects of AAT. Finally, we suggest using larger sample sizes and collecting biomarkers in further studies to minimize research bias.

CONCLUSION

Animal assisted therapy can be effective at reducing of psychopathology symptoms and stress in middle-age and older adults with schizophrenia, particularly improving negative symptoms. In addition, there may also be improvements in anxiety, depress and well-being. Therefore, AAT represents a potential adjunct therapy for patients with schizophrenia. However, future higher quality research is required in order to better understand the mechanisms underpinning AAT and studies assessing biomarkers are needed.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Chang Gung Medical Foundation Institutional Review Board. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

T-TC, C-FH, and C-RC conceived, designed, and conducted this study. T-TC, M-LC, and C-RC conducted intervention. W-TT and C-FH contributed in the statistical analysis and interpretation. T-TC, T-LH, and C-RC drafted the manuscript. All authors approved this manuscript.

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Yoga-Based Group Intervention for In-patients With Schizophrenia Spectrum Disorders—A Qualitative Approach

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Background: Yoga may pose a promising complementary therapy in the multimodal treatment of in-patients with schizophrenia spectrum disorders (SSD). However, to date, no studies have qualitatively examined in-patients' with SSD experiences of Yoga as well as their perceptions of its limitations and benefits as a treatment component. This qualitative study aimed to explore for the first time the mechanisms and processes of Yoga-based Group Intervention (YoGI) for in-patients with SSD in Germany by asking for their subjective experiences. Findings could serve as a preliminary basis for developing an effective and evidence-based YoGI manual tailored to this patient group.

Materials and Methods: In total, 25 semi-structured interviews were conducted directly after YoGI, for which responses were either noted down by hand or audio-recorded. The interview guide was pilot-tested and consisted of 14 questions to explore the personal articulated experiences of participation in YoGI from in-patients with SSD. Positive, negative, depressive, and anxiety symptoms were assessed during a diagnostic interview and through questionnaires. The interview data was transcribed, coded by two independent researchers, and analysed using an inductive thematic approach. The research team collaboratively discussed emerging categories to reduce redundancy and form meaningful themes and subthemes.

Results: The analysis revealed seven main themes. YoGI was perceived as feasible and focusing on individual adaptation, captured by the theme *inclusivity*. Nevertheless, participants encountered *challenges*; thus, physical limitations need to be considered. While practising together, participants experienced *interconnectedness* and developed a *mindful stance* as they accepted their limitations and adapted exercises with self-compassion. Patients described that following the flow of the asanas required physical persistence, which ultimately led many participants to experience *confidence* and *relaxation*. YoGI affected *symptom representation* as heightened awareness led participants to notice impeding as well as improved symptoms.

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Conclusion: YoGI showed various promising effects on in-patients with SSD. Future research should examine to what extent these effects can be sustained and how the mindful approach during YoGI can be transferred to areas outside the Yoga class. Furthermore, a randomised controlled trial could investigate the effectiveness of a manualised YoGI.

Keywords: yoga therapy, schizophrenia spectrum disorder, qualitative study, body-mind therapies, complementary therapies, mechanisms, mindfulness, embodiment

INTRODUCTION

As the first line of treatment, patients with schizophrenia spectrum disorders (SSD) usually receive antipsychotic medication, which seems to be especially effective for the treatment of positive symptoms (PS) of schizophrenia such as hallucinations and delusions (1, 2). Despite adequate pharmacological treatment, however, a considerable proportion of patients does not show any symptom improvement (3, 4). While the latest German treatment guidelines recommend Cognitive-Behavioural-Therapy to be offered to all patients (5), it is only received by a few (6). Especially negative symptoms (NS), consisting of blunted affect, diminished speech, anhedonia, social withdrawal, and lack of motivation (7), as well as cognitive dysfunctions, remain challenging to the available treatment options. The persistence of NS and cognitive dysfunctions emphasises the need for researching and implementing complementary treatments for this patient group within a multidisciplinary strategy. Yoga as an adjunctive therapy has been growing in research and application in mental health care in general and just recently for patients with SSD specifically (8, 9).

Yoga, a philosophical doctrine that originated in ancient India and encompassed mental, physical and spiritual practises, has been increasingly adopted in the form of a secular mind-body therapy in the West (10–12). Studies show that Yoga Therapy (YT) constitutes a suitable add-on treatment for psychiatric disorders because it can be easily implemented, is cost-effective, and can be instructed by various professionals working in mental health (10). YT (13) is composed of breathing exercises (*pranayama*), postures (*asanas*), and relaxation (*shavasana*) and is usually delivered in a group setting.

From a linguistic perspective, the term Yoga is derived from the Sanskrit word *yuj*, meaning "*to yoke together*" or "*to unite*." Concurrently, the linguistic development of the term schizophrenia moved toward a more integrative understanding of the disorder focusing on the failure on integration (14): Schizophrenia was renamed *integration disorder* in Japan (15) and *attunement disorder* in South Korea (16). Thus, Yoga, as a form of (re-)connexion may target disintegration and hence, seems intuitively applicable for a modern treatment approach for SSD. The symptomatology and underlying processes have been described as a disconnection syndrome at several levels of brain networks (17), and functionally as a disintegration of mental processes, affect but also interpersonal relationships (18). Further, YT might be especially suitable to be offered to in-patients with SSD because it has positive effects on clinical insight and medication adherence (19). Better medication adherence might prevent relapses, benefit the overall course of the illness, and reduce the chance of future hospitalisations. During hospitalisations, YT can reduce stress in acutely ill patients, which is of crucial importance at the beginning of their treatment (20, 21) when symptoms and difficulties tend to be exacerbated. Already after a single yoga session, people with SSD display decreased state anxiety, reduced psychological stress, as well as increased subjective well-being (22). Furthermore, studies report increased quality of life for up to 6 months after YT (23, 24). Moreover, studies on YT show improvements in cognition, including attention precision and speed in abstraction, attention (25), and memory (26). Also, facial-emotion recognition (27, 28) improved after YT, which is linked to increased socio-occupational functioning (27–29). In fact, recent research found that persons with schizophrenia who attended a YT over the course of 6 weeks significantly improved in social cognition performance compared to those in the waitlist control group (30).

The empirical evidence of YT on the general psychopathology of SSD seems to be more heterogeneous: A meta-analysis in 2018 reports that mindful exercises have more beneficial outcomes on psychiatric symptoms than non-mindful exercises, and Yoga specifically seemed to be a promising intervention for NS (31). Meta-analyses from the following year obtain similar results, concluding that mind-body therapies, including Yoga, can improve NS, yet effects are small (32) to moderate (33) and display high heterogeneity. But even small effects might be of clinical relevance because NS pose a great subjective burden to people with SSD who describe the experience of losing concentration and motivation, withdrawal, and numbness feelings as disabling and persistent (34). A more recent meta-analysis showed moderate positive effects of mind-body exercises, including Yoga, on PS, NS, as well as depression in patients with schizophrenia (35). People with SSD receiving YT in in-patient (29, 36) and outpatient care (27, 29) both experienced reductions in PS, NS as well as general psychopathology. According to the NICE treatment guidelines for psychosis and schizophrenia in adults (37), Yoga can, compared with aerobic physical activity, improve quality of life at short term follow up as supported by one study with high quality evidence (29). However, a majority of randomised controlled trials are of low quality and research on YT for patients with SSD is methodologically flawed by missing or inadequately reported outcomes and procedures (38, 39). According to a Cochrane Review, there is currently not sufficient high-quality evidence to neither support nor discourage the use of YT as an adjunctive treatment for schizophrenia (40), emphasising the need for further research.

Various schools of Yoga highlight different elements, yet despite this heterogeneity, YTs show no significant differences in their effects (41) and they might share common underlying factors inherent to Yoga or other mind-body therapies exerting these effects. One of these factors could be mindfulness (42). Yoga is also referred to as “mindfulness in motion” (43) because one moves with intentional awareness through various poses while being anchored in ones’ breath. This embodied practise of mindfulness, unifying the mind and body through the breath, might lead to an experience of re-connexion on several levels (18), possibly affecting practitioners lives beyond the yoga mat. Therapies integrating mindfulness-based approaches can provide guidance in coping with symptoms rather than curing these (44), which is especially relevant in the treatment of patients with SSD with a chronic course. Dealing with symptoms in a mindful way includes acting with awareness of the present moment experience and having a non-judgmental and non-reactive attitude (45, 46). Present moment awareness is achieved by placing awareness on experiences related to body, feelings, mind, and phenomena (47). Yoga extends the role of the body as present moment awareness is inherently linked to entering different asanas, yet Yoga, and other mind-body therapies, have been rarely implemented in Western medical care until recently (12, 43).

Consequently, research on YT for patients with SSD is still limited in scope and due to the wide variety of Yoga styles, participants, as well as outcomes examined (32, 33, 38), it remains difficult to obtain conclusive evidence on the underlying mechanisms of YT. Particularly regarding this patient group, there is only one qualitative study of in-patients with psychotic disorders whose YT experience was characterised by relaxation, calm/reduced stress, improved energy/focus, and motivation to engage with life (48). These findings provide the first insights into working mechanisms of YT for patients with psychotic disorders, yet more qualitative research involving in-patients with SSD is needed to gain a deeper understanding of their experience of YT and its underlying factors.

Despite the therapeutic potential of Yoga for patients with SSD, the current body of research on Yoga as an add-on treatment for SSD lacks the perspective of this patient group. Primarily, the present study aims to close this gap by conducting semi-structured interviews to explore the subjective experiences of a newly developed **Yo**ga-based **G**roup **I**ntervention (**YoGI**) by in-patients with SSD. The close iterative process allows for gaining an in-depth understanding of the mechanisms and processes underlying YoGI and possibly provides novel impulses for further research and treatment adaptions. Furthermore, the participants’ feedback is used to address current limitations concerning the applicability, practicality, and utility of this intervention. Thereby, this study is a first contributing step to an evidence base necessary for developing a YoGI manual specifically tailored to patients with SSD receiving treatment in a hospital setting.

MATERIALS AND METHODS

Design

A qualitative approach was chosen to yield an in-depth understanding of in-patients with SSD experiences with YoGI. In addition, quantitative measures were obtained with the intention to provide a comprehensive clinical characteristics description allowing the assessment of exclusion criteria.

Participants and Procedure

Participants were recruited from the in-patient ward for psychotic disorders of the Charité -Universitätsmedizin Berlin, Department of Psychiatry and Psychotherapy at Campus Benjamin Franklin. Patients in the age between 18 and 65 years with an ICD-10 F2x-spectrum-diagnosis, who received in-patient care at the ward for psychotic disorders and who provided informed consent were eligible to participate in the study. Patients who presented with severe psychotic symptoms, as indicated by any item ≥ 6 on the Positive Syndrome Subscale of the Positive and Negative Syndrome Scale (PANSS) (47), or who displayed a severe neurological disease assessed by a licenced psychiatrist were excluded from participation.

At the ward, 29 patients who fulfilled the inclusion criteria were approached by the interviewer, who informed them about YoGI and the possibility of participating in a study afterwards. Four patients declined to try YoGI due to lack of motivation, disinterest in Yoga and/or meditation, as well as concerns about required levels of fitness and flexibility. Since patients needed to attend at least one session of YoGI, those who refused to engage in the intervention could not participate in the study either. However, all patients who took part in YoGI and were offered participation provided informed consent to participate in the data collection process taking place at two timepoints. First, the PANSS interview was administered within a week of attending YoGI. The PANSS interview was conducted by an experienced psychologist to determine the presence and severity of PS and NS as well as general psychopathology. Secondly, directly after attending YoGI, participants were invited to take part in a subsequent one-on-one interview session. In this session, demographic data such as age, sex, living situation, occupation, and medical information, including diagnosis, the onset of the disorder, length of stay at the hospital and psychiatric medication were assessed. Afterwards, the Patient Health Questionnaire (PHQ-4) (48) was administered to assess symptoms of depression and anxiety. Finally, the interview was conducted, transcribed, and analysed by means of inductive thematic analysis (see **Figure 1**). Respondents received no compensation for participating in the study. The study was approved by the ethical committee of the Charité Universitätsmedizin Berlin, EA4/169/20.

Quantitative Measures

The Positive and Negative Syndrome Scale (PANSS) (47) is a semi-structured interview that assesses global psychopathology, PS, and NS. The standard version was used consisting of 16 items for global psychopathology (cronbach’s alpha = 0.55), seven items for PS (cronbach’s alpha = 0.62) and seven items for

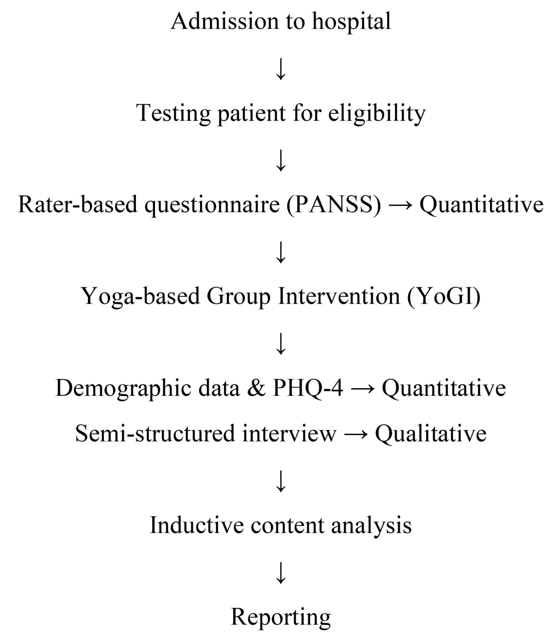

FIGURE 1 | Study flow diagram.

NS (cronbach's alpha = 0.92), all subscales display moderate to high internal consistency (49). The Patient Health Questionnaire (PHQ-4) (48) is a brief 4-item questionnaire to assess depressive and anxious symptoms and displays good internal consistency (cronbach's alpha = 0.85).

Intervention

YoGI took place as part of an extensive interdisciplinary treatment programme for in-patients with SSD, including inter alia pharmacological treatment, individual- as well as group psychotherapy, occupational therapy, and exercise therapy. YoGI was offered on a weekly basis and patients were able to join the intervention at any time as sessions did not consecutively build upon another. Group sizes ranged from 3 to 10 participants and interviewees participated in different sessions over the course of 6 months. YoGI had a duration of 50 min and began with breathing exercises (*pranayama*) and checking in with one's own body. This was followed by a short round in which each participant briefly verbalised their current state of mind, body, or set an intention for class. Afterwards, the participants were guided through various *asanas* (exemplary YoGI protocol in **Supplementary Materials**) supported with mindful instructions that emphasised noticing any bodily sensations and explicitly instructed breathing in and out. YoGI ended in *shavasana*, yet instead of relaxing in silence, the final relaxation was guided by body scan instructions.

Interviews

The qualitative data were collected by means of semi-structured interviews that aimed to explore the subjective experience of a YT. The initial list of questions was based upon a semi-structured interview guide investigating a Mindfulness-based group therapy for in-patients with SSD (50). The set of questions was refined in an iterative process with the patients during a pilot phase of five interviews which led to slight adaptations of the order and phrasing of questions. A team of researchers discussed the interview guide to ensure a comprehensive set of questions while reducing redundancy. Subsequently, a final list of 14 questions was established (see **Table A1** in Appendix). The questions were phrased openly to allow participants to express what they considered most relevant. For example, participants were asked to 1. "*Describe what first comes to mind when thinking of YoGI*" and 5. "*How and what did you perceive during the exercises.*" Other questions invited participants to share 4. feelings and 6. potential challenges and report on 14. their current symptoms. Furthermore, specific questions such as 8. "*What did you manage well and what did you like?*" and 12. "*What did you miss? What could have been done better or differently?*" aimed at gathering opinions on what elements of YoGI were considered as either valuable or in need of adjustment.

TABLE 1 | Sample characteristics (*n* = 25).

	M	SD	Range
Age (years)	41.9	13.98	20–64
Length of current hospital stay (days)	63.44	33.63	13–146
PHQ-4 (*n* = 24)	10.29	1.14	4–16
PANSS, Positive Syndrome Scale (*n* = 24)	16.04	5.14	8–27
PANSS, Negative Syndrome Scale (*n* = 24)	17.54	7.02	7–32
PANSS, General Psychopathology Scale (*n* = 24)	32.95	8.93	19–52

M, mean; SD, standard deviation; PANSS, Positive and Negative Syndrome Scale (51); PHQ-4, Patient Health Questionnaire (52).

Data Collection and Storage

In total, the present study collected full data from 25 interviewees to represent a comprehensive account of the subjective experience of YoGI of in-patients with SSD. A sample size of $N = 25$, including five interviews conducted in the pilot phase, was chosen because code saturation and meaning saturation are reached after nine and 16–24 interviews, respectively (53), and guidelines consider sample sizes of around 25 as adequate number (54). In this sample the five interviews conducted in the pilot phase were included, which we deemed appropriate since only minor changes have been applied to the interview guide. The data collection process was started on the 26th of May 2020 and finished on the 14th of October 2020. Interviews were conducted after participating in at least one but no more than three sessions of YoGI. On average, the semi-structured interviews lasted 42 min, ranging from 25 to 70 min. Before the one-on-one interviews, participants were explicitly asked for consent to either have their answers noted down by hand or audio-recorded by the interviewer. Six interviewees opted for the first option and 19 for the latter. Moreover, interviewees chose a place to conduct the interview, 17 respondents wanted to stay in the room where YoGI took place, and eight decided to sit down outside in the park of the hospital to be interviewed. The interviews were conducted by TS, a female psychologist at the ward for psychotic disorders who has practised Yoga for several years and co-instructed YoGI together with IH, a licenced psychologist. The interview process and the instruction of YoGI were supervised by a team of psychologists and a licenced psychotherapist on a regular basis. Participants might have been in contact with the interviewer during other group therapies or studies offered at the ward before attending YoGI. The interviewer informed participants about the nature of the intervention and its embedment in the research for her thesis project.

Data was securely stored in locked cabinets, and electronic data was password protected. The pseudonymisation of participants' data was recorded on a separate, password-protected list. All data were accessible only by members of the research team. After completion of data collection, the decoding list, as well as any handwritten data, was deleted. Hence, only pseudonymous data will be available, which prevents any re-identification. The data will be stored for a maximum period of 10 years at the Charité–Universitätsmedizin Berlin, after which it will be deleted.

Data Analysis

Illness severity scales (PANSS, PHQ-4) and sociodemographic data were analysed using Microsoft Excel 365 for Windows 10. The qualitative data from the semi-structured interviews were analysed following an inductive thematic approach. The coding was done in MAXQDA 2020 for Windows 10. The goal of the inductive thematic analysis was to organise identified categories into a model to summarise the raw data and highlight key themes (55, 56). The inductive thematic analysis followed the six phases outlined by Braun and Clarke (57). First, all interviews were transcribed using the same formatting. Afterwards, the transcripts were read and re-read by TS and FM who were involved to various degrees in the research process. Once the two readers were familiar with the text and reached a good understanding of its themes, they generated initial codes in a ground-up approach while reading (*in vivo* coding) across the entire data set in the second phase. In the third phase, codes were collated into potential themes. In phase four, these themes were reviewed as it was checked whether themes work in relation to the coded segments and the whole data set. Themes were clearly defined and named in the fifth phase. In the final phase, representative quotes of the interviewees were selected, translated from German to English, and the report was produced.

RESULTS

Participant Characteristics

In the present study, 25 participants (12 identified with the female, 13 with the male, and no one identified with the diverse gender), with a mean age of 41.9 years (SD = 13.98), from the inpatient-ward for psychotic disorders were included. Of these, 17 participants were diagnosed with schizophrenia (F20), five with schizoaffective disorder (F25), two with delusional disorder (F22), and one with acute polymorphic psychotic disorder (F23), all according to ICD-10 criteria. Except for one participant, all received psychotropic medication. On average, participants showed moderate PS and NS and severe depressive and anxious symptoms. A detailed summary of sample characteristics is presented in **Table 1**.

Qualitative Results

During the interviews, respondents foremost reported their experiences of the previous YoGI session, and many gave detailed feedback on poses they particularly liked or that they struggled with. Most interviewees had neutral to positive attitudes towards Yoga before participating and except one participant, all reported to have felt relaxed at some point and to have benefitted from the intervention. Prior Yoga experiences ranged from non-existent to multiple years of following a regular individual practise; however, none of the participants had been practising Yoga regularly in the near past or were offered to practise Yoga in a therapeutic context before.

In the inductive thematic analysis, seven main themes emerged from the semi-structured interviews that describe participants' subjective experience of YoGI. Overall, YoGI was characterised by **inclusivity**, as the intervention was perceived as feasible and encouraged individual adaptation at all times. Yet, participants also encountered **challenges** during the practise related to physical limitations or the ability to engage with the intervention. YoGI affected **symptom representation** as heightened awareness led participants to notice impeding as well as improved symptoms. Through practising Yoga in a group, participants experienced a sense of **interconnectedness**. However, YoGI did not only strengthen participants' awareness for connection among each other but also to themselves. They developed a **mindful stance** as they accepted their limitations and adapted exercises with self-compassion. Through following the flow of asanas, participants were guided into trying new postures that resulted in building **confidence** and synchronising movement and breath helped many to enter a **state of relaxation**. A summary of themes, subthemes, and the corresponding codes can be found in **Table 2**.

Inclusivity

The theme **inclusivity** depicts that YoGI is an inclusive practise as it displays *feasibility* for a wide range of participants and continuous emphasis on individual *adaptation*.

Feasibility. Most patients portrayed YoGI as a feasible intervention due to its suitable length, the mix of different exercises, and its perception as a safe space. Despite different levels of prior experience, all participants deemed the level of difficulty as appropriate, while most interviewed described YoGI as easy. One participant depicts the presented postures as:

> *"pleasant, not too difficult. Overarching different age and skill levels. Almost everyone can participate. If one has a physical disability, e.g. being blind, it* [participation] *was difficult; maybe that's a marginal case* [for participation]. *But it's a really large range of people who can participate." (Informant 5)*

The perception of *feasibility* is also intertwined with the following subtheme *adaptation,* as one participant added:

> *"I realised that I probably would not be able to do this* [exercise] *optimally, but I'll do it the way I can, according to my capability and*

TABLE 2 | Themes, subthemes, and codes.

Themes	Subthemes	Codes
Inclusivity	*Feasibility*	Mix of exercises Level of difficulty Length of session Easy participation Different levels of prior experience Calm and safe setting
	Adaptation	Adapting exercises Instruction to individually adapt practise Adaptation chair Yoga Tailored instructions Experimenting with one's body Breathing in own rhythm
Confidence	*Motivation*	Motivation to practise Motivation to continue Yoga Motivation for other activities
	Self-efficacy	Self-knowledge Insight interplay body, mind, breath Empowered Self-confidence
	Feeling achievement	Feeling achievement Proud Content Flow
	Sense of competence	Physical perseverance Physical activity helps focus Sufficient concentration Learning and progress Trying new things and challenging oneself
State of relaxation		Calm mind Relaxed body Feeling relaxed Interplay tension relaxation Challenging elements Relieving tension Relaxing exercises Relaxed music Closing eyes
Mindful stance	*Awareness*	Body awareness Loss of ability Breath Present moment
	Acceptance	Acceptance of condition Accepting own limitations
	Self-compassion	Self-care No pressure to achieve Listening to oneself
	State of oneness	
Interconnectedness	*Dialogue with instructor*	Appreciating instructions Watching instructor Listening to instructions Empathic attitude
	Practising and learning together	Practising together Awareness of others Comparing oneself Imitating others Group helps with motivation
	Feeling connected	Empathy Connecting to and Appreciating Others Acknowledging Others Experience
Challenges	*Physical limitations*	Pain Overweight Dizziness
	Engaging in practise	Breathing rhythm irritating Understanding exercises Starting practise Interruptions by others
Symptom representation	*Ease of symptoms*	Well-being Lifted mood Improved pain Distraction from symptoms Distance to problems and worries Less strain through voices Fewer thoughts Bliss afterwards Improved interactions afterwards
	Symptoms impeding practise	Difficulty concentrating Experiencing hallucinations Mistrust Demotivation

> *what feels good to my body. And because of that, I did not perceive it* [exercise] *as difficult." (Informant 25)*

Adaptation. While most participants practised the asanas on the mat, four interviewees took part in YoGI while sitting on a chair due to physical limitations. Those participants received tailored cues for their practise (please see YoGI protocol for more details). Everyone was encouraged to follow their own breathing rhythm and individually adapt the postures if needed. Many participants experimented with their body and subsequently adapted exercises, such as a participant who said:

> *"Sometimes I had to pause the practise. If one realises it doesn't work at all, or it's too exhausting physically or hurts, it is better to move back into an easier posture for a while." (Informant 8)*

Another participant also expressed appreciation of the focus on adaptation:

> *"I liked that one had the freedom to adapt it* [Yoga practise] *to one's own needs. (...). I considered that relaxing knowing it's not about performance but engaging with the postures in a relaxed manner that serves my well-being instead of delivering maximum performance." (Informant 22)*

Challenges

The **challenges** participants experienced throughout YoGI can be divided into difficulties with *engaging in practise* and *physical limitations.*

Physical Limitations. A proportion of participants stressed the challenges imposed by physical limitations such as dizziness and overweight, which they noticed while engaging in certain exercises. One participant explained:

> *"My arms are so heavy. For a while, I can do the exercise, but then I cannot anymore, because the arms weigh so much. And sometimes, I do not have the strength to hold them up for so long. But I made an effort, and I was very exhausted then." (Informant 13)*

Many participants also reported awareness of and difficulties due to pain.

Engaging in Practise. Participants reported difficulties to start the practise, especially when they did not enter the class in a calm state, and a few mentioned difficulties in understanding the exercises. A crucial factor for interruption of the practise was the presence of others; one participant stated:

> *"There were moments in which I was pretty stressed. Not by Yoga but by other patients who always went in and out of the room and rummaged around in their bags or talked. I perceived that as very disruptive." (Informant 13)*

Moreover, finding one's own breathing rhythm or following the proposed one seemed challenging at times, as one interviewee explained:

> *"I don't know, it* [breathing exercise] *doesn't relax me. Mostly it's too slow because I breathe quickly. (laughs) And then I take two breaths while just one* [inhale] *is instructed and then…I don't know." (Informant 21)*

Interconnectedness

The theme **interconnectedness** describes a sense of connection participants felt among each other and with the instructor. The theme arose by combining the subthemes *dialogue with instructor*, *practising and learning together,* and *feeling connected.*

Dialogue with instructor. Participants listened to instructions and observed the instructor entering postures. By instructing the participants to notice bodily sensations and adapt the practise if needed, a dialogue between instructor and participants was created, which one participant described as follows:

> *"The therapist raises the question 'look what it is like for you, whether it feels good to you or whether you need something else' and then one forwards this question to one's own body. And then one answers if one manages to listen to oneself." (Informant 25)*

This quote demonstrates how this interviewee internalised the instructions and actively engaged with the questions asked by the instructor. Generally, instructions were considered helpful and the empathic attitude in communication was appreciated.

Practising and Learning Together. Participants noticed the presence of others and perceived it as helpful to watch and imitate others doing the postures. This subtheme illustrates how a cooperative group atmosphere allowed participants to learn with and from each other. One participant stated:

> *"I always looked at you* [instructor] *and then it worked. If one observes someone else, and how this person does the posture, then one can see what you* [instructor] *described, which then makes it relatively easy." (Informant 8)*

Some participants also compared themselves to other participants and described that practising in a group motivated them.

Feeling Connected. Interviewees reported feeling connected to each other as they acknowledged others experiences and appreciated their presence generally. Some communicated that they felt empathy during YoGI. For example, participants said:

> *"To some extent, I felt the need that others also keep up with the group, so I observed a little whether they looked happy, too." (Informant 25)*
> *"For me, that's part of Yoga, that it transports something. Like the atmosphere we had today, the participants were all very motivated, wanted to engage in the practise. A good mood, because the people got involved with the class." (Informant 6)*

State of Relaxation

This theme summarises that most participants entered a **state of relaxation** during YoGI. To describe where they felt relaxed, most interviewees referred to the *body*: "*in my body, it wasn't so stiff anymore. It was more relaxed…everywhere, my muscles were eased, more relaxed and thereby I was able to relax and not be so stiff anymore.*" *(Informant 11)*. Others also highlighted the relaxing effect they felt on their *minds*; one participant explained she noticed relaxation by "*[…] not ruminating, having no special thoughts. I would say the relaxation was more in my mind. My mind was relaxed.*" *(Informant 23)*. Other participants expressed their feelings of relaxation in a pictorial manner:

> *"Like a fish, I slid into the water. […] Like fish and water belong together, it felt like what exactly is right for one at that moment. And it is something weightless too, that one is unburdened, floating, free of worries. That one is shielded from daily worries and from whatever is burdensome." (Informant 25)*

Participants experienced some exercises as predominantly relaxing or challenging or both simultaneously. This interplay played a crucial part in entering a state of relaxation as one participant stated that:

> *"I can only feel this contrast between tension and relaxation and enjoy the relaxation after I truly was tense." (Informant 23)*

Another participant emphasises the role of physical engagement and repetition of exercises for relaxation as she stated:

> *"I became calmer, so the longer or the more often one does exercises, the more positive the effect will be." (Informant 18)*

Overall, most participants ascribed a calming effect to the music, and many closed their eyes during parts of the practise.

Symptom Representation

The **symptom representation** theme summarises how participants experienced their symptoms as either less straining during YoGI or as impeding the practise.

Ease of Symptoms. During YoGI, many participants experienced an increase in well-being, improved pain as well as lifted mood. While many continued to experience auditory hallucinations, interviewees reported less engagement with voices and less strain imposed through these. Generally, during YoGI, participants were distracted from their symptoms and seemed to have fewer thoughts as they focused on the Yoga practise. Moreover, they gained distance to problems and worries, which is pictured by one participant as follows:

> *"One is very relaxed and everything else is not so important at this moment: problems, thoughts about what to do tomorrow or in a few hours. Everything stops for a while and it's just about me. [. . .] The strain of problems is gone. One escapes the 'problem-prison,' and I will just call it like that, leaving stress and pressure behind for a while." (Informant 2)*

After YoGI, some participants reported improved interactions with others as well as experiencing bliss, a state thought to occur after self-realisation is achieved (58). One participant portrays the following, for instance:

> *"When I walk out* [of the session], *I feel my back or shoulder, but in a positive way and think 'ah what a good day!'. It's as if they* [back and shoulder] *introduced themselves again and became friends, like in an emotionally positive sense. Having everything 'on board' again, having positive interconnections and that's how I recognise it* [pleasant body feeling]. *I was very grateful for this incredible euphoric feeling of well-being that I was allowed to experience." (Informant 25)*

Symptoms Impeding Practise. Toward the beginning of the session, some participants struggled with staying motivated. During YoGI, feelings of mistrust and hallucinations sometimes prevented full engagement with exercises. However, difficulty concentrating seemed to be the symptom impeding participation in YoGI in most cases:

> *"In my head, there was still this mess, back and forth, pushing thoughts around, crisscross, that persisted* [during the exercises]. *That made it kind of difficult to focus on all the exercises." (Informant 11)*

Confidence

Participation in YoGI facilitated experiencing **confidence** which developed through a *sense of competence* and *achievement*, followed by *self-efficacy* and *motivation*; the four subthemes of this category are displayed in **Figure 2**.

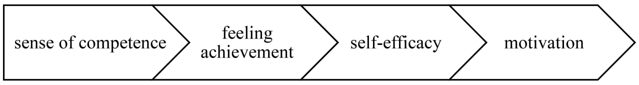

FIGURE 2 | Subthemes of theme "confidence".

Sense of Competence. Following the flow of asanas required physical perseverance. According to participants, being physically engaged helped to stay focused throughout YoGI. Many interviewees positively acknowledged having sufficient concentration to actively participate whereby they learned new postures. The Yoga class invited participants to try new exercises and challenge themselves which created learning opportunities and consequently, many progressed. The cognitive process of becoming aware of one's learning progress, such as knowing how to adapt a pose suitable for oneself, facilitated experiencing a sense of competence. One participant reviews a moment of progress:

> *"The horizontal balance wasn't so easy. That was actually the most difficult thing. It did not work out from the start. I kept trying to hold my leg up and stretch to the front, always a little more and a little more. Until I was somewhat content or rather you* [instructor] *finished the exercise. But I put so much effort into it that I was content then." (Informant 10)*

Feeling Achievement. This sense of competence acquired through the physical practise led many participants to feel proud of their achievement. One participant points out: "*I always like shavasana at the end. It's like you earned it – you do something hard and then you get something sweet as a result.*" *(Informant 1)*. The interviewee indirectly expresses pride at the end of the practise which illustrates the affective component of the confidence theme: to feel achievement. Furthermore, some participants felt flow during YoGI. One participant explains her experience as follows:

> *"I did not monitor myself so much anymore. I can only say that there was nothing else except the class. Yes, and for me, that was like a flow. [. . .] I remember when receiving a F-diagnosis that I thought that other people will always be happier than me, that they are healthier and so on. But that was a moment in which I caught myself thinking, 'right now, at this moment I wouldn't want to change with anyone in this world.'" (Informant 25)*

Self-efficacy. By engaging in pranayama and asanas, participants gained insight into the interplay of the breath, body, and mind. For many, Yoga posed an opportunity to learn about themselves, for example, through noticing how one feels today or adjusting postures to a suitable level of difficulty. Furthermore, the physical practise was an empowering experience for some. One participant said:

> *"One mobilises powers not knowing that these even played a role. That one consciously concentrates and holds a posture means to challenge oneself and one's body, becoming active to feel better." (Informant 6)*

Similarly, another participant describes how becoming active through Yoga can lead to feelings of self-efficacy:

> *"I like that with Yoga; there are little steps to becoming active again. Not taking 100 stairs at a time but simply paying attention*

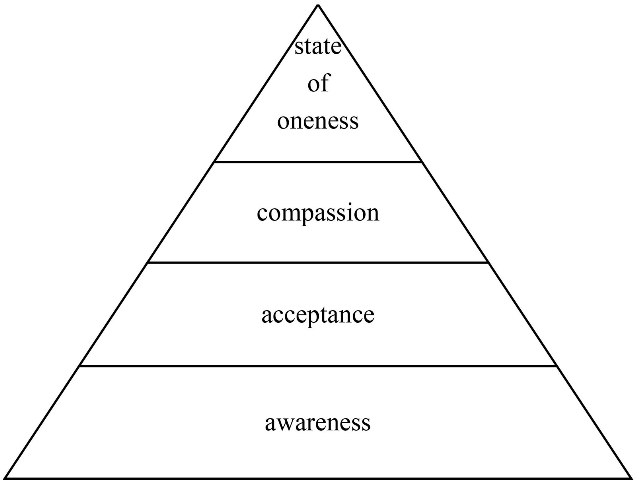

FIGURE 3 | Subthemes of theme "mindful stance".

> *to the breath, noticing how the ribcage expands. Feeling able to do something again, to conquer things." (Informant 5)*

Motivation. Before attending YoGI for the first time, many patients displayed curiosity and motivation to engage in the intervention. Most participants attended YoGI on a regular basis and reportedly left the class feeling motivated to continue their Yoga practise beyond the hospital stay. Additionally, the practise had an activating effect:

> *"It* [Yoga] *is relaxation, equanimity for the body…something motivating one in a positive way. One feels better afterwards. Then I also feel motivation to do something else." (Informant 18)*
> "Yoga *motivated me to continue doing sport. It motivated me to do push-ups today and train my abs and maybe I also do squats. It* [Yoga] *motivated me to still do that* [exercises] *today."* *(Informant 19)*

Mindful Stance

The theme **mindful stance** illustrates how participants practised *awareness*, *acceptance*, and *self-compassion* during YoGI. For some, this resulted in a *state of oneness*. A representation of the subthemes and how these build upon another can be found in **Figure 3**.

Awareness. YoGI guided participants through various exercises, which allowed them to practise awareness of their body, thoughts, and breath. One participant describes heightened awareness of the self through experiencing one's body capabilities:

> *"One develops a good feeling for one's body to see what kind of exercises one can do and to feel oneself. I think that's the effect. One concentrates on the body, which poses it can enter and thereby experiences oneself." (Informant 22)*

Acceptance. While many participants were aware of limitations, some pursued this mindfully as they practised acceptance of these and adapted the exercises to their own pace and intensity. One participant expresses how she accepted her own capacities in the face of difficulties:

> *"Throughout the whole class, I never felt pressure, neither from you* [instructor] *or in general. […] But there were those brief moments in which I told myself, 'why don't you manage to balance.' But then I just accepted that is like that or was like that." (Informant 23)*

Self-compassion. Many participants treated themselves with compassion as they listened to bodily sensations instead of forcing themselves into postures. Some utilised Yoga as a form of self-care, such as one participant who illustrated it as:

> *"a time in which one takes care of one's well-being and won't get distracted. You* [instructor] *masked the clock so that one does not get side-tracked by the time or other worries and fully concentrates on doing something good for one's body." (Informant 25)*

State of Oneness. The previously described subthemes of **mindful stance** develop in progressive stages, for example, one needs to be aware of pain to be able to accept it and, in turn, accept it to treat oneself in a compassionate manner. For a handful of participants, being mindful led to a *state of oneness*, during which one experiences interconnectedness in the sense of transcending boundaries. One interviewee shares her experience and emphasises the cognitive shift when moving into a state of oneness: "*Then I have completely different thoughts. It's a collective thought and it's not so much about me as an individual anymore.*" *(Informant 19)*. She refers to the group of Yoga practitioners as they posed the immediate environment, however, one could also feel interconnected to nature for instance when experiencing a state of oneness.

DISCUSSION

The aim of this study was to investigate the experiences of in-patients with SSD who participated in YoGI in a German university hospital. This is the first study to examine the perspective of this patient group in-depth regarding Yoga's underlying processes and its perceived benefits and limitations as a treatment component. Semi-structured interviews were conducted directly after participation in YoGI to ensure detailed and lively descriptions of participants' experiences. In the thematic analysis, seven themes emerged. Overall, YoGI was perceived as feasible and participants appreciated the focus on adaptation, summarised by the theme **inclusivity**. Nevertheless, participants encountered **challenges** during the practise and the theme **symptom representation** captures impeding as well as improved symptoms. The themes **interconnectedness**, **state of relaxation**, **confidence** and **mindful stance** provide insight into the various experiences made by participants during YoGI.

YoGI: A Feasible and Promising Adjunctive Therapy

When implementing complementary therapy for in-patients with SSD, it is a major benefit that all patients at the ward can participate. Persons with SSD face stigma and discrimination in private and public settings, including psychiatric and health care (59). Participants reported that none of them had been offered YT before, this could reflect the novelty of Yoga as a complementary therapy for patients with SSD, however, it might also point to the delay this patient group experiences in receiving innovative treatment approaches. Thus, an inclusive intervention is of particular importance for this patient group. To ensure **inclusivity** of YoGI, attention needs to be paid to all participants' capabilities and limitations, making adaptability of the Yoga practise a prerequisite. The wide age range of participants (20–64 years) who had different levels of physical and cognitive functioning as well as diverse symptoms representations suggests that YoGI posed a feasible intervention for many in-patients. In addition to *feasibility*, a focus on *adaptation* fosters inclusivity as it eased access to the practise. For instance, participants could follow the Yoga class while sitting on a chair instead of a mat, thereby easing the participation of patients with overweight or old age who initially did not dare to practise Yoga. Furthermore, adaptation offered an accepting attitude inherent to Yoga to deal with arising **challenges** such as inflexibility, pain, or dizziness during YoGI. More importantly, the notion of listening to the body instead of forcing it into poses reduces the risk of injuries and adverse effects. This might increase the safety of the practise while simultaneously promoting agency on the side of the participants.

YoGI's overarching inclusivity and its manageable challenges show that it qualifies as a feasible complementary therapy for patients with SSD. Nevertheless, the practise requires physical exercise and perseverance, which might be of virtue because patients with SSD are significantly less active in comparison to healthy controls (60) as they are faced with complex barriers to uptake physical activities such as impact, especially of negative symptoms of SSD, effects of sedating medication and depression or anxiety (61). Yet, interventions that encourage physical activity are advised for patients with SSD (60, 61), and interviewees stressed how YoGI required physical perseverance, which they treated as a welcome challenge.

In fact, staying physically engaged may put the development of **confidence** in motion: being able to hold postures and having sufficient concentration resulted in a *sense of competence* that was followed by *feelings of achievement,* such as when managing to balance. Learning new asanas and choosing one's level of difficulty set the groundwork for *self-efficacy:* through practising Yoga, participants gained self-knowledge and understood their impact on the interplay of body, mind, and breath. This can pose an empowering experience and may raise self-confidence translating into *motivation* to practise Yoga and engage in other activities (see **Figure 1**). As lack of motivation constitutes a core symptom of SSD (7), a group therapy with a low barrier to join that leaves participants feeling motivated seems like a promising adjunctive therapy for patients with SSD. In patients with posttraumatic stress disorder YT seemed to set similar processes in motion: themes such as "empowerment" (62) and "feelings of energy and renewal as well" as well as "self-esteem" (63) emerged during the qualitative research processes. This is an example of how Yoga might address the motivational dimension of psychological transdiagnostic processes (64) necessary for fostering human prosperity in line with a process-based care approach that moves beyond a syndromal approach focused on reducing psychopathology (65). In fact, *motivation* and *self-efficacy* could be supportive factors in building personal resources, which alongside NS, predict depression in SSD and, therefore, should be fostered by complementary therapies (66). Also, the clinical relevance of gaining *confidence* should be emphasised since research stresses the importance to strengthen resilience and self-esteem in patients with SSD (67), especially since low self-esteem is closely related to suicide risk in this patient group (68).

On another note, physical perseverance set the stage for an interplay of tension and relaxation, which ultimately led to a **state of relaxation** during YoGI. Except one, all participants reported feeling relaxed at some point during the practise. Achieving a state of relaxation might be especially valuable in the hospital setting (20, 21), where patients are being treated for acute episodes with pronounced symptoms outside of their familiar environment. Previous research has already shown that YT can reduce stress in acutely ill patients at the beginning of their hospital stay (20, 21). Also, a study exploring Yoga experiences of stroke survivors identified the theme "feeling calmer" (69) and "calmness" (70) emerged as a key theme among yoga practitioners, showing that relaxing effects of Yoga span different settings and various participant groups. Further research should follow up these participant reports to investigate the strength and longevity of YoGI's relaxing effects, how these can be utilised and fortified as well as possible side effects.

How Yoga Affects Symptom Representation

The need for complementary therapies in the treatment of SSD is evident as cognitive dysfunctions and NS are not effectively targeted by current treatment while being experienced as enduring and persistent symptoms by people with SSD (34). Severe NS can impede participation, yet YoGI shows potential to adjust to and affect some of the five constructs of NS; blunted affect, diminished speech, anhedonia, social withdrawal, and lack of motivation (7). For example, diminished speech did not seem to pose a barrier to practising Yoga. Nonetheless, practitioners were verbally engaged as they were asked to briefly share their intention at the beginning of the session. This might have created an explicit dialogue in addition to the connexion evolving through the non-verbal shared consciousness of practising Yoga together, thereby offering an opportunity for social relations. While many patients with SSD experience a lack of motivation, most participants at the ward managed to attend YoGI regularly. Furthermore, after YoGI, some left feeling motivated to engage in an additional individual Yoga practise or engage in other tasks reflecting the effect the intervention had on anhedonia. Interviewees mentioned that they experienced elevated mood and positive emotions, such as joy, during as well as after the Yoga class. The mechanisms underlying this effect of YoGI are not yet established, thus study designs involving a control group that assess a variety of external factors need to follow up the reported experiences to be able to establish causal relationships. However, similar processes have been observed with mindfulness practises showing an increase in positive emotions and anticipatory pleasure (71). Since a lack of anticipatory pleasure has been linked to NS (72, 73), interventions facilitating these processes might indirectly target clinical manifestations of SSD. Moreover, YoGI might have a preventative effect on negative mood spirals, similar to a reduction in negative thinking that has also been observed as a mechanism of mindfulness (74). During YoGI, the asana practise requires one to notice one's body in a mindful manner, thereby providing an activity that demands continuous attention to inner sensations, preventing participants from engaging in rumination that could maintain and intensify low mood (75). Yet, randomised controlled trials of YoGI are needed to investigate the sustainability of the proposed effect. Some participants continued to experience auditory and visual hallucinations during YoGI. However, voices were perceived to be less frequent, quieter, and participants reported less engagement and less strain imposed through these. This observation is in line with the rationale for applying mindfulness to distressing psychotic sensations (76). According to the model, distress may arise as one is not able to notice and accept psychotic (and any other possibly unpleasant) sensations as temporary experiences, instead, a *mindful response* involving clear awareness could pose a more adaptive reaction. Most importantly, there was no increase in hallucinations or other PS consistent with previous research on Yoga and mindfulness-based interventions, showing that these are safe interventions for patients with psychosis (77–80). Additionally, patients seemed to feel safe as only very few reported incidents of mistrust of others, such as feeling nervous or watched, or not being able to close their eyes during Yoga. This outcome is particularly noteworthy since mistrust constitutes one of the core symptoms of SSD. As a prerequisite, instructors need to ensure that the group and the room setting is experienced as a safe space allowing participants to fully engage in YoGI. In this environment, the majority experienced a feeling of **interconnectedness.** Also, Visceglia (81) describes examples of how people with schizophrenia felt connected to others during the Yoga practise and underlines how interconnectedness can enhance well-being (82). In qualitative YT studies with other patient groups themes that can broadly be categorised under "connection" regularly emerge: "relatedness" was found in patients with posttraumatic stress disorder practising Yoga (62). In addition, "belonging" and "sustaining community connection" was reported by YT participants who had a traumatic brain injury (83) and "becoming connected" arose as a theme among stroke survivors joining a Yoga programme (69). Although while practising Yoga participants usually do not directly interact, interviewees reported that they became aware of others presence through observing each other entering poses. Despite the absence of direct verbal exchange, practising and learning together created a supportive group atmosphere. This non-verbal shared consciousness can facilitate equal or even greater benefit than verbally shared consciousness (84).

Yoga—An Embodied Form of Mindfulness?

The theme **mindful stance** (see **Figure 3**) shows the progressive development of mindfulness during YoGI: Most participants were able to become aware of bodily sensations, many adopted an accepting attitude toward these, and for some, this resulted in treating oneself more compassionately. Similar experiences have been reported from patients with pain who participated in YT and describe "renewed awareness of the body" (85, 86) and "increased acceptance of pain and disability" (86) as well as a "transformed relationship with the body in pain" (85). These examples illustrate Yoga's inherent focus on enhancing body awareness which constitutes Yoga as a practise that integrates an accessible form of mindfulness. Through mindful instructions, participants are guided to (re-)direct their attention to notice any bodily sensations, which corresponds to continuous access to bottom-up sensations necessary for "*embodied mindfulness*" (47). In the conceptualisation of *embodied mindfulness,* present moment awareness, a core element of mindfulness, emerges through the interaction of top-down and bottom-up processes that underlie the unfolding of any conscious experience in the here and now (47). In YoGI, participants engage in this interaction as they assess to what extent entering a specific asana might be too intense or even hurt *(bottom-up process)* and based on this sensation, they might adapt the pose to their capabilities and liking *(top-down process)*. By continuously integrating bottom-up and top-down processes, some participants experienced a *state of oneness*, also known as "*the sense of calmness, equanimity, and peace associated with meditative practices*" (87).

The **mindful stance** adopted during YoGI, involving *awareness, acceptance*, and *self-compassion*, might have the potential to extend beyond the Yoga class, as participants of a long-term Yoga intervention showed a significant increase in trait mindfulness (88). Further research should investigate if and how mindfulness practise acquired through YoGI can be utilised to enhance well-being and advance current treatment approaches. A model by Cox and Tylka (89) proposes how Yoga may promote positive embodiment through mindfulness, possibly lasting beyond the Yoga class: First, Yoga cultivates embodying experiences that can be understood as being in a state of mindfulness. Second, by building on these embodying experiences, people might develop trait mindfulness over time. Third, being more mindful might promote engaging in embodying practises such as mindful self-care. Participants of YoGI expressed how their participation and the dialogue with the instructor activated them to engage in self-care beyond the Yoga class (see **Figure 4**). Moreover, a large proportion of participants regularly joined YoGI and showed interest in continuing their Yoga practise after discharge from the hospital. This reflects a wish to continue mindful practises and shows the potential of YoGI to become a complementary therapy sought out by patients, possibly bridging the gap between in- and outpatient treatment.

Limitations and Strengths

A limitation of this study is the use of a convenience sample as this enables selection bias. It might be that those who chose to participate in YoGI, as well as the study, had a more favourable attitude toward Yoga in the first place. Their voluntarily participation indicates motivation to

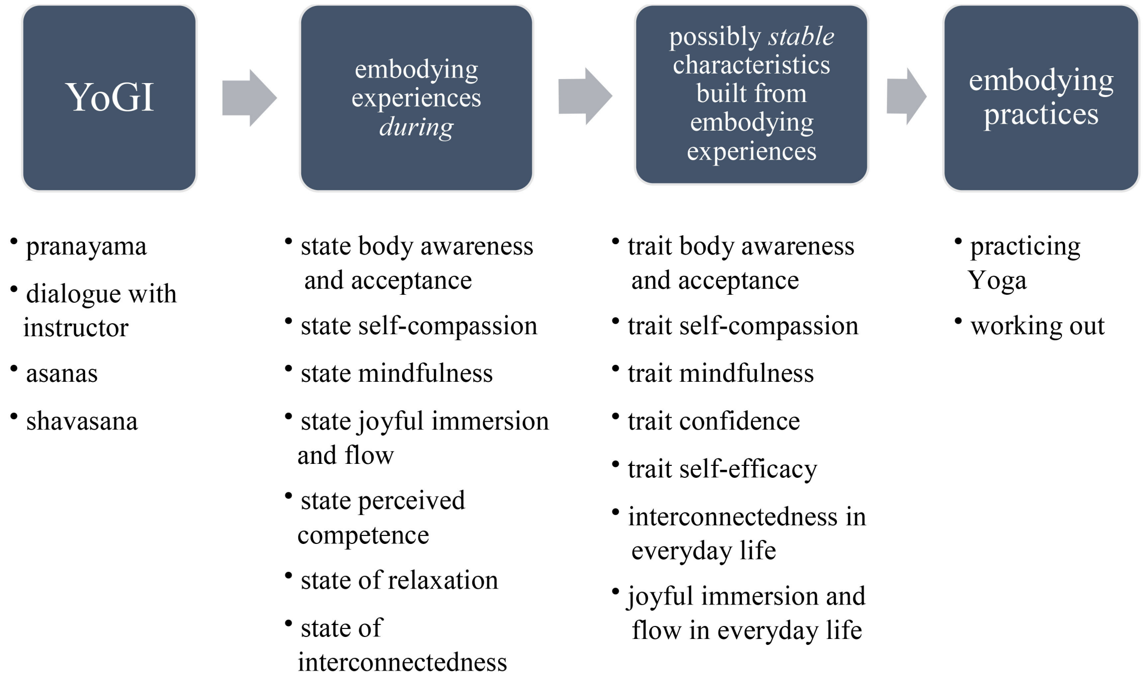

FIGURE 4 | Model of how Yoga may promote positive embodiment by Cox and Tylka (89) fit to YoGI and its proposed underlying mechanisms.

practise Yoga even before the intervention and assessment, thus, the described therapeutic effects cannot be ascribed to participation in YoGI. The interviewer was involved in co-instructing YoGI, which makes the responses susceptible to social desirability bias. Hence, results need to be regarded with caution and should be followed up in further research systematically separating tasks of instructors and interviewers to avoid social desirability bias on the side of participants. Furthermore, one of the researchers was involved in the interviews and the thematic coding process; thus, it cannot be ruled out that the researcher's preconceptions of YoGI might have influenced the participants' answers and interpretation of data. The interview was conducted directly after YoGI and usually, participants were interviewed after visiting their first session and latest after no more than three sessions. It might be that different themes relating to practise and long-term effects would have formed if participants were interviewed after visiting several sessions of YoGI. However, neither the exact number of sessions nor the total number of YoGI sessions attended was recorded. In addition, dosage details of medication, education, and socioeconomic status were not assessed. Yet, these factors might change how participation in a Yoga-based group intervention is experienced and hence, these should be systematically assessed in future studies.

Moreover, generalisations of the described findings to other settings and patients cannot be made. The setting of YoGI poses an important factor as the ward itself provides a safe space and most participants knew each other beforehand. Hence, different experiences might arise if YoGI would be offered in, for example, an outpatient setting. Additionally, patients with severe positive symptoms of psychosis were excluded from participation (any item from the P-scale of the PANSS rated equal to six or higher). Thus, preventing any generalisations of the reported experiences to those experiencing severe psychotic symptoms or not receiving treatment in an in-patient setting. An area for improvement poses the delivery of YoGI as the psychologists who instructed the intervention did not complete a certified Yoga teacher training yet. However, the YoGI protocol was developed in collaboration with a team of psychologists and trained Yoga teachers who guided psychologists in instructing YoGI until they resumed instruction of the intervention. These limitations can, however, be seen alongside several strengths. The semi-structured interview guide was pilot tested during a period of five interviews; hence questions were optimised regarding understandability and appropriateness. In the data collection and analysis process, data saturation has likely been achieved after conducting 25 interviews (53). During data analysis, two researchers independently analysed the data to prevent the impact of subjective bias and strengthen the reliability of data coding and interpretation.

The present study is the first to offer in-depth insights into the experience of patients with SSD practising Yoga in a German hospital setting. The detailed feedback interviewees provided on sessions allowed continuous adaptation and refinement of the intervention that provides a first basis for developing a YoGI manual in the future. Furthermore, given participants' overall positive experience of the intervention, a randomised controlled trial is planned to systematically investigate the size and longevity of YoGI's various effects.

CONCLUSION

The present study is the first to describe in-depth experiences of patients with SSD who participated in YoGI in a German university hospital setting. The qualitative approach allowed participants to report their experiences in detail, thereby exploring underlying mechanisms of YoGI as well as its benefits and limitations in the treatment of SSD. Based on the outcomes, one can conclude that YoGI qualifies as a feasible and promising complementary therapy for this patient group. However, physical limitations need to be taken into consideration, and individual adaptation should be encouraged to ensure inclusivity of the Yoga practise. In addition to the positive effect on the symptomatology of in-patients with SSD, YoGI increased many psychological resources such as confidence and mindfulness. Moreover, among a patient group that experiences high levels of stress and has social interactions and relationships possibly impeded by mistrust, Yoga seemed to have particularly positive effects: Most participants experienced a state of relaxation and interconnectedness while practising Yoga. To what extent the various effects of YoGI can be sustained and how participants might transfer the mindful approach to the Yoga practise to their lives off the mat should be examined in future research.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the ethics committee of the Charité Universitätsmedizin Berlin. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

TS designed and executed the study, conducted the data analyses, and wrote the paper. EH collaborated with the design and editing of the final manuscript. IH and NB collaborated with the design and execution of the study and editing of the manuscript. LF and GP assisted with the study design and edited the manuscript. FM assisted with conducting the data analyses. MZ assisted with the editing of the final manuscript. TT collaborated with editing the final manuscript. KB designed the study and edited the manuscript. All authors contributed to the article and approved the submitted version.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2021.715670/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

APPENDIX

TABLE A1 | Guideline for the semi-structured interview.

1. Could you describe what first comes to your mind when thinking of the Yoga-based group intervention?
2. Do you have any previous experience with Yoga, or does it remind you of other exercises?
3. How would you characterise the exercises?
4. What did you feel during the exercises?
5. How and what did you perceive during the exercises?
6. Did you notice any challenges or difficulties during the exercises? If so, which ones?
7. Which exercise did you dislike and why?
8. What did you manage well and what did you like?
9. Which exercise did you like best and why?
10. Did the exercise affect you anyhow? If so, how?
11. What can you take away for yourself from this exercise?
12. What did you miss? What could have been done better or differently?
13. What do you think of the room, structure and group size of the Yoga-based group intervention?
14. What did you perceive regarding your symptoms during and after the exercises? Time for remarks and comments

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Clubhouse Model of Psychiatric Rehabilitation in China to Promote Recovery of People With Schizophrenia: A Systematic Review and Meta-Analysis

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Background: Whether the clubhouse model of psychiatric rehabilitation is well-implemented in China and whether patients with schizophrenia successfully achieve symptom remission and functional recovery through engaging in the clubhouse remain unclear.

Methods: Seven electronic databases were searched for relevant articles from inception to April 21, 2021. Quality assessment, data synthesis, and subgroup analysis were performed on the included studies.

Results: Seven randomized controlled studies with 682 participants were included in the present meta-analysis. The clubhouse model of psychiatric rehabilitation has a significant effect on promoting the remission of psychiatric symptoms, especially negative symptoms. However, it does not show a definite effect on promoting recovery of positive symptoms. The clubhouse model of psychiatric rehabilitation has a significant effect on promoting social functioning recovery, reducing the family burden, improving the quality of life, and promoting the remission of depressive and anxiety symptoms of patients with schizophrenia in China.

Conclusions: Our findings suggest that the clubhouse model of psychiatric rehabilitation can promote the remission of symptoms and functional recovery of Chinese with schizophrenia. It may be suitable to address the urgent need for better mental health services in China.

Keywords: clubhouse, psychiatric rehabilitation, china, schizophrenia, meta-analysis

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INTRODUCTION

Although China has made substantial advancements in the treatment and management of mental disorders, these disorders still pose a heavy burden. An epidemiological survey estimated that about 173 million Chinese suffer from diagnosable mental disorders, of whom 158 million have never received any treatment (1). Furthermore, ∼16 million Chinese are affected by severe mental illness (SMI) (1). A recent study estimated that the lifetime prevalence of most mental disorders and schizophrenia in China was 1.3% (∼17 million Chinese citizens) and 0.6% (∼8 million Chinese citizens), respectively (2). Globally, the economic burden of schizophrenia was estimated to range from 0.02 to 1.65% of the gross domestic product (3). In high-income countries, SMI has already become the leading cause of disability. Other countries including China may experience a similar reality (4). Despite substantial advances in clinical treatment, patients with SMI continue to suffer poor social predicaments, including high rates of unemployment, stigma, and homelessness (5–7). These challenges highlight the necessity of delivering mental health service that addresses both social and clinical needs. A primary difficulty in developing mental health service has been that professionals and patients with SMI often disagree on treatment goals. Professionals often emphasize multiple medications to relieve symptoms of a biological disorder, whereas patients with SMI emphasize the need for supports to promote functional recovery and to reduce psychological distress. Similarly, professionals highly value symptom control as a primary goal, whereas patients with SMI prioritize having a satisfying and meaningful life (8). In part because of the difference, some patients with mental disorders avoid the mental health system. In response to patients' dissatisfaction with the traditional emphasis on symptom control and stability, mental health policy makers in some countries now advocate the concept of personal recovery (9).

Despite substantial advancements in pharmacological treatment of patients with SMI, medications alone are not sufficient to achieve a complete functional recovery and symptom remission (10). In the recent years, treatment of SMI has gradually shifted from stabilization and management of clinical symptoms to the more ambitious and much broader goal of achieving functional recovery. In this process, psychiatric rehabilitation (also known as psychosocial rehabilitation) has been accepted by the mental health field as one of the preferred methods for helping patients with mental disorders (11). Psychiatric rehabilitation aims to promote recovery and community integration and to improve the quality of life of patients with mental disorders using the development of skills and supports as its primary types of interventions. The term "psychiatric rehabilitation" reflects the focus of the mental health field on patients with psychiatric disabilities and their improved abilities within their specific preferred role in the "real" world (12, 13). Although psychosocial rehabilitation services focus on achieving personal recovery, they are still hard to access for patients with SMI in the developed countries such as America, let alone the developing countries including China. In America, <5% of patients with SMI can access high-quality psychiatric rehabilitation services (11). In China, 1.3% of patients with SMI can access psychiatric rehabilitation services (14). Several psychiatric rehabilitation models, such as the clubhouse model, workstation programs, farming programs, and family-based collaborative care model, have emerged in China (15). The clubhouse model of psychiatric rehabilitation has been in existence for over 70 years around the world and helps thousands of people with SMI (16). Clubhouses define their service users as members, rather than clients or patients, because all members actively engage in all aspects of the clubhouse compared with other passive service users. This means that clubhouse members are afforded self-determination. Clubhouses provide social events, work experiences, and housing to strengthen and increase the social networks of people with SMI. One of the outstanding characteristics of the clubhouse is that it creates an environment through peer support to promote a sense of community and belonging (17–19). The clubhouse model of psychiatric rehabilitation is a promising practice (19–21). In mainland China, the first accredited clubhouse, the Changsha Heart Wing Clubhouse, was founded in 2007. At present, six clubhouses are operating in mainland China (22). However, some concerns aroused during the glocalization of clubhouse models, including whether and how it is affected by different societal contexts. Some studies indicated that the clubhouse, to some extent, modifies or translates the model to fit its national and local context (23, 24). China is characterized by Confucian social ethics, which means that Chinese rely more on the family and organized civil society. The family is regarded as the main caregivers for people with mental disorders. Moreover, significant differences exist in the welfare system, politics, economy, and culture between China and other countries. Whether the clubhouse model of psychiatric rehabilitation is well-implemented in China and whether patients with schizophrenia successfully achieve symptom remission and functional recovery through engaging in the clubhouse remain unclear. To address these concerns, we conducted the present systematic review and meta-analysis.

METHODS

A systematic review and meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (25). The review protocol was registered at PROSPERO as CRD 42021251534.

Search Strategy

Two authors (YD and HY) independently identified relevant articles published in Scopus, Embase, PubMed, Web of Science, China National Knowledge Infrastructure, WANFANG DATA, and VIP Database for Chinese Technical Periodicals from inception to April 21, 2021. We applied the following terms in retrieving the PubMed database: (China OR Chinese) AND (psychiatric rehabilitation OR psychosocial rehabilitation OR clubhouse OR clubhouse model). Some modifications were made as required for retrieving other databases. In addition, the reference lists of the included articles were hand-searched to find additional relevant articles.

Study Selection Criteria

Longitudinal, controlled studies that aimed to determine whether the clubhouse model of psychiatric rehabilitation in China can promote recovery of people with schizophrenia were included in the review. In order to ensure the credibility of the conclusions, we only included studies which reported that the clubhouses had been accredited by Clubhouse International and/or reported following the International Clubhouse Standards at the time of the study. Individual and cluster randomized controlled trials were included in the meta-analysis. Longitudinal, case-controlled studies were included in the qualitative synthesis. Self-controlled case series studies and conference abstracts were excluded.

Data Extraction and Quality Assessment

Two authors (YD and HY) independently extracted the following data from the included articles: the name of the first author; publication dates of the included articles; the cities or regions; the name of the clubhouse; the type of study design; participants; the guideline used in diagnosis; the interventions of the experimental and control groups; the time of intervention; dropout data; the sample sizes of the experimental and control groups; the sex ratio, illness duration, educational level, and marital status of the experimental and control groups; the scales used for assessment; the post-treatment mean score and standard deviation of the experimental and control groups; employment data; and relapse data.

The Cochrane Collaboration risk of bias tool was applied to assess the quality of studies included in the meta-analysis. A rating of low, high, or unclear risk of bias was given for the following domains: sequence generation, allocation concealment, masking of assessors, selective outcome reporting, incomplete data, and other sources of bias. Blinding of participants and workers delivering the intervention was not possible to implement due to the nature of the interventions. Therefore, this criterion was excluded in the quality assessment. The Mixed Methods Appraisal Tool was applied to assess the risk of bias of all non-randomized controlled studies (26, 27).

In data extraction and quality assessment, a third team member (WG) performed the verification. All discrepancies were discussed and resolved by the three authors.

Data Analysis

Data analyses were performed using RevMan 5.4 software. For continuous variables, the standardized mean difference (SMD) with 95% confidence interval (CI) was calculated using a random effect model in order to pool outcomes of different scales. SMD is a summary statistic that represents the size of the intervention effect in a study relative to the variability (clubhouse model of psychiatric rehabilitation) observed in that study. The following cutoffs were used to guide the interpretation of the strength of effect: 0.2–0.5 represents a "small" effect, 0.5–0.8 represents a "medium" effect, and more than 0.8 represents a "large" effect (28). For any scales in which a higher score means better outcome, the mean scores were inverted before calculating the SMD. For binary variables, the odds ratio and 95% CI were calculated using a random effect model. Chi-square statistic (significance level of $p < 0.05$) and I^2 (significance level of $I^2 > 50\%$) were applied to assess heterogeneity across studies. Subgroup analysis was performed according to participants, scales applied for assessment, and time points to explore the potential source of heterogeneity.

RESULTS

Literature Search

Our initial search identified 815 records in the seven electronic databases (88 records in Scopus, 192 records in Embase, 115 records in PubMed, 71 records in Web of Science, 139 records in China National Knowledge Infrastructure, 180 records in WANFANG DATA, and 30 records in VIP Database for Chinese Technical Periodicals). A total of 764 records were excluded after removing duplicates (283 articles) and screening titles and abstracts (481 articles). Accordingly, 51 potentially relevant articles were retrieved for detailed full-text evaluation. We excluded 37 records (participants in 2 records were not psychosis patients; 15 records were reviews or commentaries; 4 records were conference articles; 11 records did not report the treatment effect of the clubhouse model on psychiatric rehabilitation; 2 records were cross-sectional studies, 3 records were not controlled studies). Finally, 14 articles were included [7 non-randomized controlled trials (29–35) were included in the qualitative synthesis, and 7 randomized controlled trials (36–42) were included in the quantitative synthesis]. A PRISMA diagram of the article selection is shown in **Figure 1**.

Characteristics of Included Studies

Seven randomized controlled studies (36–42) were included in this meta-analysis. All included studies had a total of 682 participants (286 males and 396 females) with a median sample size of 90, ranging from 51 to 160. In four studies (38, 39, 41, 42), the participants were patients with first-episode schizophrenia. In three other studies (36, 37, 40), the participants were patients with schizophrenia and were not specific to first-episode schizophrenia. In the study of Xiang et al. (37), the participants were women with schizophrenia. Four studies (37–39, 41) applied the third version of the Chinese Classification of Mental Disorders (CCMD-3), 2 studies (40, 42) applied the 10th version of the International Statistical Classification of Diseases and Related Health Problems (ICD-10), and 1 study (36) applied the 4th version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) guidelines for diagnosis. In all seven included studies, the participants were in a stable state with a low-dose medication treatment. In five studies (37–39, 41, 42), the clubhouse model of psychiatric rehabilitation plus general psychiatric rehabilitation was applied in the experimental group, while only general psychiatric rehabilitation was applied in the control group. In one study (40), the clubhouse model of psychiatric rehabilitation was applied in the experimental group, and psychiatric rehabilitation was not applied in the control group. In another study (36), the clubhouse model of psychiatric rehabilitation was applied in the experimental group, while general psychiatric rehabilitation was applied in the control group. The interventions in general psychiatric rehabilitation included holding lectures about keeping healthy and medication use management and giving advices about diet and excise. The time of intervention was 18 months in 1 study (37), 12 months in 2 studies (41, 42), 6 months in 3 studies (36, 38, 39), and 3 months in 1 study (40). Four

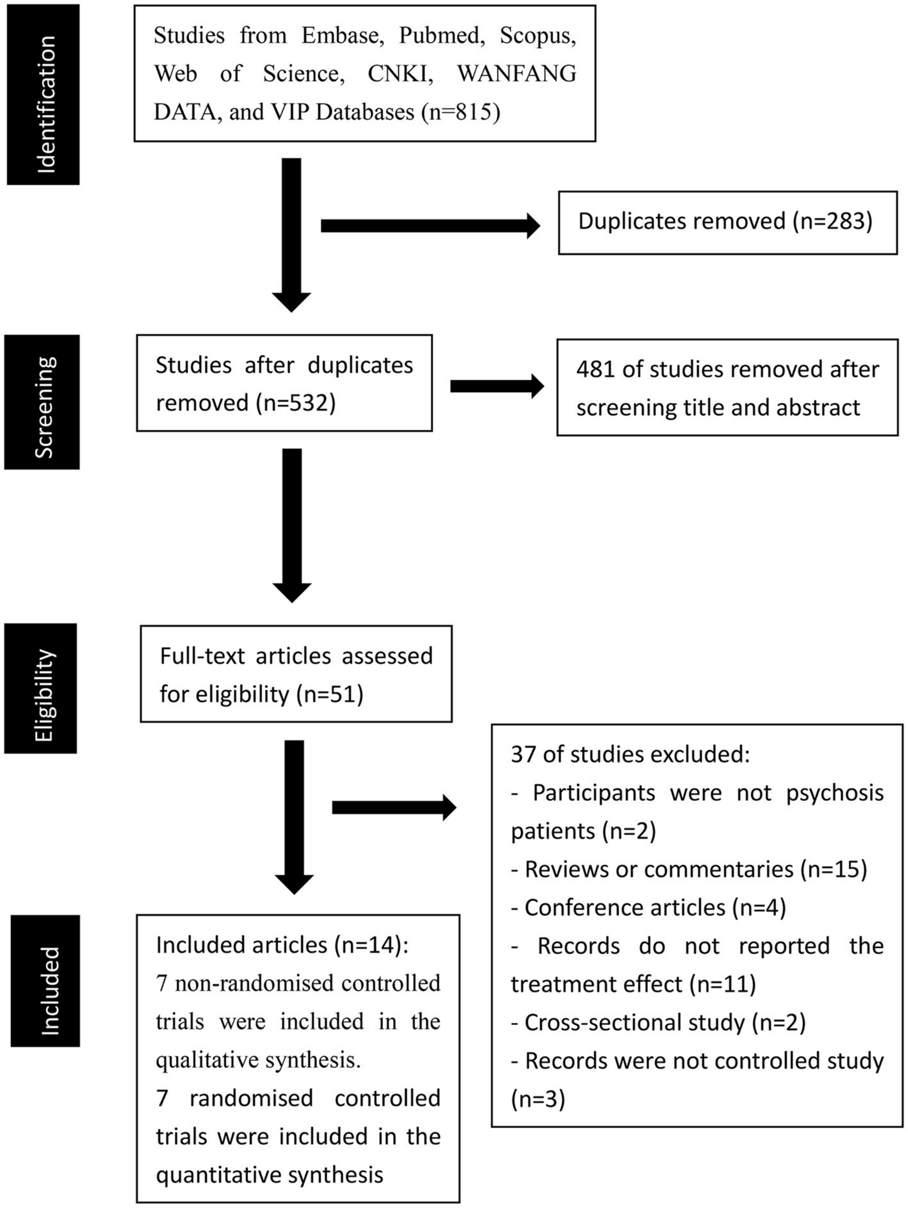


FIGURE 1 | PRISMA diagram of the article selection.

studies measured the outcomes at different time points (37–39, 41). Five studies reported the dropout data (36–38, 40, 42). Positive and Negative Syndrome Scale (PANSS) and Brief Psychiatric Rating Scale were applied to assess the severity of psychiatric symptoms. The Activity of Daily Living Scale, Personal and Social Performance Scale, and Social Disability Screening Schedule were applied to assess social functioning. The Family Burden Scale (FBS) was applied to assess family burden. The Schizophrenia Quality of Life Scale and life satisfaction index (LSI) were applied to assess the quality of life. The Self-Rating Depression Scale and Hamilton Depression Scale were applied to assess depressive symptoms. The Self-Rating Anxiety Scale and Hamilton Anxiety Scale were applied to assess anxiety symptoms. Only one study (36) reported employment and relapse data. The characteristics of the seven included articles are summarized in **Table 1**.

The results of quality assessment are shown in **Supplementary Figure 1**. Overall, the included studies had low to moderate risk of bias. No studies adequately described the allocation concealment. Only one study (42) clearly described the blinding of outcomes assessment.

TABLE 1 | Characteristics of the included randomized controlled studies.

References	City	Participants	Diagnosis	Intervention	The time of intervention	Experimental group: sample size and demographic characteristic	Control group: sample size and demographic characteristic	Dropout data
Xiang et al., (37)	Wuhan	Women with schizophrenia	CCMD-3	Experimental group: A+B Control group: B	18 months	45 (Man: 0; Age: 36.31 ± 4.79 (y); Marital status: Single 30, Married 15; Educational level: Primary and Secondary 10, Tertiary 35)	45 (Man: 0; Age: 37.42 ± 5.33 (y); Marital status: Single 27, Married 18; Educational level: Primary and Secondary 8, Tertiary 37)	clubhouse 0; control 0
Shen et al. (41)	Shenzhen	Patients with first-episode schizophrenia	CCMD-3	Experimental group: A+B Control group: B	12 months	81 [Man:38; Age: 45.26 ± 8.41 (y)]	30 [Man:13; Age: 45.18 ± 8.61 (y)]	NA
Liu et al. (39)	Wuhan	Patients with first-episode schizophrenia	CCMD-3	Experimental group: A+B Control group: B	6 months	58 [Man: 25; Age 37.34 ± 4.12 (y); Educational level: Primary 8, Secondary 38, Tertiary 12]	40 [Man: 17; Age 38.72 ± 4.62 (y); Educational level: Primary 6, Secondary 26, Tertiary 8]	NA
Liu et al. (38)	Guangzhou	Patients with first-episode schizophrenia	CCMD-3	Experimental group: A+B Control group: B	6 months	45 [Man: 20; Age: 40.50 ± 2.30 (y)]	45 [Man: 18; Age 38.70 ± 3.90 (y)]	clubhouse 0; control 0
Huang et al. (2)	Chongqin	Patients with first-episode schizophrenia	ICD-10	Experimental group: A+B Control group: B	12 months	80 [Man: 42; Age: 40.82 ± 8.96 (y); illness duration:1.37 ± 0.28 (y); Educational level: Primary 0, Secondary 55, Tertiary 25]	80 [Man: 41; Age: 40.17 ± 8.05 (y); illness duration: 1.19 ± 0.22 (y); Educational level: Primary 0, Secondary 56, Tertiary 24]	clubhouse 0; control 0
Chen et al., (36)	Chengdu	Patients with schizophrenia	DSM-IV	Experimental group: A Control group: B	6 months	28 [Man: 20; Age 38.96 ± 10.23 (y); Illness duration: 16.97 ± 8.83 (y); Educational level: Primary 2, Secondary 22, Tertiary 4; Marital status: Single 12, Married 5, Separated 11]	23 [Man: 14; Age: 39.13 ± 11.57 (y); Illness duration: 17.30 ± 10.19 (y); Educational level: Primary 1, Secondary 17, Tertiary 5; Marital status: Single 10, Married 6, Separated 7[	clubhouse 0; control 5
Yang et al. (40)	Chongqin	Patients with schizophrenia	ICD-10	Experimental group: A Control group: None	3 months	41 [Man: 18; Age:43 ±10 (y); Illness duration: 7–30 (y); Educational level: Primary 4, Secondary 28, Tertiary 9]	41 [Man: 20; Age: 44 ± 10 (y); Illness duration 8–27 (y); Educational level: Primary 5, Secondary 31, Tertiary 5]	clubhouse 2; control 2

CCMD-3, the third version of Chinese Classification of Mental Disorders; ICD-10, the 10th version of the International Statistical Classification of Diseases and Related Health Problems; DSM-IV, the 4th version of the Diagnostic and Statistical Manual of Mental Disorders; A, clubhouse model of psychiatric rehabilitation; B, general psychiatric rehabilitation; NA, not available.

The characteristics and quality assessment of the non-randomized controlled trials are summarized in **Supplementary Tables 1**, **2**, respectively.

Meta-Analytical Results

Psychiatric Symptoms

The clubhouse model of psychiatric rehabilitation had a significant effect on promoting the remission of psychiatric symptoms (SMD = −1.48, $p < 0.001$, 95% CI = −1.96 to −1.01, $I^2 = 86\%$, k = 7, $n = 682$, **Figure 2**) (36–42). The pooled SMD indicated that the clubhouse model of psychiatric rehabilitation had a strong effect on promoting the remission of psychiatric symptoms when the outcomes measured with PANSS were pooled (SMD = −1.38, $p < 0.001$, 95% CI = −1.89 to −0.87, $I^2 = 86\%$, k = 6, $n = 571$, **Supplementary Figure 2**) (36–40, 42). The clubhouse model of psychiatric rehabilitation had a strong effect on promoting the remission of psychiatric symptoms of patients with first-episode schizophrenia (SMD = −1.49, $p < 0.001$, 95% CI = −2.25 to −0.72, $I^2 = 91\%$, k = 4, $n = 399$, **Supplementary Figure 3**) (36, 38, 39, 42). We also pooled the outcomes measured at different time points. The clubhouse model of psychiatric rehabilitation had a medium effect on promoting the remission of psychiatric symptoms when it was performed for 3 months

($SMD = -0.67$, $p < 0.001$, 95% CI = -0.94 to -0.41, $I^2 = 33\%$, k = 4, $n = 381$, **Supplementary Figure 4**) (38–41). The clubhouse model of psychiatric rehabilitation had a strong effect on promoting the remission of psychiatric symptoms when it was performed for 6 months ($SMD = -1.18$, $p < 0.001$, 95% CI = -1.42 to -0.94, $I^2 = 1\%$, k = 4, $n = 350$, **Supplementary Figure 4**) (36, 38, 39, 41) and 12 months ($SMD = -1.71$, $p = 0.01$, 95% CI = -3.02 to -0.40, $I^2 = 96\%$, k = 3, $n = 361$, **Supplementary Figure 4**) (37, 41, 42).

The clubhouse model of psychiatric rehabilitation had a strong effect on promoting recovery of negative symptoms ($SMD = -1.68$, $p = 0.007$, 95% CI = -2.90 to -0.46, $I^2 = 94\%$, k = 3, $n = 293$, **Figure 2**) (36, 40, 42). However, it did not show a definite effect on promoting recovery of positive symptoms ($SMD = -1.50$, $p = 0.06$, 95% CI = -3.07 to 0.08, $I^2 = 97\%$, k = 3, $n = 293$, **Figure 2**) (36, 40, 42).

Social Functioning

The clubhouse model of psychiatric rehabilitation had a strong effect on promoting social functioning recovery ($SMD = -2.02$, $p < 0.001$, 95% CI = -3.00 to -1.03, $I^2 = 94\%$, k = 5, $n = 432$, **Figure 3**) (36, 38–41). In addition, it had a strong effect on promoting social functioning recovery in patients with first-episode schizophrenia ($SMD = -1.73$, $p = 0.001$, 95% CI = -2.75 to -0.71, $I^2 = 93\%$, k = 3, $n = 299$, **Supplementary Figure 5**) (38, 39, 41). We pooled the outcomes measured at different time points. The clubhouse model of psychiatric rehabilitation had a strong effect on promoting social functioning recovery when it was performed for 3 months ($SMD = -1.48$, $p = 0.009$, 95% CI = -2.59 to -0.37, $I^2 = 95\%$, k = 4, $n = 381$, **Supplementary Figure 6**) (38–41) and 6 months ($SMD = -1.36$, $p < 0.001$, 95% CI = -1.80 to -0.92, $I^2 = 69\%$, k = 4, $n = 350$, **Supplementary Figure 6**) (36, 38, 39, 41). One study reported the promotion of social functioning recovery when this intervention was performed for 12 months ($SMD = -2.89$, $p < 0.001$, 95% CI = -3.46 to -2.32, $n = 111$, **Supplementary Figure 6**) (41).

Family Burden

Family burden was assessed using the FBS. The clubhouse model of psychiatric rehabilitation had a strong effect on reducing the family burden ($SMD = -1.17$, $p < 0.001$, 95% CI = -1.43 to -0.92, $I^2 = 0\%$, k = 3, $n = 278$, **Figure 3**) (37–39). In addition, it had a strong effect on reducing the family burden of patients with first-episode schizophrenia ($SMD = -1.13$, $p < 0.001$, 95% CI = -1.44 to -0.82, $I^2 = 0\%$, k = 2, $n = 188$, **Supplementary Figure 7**) (38, 39). The clubhouse model of psychiatric rehabilitation had a medium effect on reducing the family burden when it was performed for 3 months ($SMD = -0.77$, $p \leq 0.001$, 95% CI = -1.07 to -0.47, $I^2 = 0\%$, k = 2, $n = 188$, **Supplementary Figure 8**) (38, 39) and a strong effect when it was performed for 6 months ($SMD = -1.13$, $p < 0.001$, 95% CI = -1.44 to -0.82, $I^2 = 0\%$, k = 2, $n = 188$, **Supplementary Figure 8**) (38, 39). One study reported the reduction of family burden when this intervention was performed for 12 months ($SMD = -0.85$, $p < 0.001$, 95% CI = -1.29 to -0.42, $n = 90$, **Supplementary Figure 8**) (37). Another study reported the reduction of family burden when this intervention was performed for 18 months ($SMD = -1.26$, $p < 0.001$, 95% CI = -1.71 to -0.81, $n = 90$, **Supplementary Figure 8**) (37).

Quality of Life

The clubhouse model of psychiatric rehabilitation had a strong effect on improving the quality of life of patients with schizophrenia ($SMD = -0.91$, $p = 0.01$, 95% CI = -1.64 to -0.19, $I^2 = 85\%$, k = 3, $n = 239$, **Figure 3**) (36, 38, 39). Two studies (38, 39) measured the treatment effect on improving the quality of life of patients with first-episode schizophrenia using LSI scales. The clubhouse model of psychiatric rehabilitation had a strong effect on improving the quality of life of patients with first-episode schizophrenia ($SMD = -1.26$, $p < 0.001$, 95% CI = -1.74 to -0.79, $I^2 = 55.0\%$, k = 2, $n = 188$, **Supplementary Figure 9**) (38, 39). The clubhouse model of psychiatric rehabilitation had a strong effect on improving the quality of life of patients with schizophrenia when it was performed for 3 months ($SMD = -1.01$, $p \leq 0.001$, 95% CI = -1.31 to -0.70, $I^2 = 0.0\%$, k = 2, $n = 188$, **Supplementary Figure 10**) (38, 39) and 6 months ($SMD = -0.91$, $p = 0.01$, 95% CI = -1.64 to -0.19, $I^2 = 85\%$, k = 3, $n = 239$, **Supplementary Figure 10**) (36, 38, 39).

Depressive and Anxiety Symptoms

The clubhouse model of psychiatric rehabilitation had a strong effect on promoting the remission of depressive ($SMD = -2.33$, $p \leq 0.001$, 95% CI = -2.71 to -1.96, $I^2 = 0\%$, k = 2, $n = 201$, **Figure 3**) (37, 41) and anxiety symptoms ($SMD = -2.03$, $p \leq 0.001$, 95% CI = -2.92 to -1.14, $I^2 = 84\%$, k = 2, $n = 201$, **Figure 3**) (37, 41) of patients with schizophrenia.

Employment and Relapse

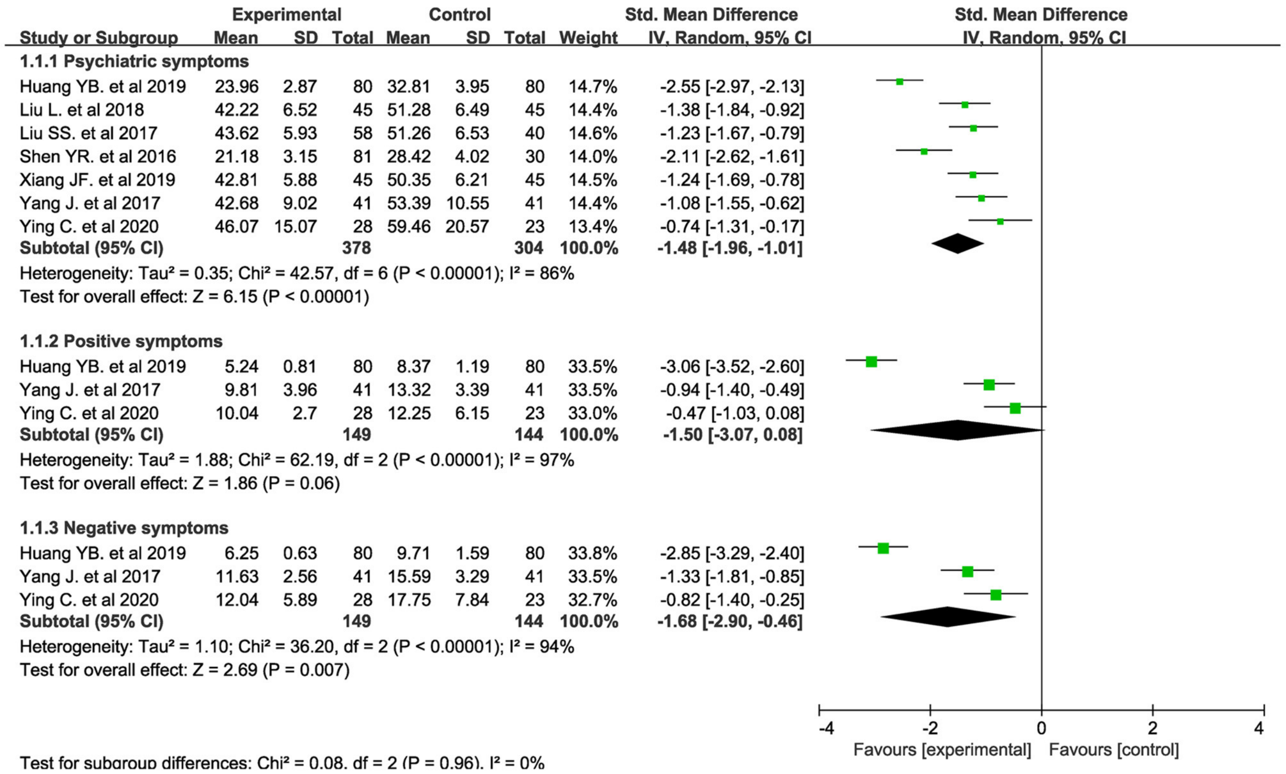
Only one randomized controlled study (36) reported the employment and relapse data. Seven participants had a transitional employment in the intervention group (7/28), and one participant had a transitional employment in the control group (1/23). Three participants were re-hospitalized in the intervention group (3/28), and seven participants were re-hospitalized in the control group (7/23).

Publication Bias

The funnel plots of psychiatric symptoms and social functioning are exhibited in **Supplementary Figures 11**, **12**, respectively. No obvious publication bias was detected. Due to the limited data, the funnel plots of other domains were not exhibited.

Non-randomized Controlled Trials

Four longitudinal, case-controlled studies (29, 32, 34, 35) reported the treatment effectiveness of the clubhouse model of psychiatric rehabilitation on psychiatric symptoms. Two studies (29, 35) reported that engaging in the clubhouse could promote the remission of psychiatric symptoms. Two other studies (32, 34) did not reach the same conclusion. Two studies (29, 32) reported that the clubhouse model of psychiatric rehabilitation resulted in more effective recovery of negative symptoms than



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.1.1 Psychiatric symptoms								
Huang YB. et al 2019	23.96	2.87	80	32.81	3.95	80	14.7%	-2.55 [-2.97, -2.13]
Liu L. et al 2018	42.22	6.52	45	51.28	6.49	45	14.4%	-1.38 [-1.84, -0.92]
Liu SS. et al 2017	43.62	5.93	58	51.26	6.53	40	14.6%	-1.23 [-1.67, -0.79]
Shen YR. et al 2016	21.18	3.15	81	28.42	4.02	30	14.0%	-2.11 [-2.62, -1.61]
Xiang JF. et al 2019	42.81	5.88	45	50.35	6.21	45	14.5%	-1.24 [-1.69, -0.78]
Yang J. et al 2017	42.68	9.02	41	53.39	10.55	41	14.4%	-1.08 [-1.55, -0.62]
Ying C. et al 2020	46.07	15.07	28	59.46	20.57	23	13.4%	-0.74 [-1.31, -0.17]
Subtotal (95% CI)			**378**			**304**	**100.0%**	**-1.48 [-1.96, -1.01]**
Heterogeneity: Tau² = 0.35; Chi² = 42.57, df = 6 (P < 0.00001); I² = 86%								
Test for overall effect: Z = 6.15 (P < 0.00001)								
1.1.2 Positive symptoms								
Huang YB. et al 2019	5.24	0.81	80	8.37	1.19	80	33.5%	-3.06 [-3.52, -2.60]
Yang J. et al 2017	9.81	3.96	41	13.32	3.39	41	33.5%	-0.94 [-1.40, -0.49]
Ying C. et al 2020	10.04	2.7	28	12.25	6.15	23	33.0%	-0.47 [-1.03, 0.08]
Subtotal (95% CI)			**149**			**144**	**100.0%**	**-1.50 [-3.07, 0.08]**
Heterogeneity: Tau² = 1.88; Chi² = 62.19, df = 2 (P < 0.00001); I² = 97%								
Test for overall effect: Z = 1.86 (P = 0.06)								
1.1.3 Negative symptoms								
Huang YB. et al 2019	6.25	0.63	80	9.71	1.59	80	33.8%	-2.85 [-3.29, -2.40]
Yang J. et al 2017	11.63	2.56	41	15.59	3.29	41	33.5%	-1.33 [-1.81, -0.85]
Ying C. et al 2020	12.04	5.89	28	17.75	7.84	23	32.7%	-0.82 [-1.40, -0.25]
Subtotal (95% CI)			**149**			**144**	**100.0%**	**-1.68 [-2.90, -0.46]**
Heterogeneity: Tau² = 1.10; Chi² = 36.20, df = 2 (P < 0.00001); I² = 94%								
Test for overall effect: Z = 2.69 (P = 0.007)								

Test for subgroup differences: Chi² = 0.08, df = 2 (P = 0.96), I² = 0%

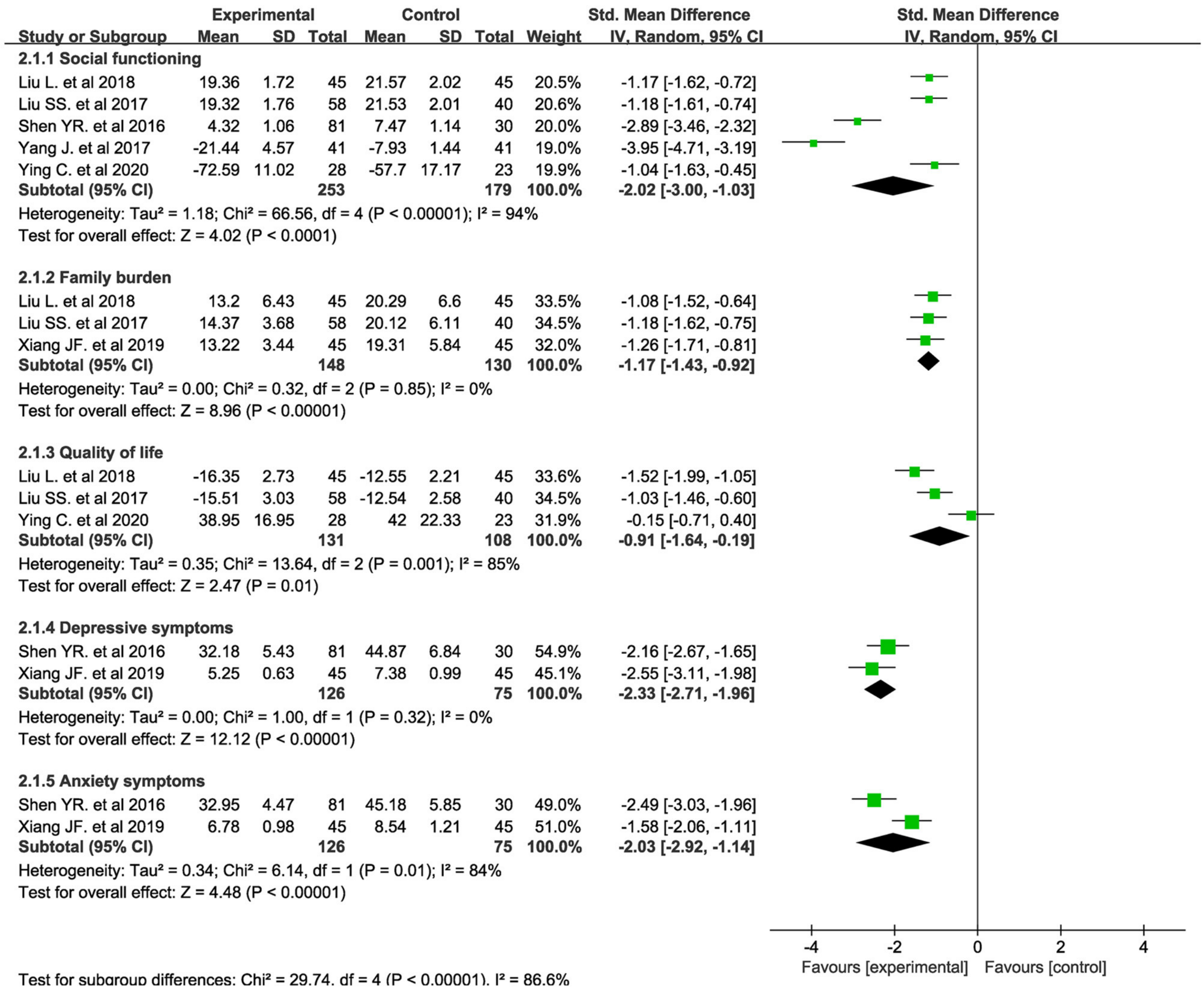
FIGURE 2 | Forest plot about the treatment effectiveness of the clubhouse model of psychiatric rehabilitation on psychiatric symptoms, negative symptoms, and positive symptoms.

medication treatment alone. One study (35) reported that the clubhouse model of psychiatric rehabilitation resulted in more effective recovery of positive and negative symptoms than medication treatment alone. Three studies (30–32) found that the clubhouse model of psychiatric rehabilitation could promote recovery in functioning of patients with schizophrenia. Four studies (30, 31, 33, 34) demonstrated significant improvements in the quality of life of participants. One study (32) found that family burden was significantly reduced after the intervention. The clubhouse model of psychiatric rehabilitation had a significant treatment effect on depression symptoms of patients with schizophrenia (29). Two studies (29, 30) reported that the clubhouse model of psychiatric rehabilitation could improve the self-esteem of participants.

DISCUSSION

To the best of our knowledge, the present article is the first meta-analysis about the treatment effect of the clubhouse model of psychiatric rehabilitation on Chinese with schizophrenia. Seven randomized controlled studies with 682 participants (286 males and 396 females) were included in the present meta-analysis. According to the pooled data, the clubhouse model of psychiatric rehabilitation had a significant effect on promoting the remission of psychiatric symptoms, social functioning recovery, reducing the family burden, improving the quality of life, and promoting the remission of depressive and anxiety symptoms. Although data about employment and relapse were limited, the clubhouse model of psychiatric rehabilitation showed a positive effect on these variables.

According to the pooled SMD, the clubhouse model of psychiatric rehabilitation has a strong effect on promoting the remission of psychiatric symptoms. This finding is consistent with the results of some quasi-experimental studies (29, 35). However, some quasi-experimental studies found that the clubhouse model of psychiatric rehabilitation did not have a significant effect on promoting the remission of psychiatric symptoms (32, 34). According to the pooled SMD, engaging in the clubhouse did not have a significant effect on promoting the remission of positive symptoms, but it had a significant effect on promoting the remission of negative symptoms. Two quasi-experimental studies (29, 32) found that engaging in the clubhouse could improve the remission of negative symptoms than positive symptoms. A previous meta-analysis about social skills training for patients with schizophrenia obtained similar results: social skills training had moderate mean effect sizes for negative symptoms and small mean effect sizes for other symptoms (43). The following reasons may explain no benefit to positive symptoms by engaging in the clubhouse: (1) Participants were in a stable stage (they had low positive symptom scores) and underwent medicine treatment while engaging in the clubhouse.



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
2.1.1 Social functioning								
Liu L. et al 2018	19.36	1.72	45	21.57	2.02	45	20.5%	-1.17 [-1.62, -0.72]
Liu SS. et al 2017	19.32	1.76	58	21.53	2.01	40	20.6%	-1.18 [-1.61, -0.74]
Shen YR. et al 2016	4.32	1.06	81	7.47	1.14	30	20.0%	-2.89 [-3.46, -2.32]
Yang J. et al 2017	-21.44	4.57	41	-7.93	1.44	41	19.0%	-3.95 [-4.71, -3.19]
Ying C. et al 2020	-72.59	11.02	28	-57.7	17.17	23	19.9%	-1.04 [-1.63, -0.45]
Subtotal (95% CI)			**253**			**179**	**100.0%**	**-2.02 [-3.00, -1.03]**
Heterogeneity: Tau² = 1.18; Chi² = 66.56, df = 4 (P < 0.00001); I² = 94%								
Test for overall effect: Z = 4.02 (P < 0.0001)								
2.1.2 Family burden								
Liu L. et al 2018	13.2	6.43	45	20.29	6.6	45	33.5%	-1.08 [-1.52, -0.64]
Liu SS. et al 2017	14.37	3.68	58	20.12	6.11	40	34.5%	-1.18 [-1.62, -0.75]
Xiang JF. et al 2019	13.22	3.44	45	19.31	5.84	45	32.0%	-1.26 [-1.71, -0.81]
Subtotal (95% CI)			**148**			**130**	**100.0%**	**-1.17 [-1.43, -0.92]**
Heterogeneity: Tau² = 0.00; Chi² = 0.32, df = 2 (P = 0.85); I² = 0%								
Test for overall effect: Z = 8.96 (P < 0.00001)								
2.1.3 Quality of life								
Liu L. et al 2018	-16.35	2.73	45	-12.55	2.21	45	33.6%	-1.52 [-1.99, -1.05]
Liu SS. et al 2017	-15.51	3.03	58	-12.54	2.58	40	34.5%	-1.03 [-1.46, -0.60]
Ying C. et al 2020	38.95	16.95	28	42	22.33	23	31.9%	-0.15 [-0.71, 0.40]
Subtotal (95% CI)			**131**			**108**	**100.0%**	**-0.91 [-1.64, -0.19]**
Heterogeneity: Tau² = 0.35; Chi² = 13.64, df = 2 (P = 0.001); I² = 85%								
Test for overall effect: Z = 2.47 (P = 0.01)								
2.1.4 Depressive symptoms								
Shen YR. et al 2016	32.18	5.43	81	44.87	6.84	30	54.9%	-2.16 [-2.67, -1.65]
Xiang JF. et al 2019	5.25	0.63	45	7.38	0.99	45	45.1%	-2.55 [-3.11, -1.98]
Subtotal (95% CI)			**126**			**75**	**100.0%**	**-2.33 [-2.71, -1.96]**
Heterogeneity: Tau² = 0.00; Chi² = 1.00, df = 1 (P = 0.32); I² = 0%								
Test for overall effect: Z = 12.12 (P < 0.00001)								
2.1.5 Anxiety symptoms								
Shen YR. et al 2016	32.95	4.47	81	45.18	5.85	30	49.0%	-2.49 [-3.03, -1.96]
Xiang JF. et al 2019	6.78	0.98	45	8.54	1.21	45	51.0%	-1.58 [-2.06, -1.11]
Subtotal (95% CI)			**126**			**75**	**100.0%**	**-2.03 [-2.92, -1.14]**
Heterogeneity: Tau² = 0.34; Chi² = 6.14, df = 1 (P = 0.01); I² = 84%								
Test for overall effect: Z = 4.48 (P < 0.00001)								

Test for subgroup differences: Chi² = 29.74, df = 4 (P < 0.00001), I² = 86.6%

FIGURE 3 | Forest plot about the treatment effectiveness of the clubhouse model of psychiatric rehabilitation on social functioning, family burden, quality of life, and depressive and anxiety symptoms.

(2) Limited studies and participants were included, and there was high heterogeneity across studies. Given that medication has a more effective effect in controlling positive symptoms than negative symptoms, the participants all have higher scores in negative symptoms than positive symptoms at baseline, indicating that the participants had few positive symptoms to be improved. Thus, more randomized controlled studies including participants who have severe positive symptoms are warranted to ensure the effectiveness of the intervention in improving positive symptoms. There was substantial heterogeneity across studies, which may come from the different scales applied to assess psychiatric symptom severity, the participants, or the time of intervention. When we pooled the outcomes that were assessed with PANSS or came from participants with first-episode schizophrenia, the results did not change. But the heterogeneity across studies was still high. When synthesizing the outcomes assessed at 3, 6, and 12 months, we found that 12 months of intervention had a stronger effect on promoting the remission of psychiatric symptoms than 6 months of intervention, and 6 months of intervention had a stronger effect than 3 months of intervention. The heterogeneity was low in synthesizing the outcomes assessed at 3 and 6 months, but it was high in synthesizing the outcomes assessed at 12 months. These findings indicated that at least in the first year engaging in clubhouse, the longer time engaged might get a better outcome in promoting psychiatric symptoms remission.

The clubhouse model of psychiatric rehabilitation had a strong effect on promoting social functioning recovery. Some quasi-experimental studies conducted in China (30–32, 43) and other countries (20, 44) reported the same results. When synthesizing the outcomes assessed at 3 and 6 months, the results did not change. The clubhouse model of psychiatric rehabilitation also had a strong effect on promoting social functioning recovery of patients with first-episode schizophrenia. Clubhouses provide social events, work experiences, and housing to strengthen and increase the social networks of people with SMI. McKay et al. believed that clubhouses provide a useful vehicle for increasing social competence and social integration and promoting recovery (19).

The clubhouse model of psychiatric rehabilitation had a significant effect on reducing the family burden. A quasi-experimental study conducted in China reported the same results (32). We pooled the data of patients with first-episode schizophrenia, and the results did not change. We found that the effect size of reducing the family burden was medium and large when engaging in the clubhouse for 3 and 6 months, respectively. This finding indicated that engaging in the clubhouse for more than 6 months might be more possible to reduce the family burden. In 2013, the economic burden of mental disorders in China was estimated to be 1.1% of the gross domestic product (45). China is characterized by Confucian social ethics, which means that Chinese rely more on the family and organized civil society. The family is regarded as the main caregivers for people with mental disorders. According to our results, the clubhouse model of psychiatric rehabilitation shines some lights on reducing the family burden of patients with schizophrenia.

The clubhouse model of psychiatric rehabilitation had a significant effect on improving the quality of life of patients with schizophrenia. We synthesized the data of patients with first-episode schizophrenia, and the data assessed when patients engaged in the clubhouse for 3 or 6 months, the results did not change. Some quasi-experimental studies conducted in China (30, 31, 33, 34) and other countries (21, 44, 46) reported the same results. However, which factor is associated with the quality of life in schizophrenia remains unclear. Narvaez et al. found that the severity of depressive and negative symptoms and neuropsychological functioning were related to the quality of life of patients with schizophrenia (47). A meta-analysis found that except for negative symptoms, the severity of positive symptoms was related to the quality of life of patients with schizophrenia (48). Many sociodemographic and clinical variables such as gender, marital status, income, and type and amount of medication are also related to the quality of life of patients with schizophrenia (49). We speculate that clubhouse members attain higher quality of life by promoting the recovery of several domains such as negative symptom remission, social functioning recovery, reduction of family burden, remission of depressive and anxiety symptoms, and being employed.

The clubhouse model of psychiatric rehabilitation had a strong effect on promoting the remission of depressive and anxiety symptoms of patients with schizophrenia. However, the conclusion may not be reliable because of the limited number of studies included. A quasi-experimental study conducted in China found that clubhouse members did not achieve better recovery in depressive symptoms compared with non-members of the clubhouse (29). In the present meta-analysis, one randomized controlled study and one quasi-experimental study reported results about employment and relapse (29). The clubhouse model of psychiatric rehabilitation may contribute to increasing the employment rate and reducing the relapse rate. Two reviews concluded that a moderate level of evidence existed regarding the effectiveness of clubhouses in increasing the rate of employment and reducing the rate of relapse of members (19, 50).

In the present meta-analysis, we found that the clubhouse model of psychiatric rehabilitation could promote the remission of symptoms and functional recovery of patients with schizophrenia. A greater flexibility to interpret and reinterpret the clubhouse model is needed to replicate the meaningful clubhouse model in other cultures (23). Although clubhouses are supposed to follow the International Clubhouse Standards, they need to make adaptations according to national and local contexts (24). The clubhouse model of psychiatric rehabilitation may be suitable to address the urgent need for better mental health services in China. However, several concerns need to be addressed. In particular, the clubhouse model of psychiatric rehabilitation might only benefit patients with a stable condition and would have limited applicability (15). Because in China once people with mental disorders access a stable stage, most of them do not want to take part in unpaid psychiatric rehabilitation programs. Instead, they choose to earn money even through a menial job to support their families' finances (15). Moreover, some other concerns about the high cost of certification and training and the need for support from the local government and close multidisciplinary cooperation were raised. The successful and widespread application of the clubhouse model of psychiatric rehabilitation requires a comprehensive consideration of the culture, economy, and politics of China. Accessing support from the local government in politics and finance, addressing mental health workforce development and educational training issues, forming a close multidisciplinary teamwork, and adherence to the core principles and localization of the services are essential for the successful application of the clubhouse model of psychiatric rehabilitation.

LIMITATIONS

This study has some limitations. First, the pooled results should be interpreted with caution because all statistical tests (including I^2 applied in the present study) may have low statistical power due to the small number of included studies and the CIs of I^2 can be large (51). Second, the small number of studies included and the substantial heterogeneity across studies diminish the reliability of the results. Third, the SMD is a statistical index, which cannot represent the true level of recovery. Fourth, the effect of the clubhouse model of psychiatric rehabilitation on some domains of personal recovery such as self-esteem and personal meaning remains unclear because only two quasi-experimental studies reported that the clubhouse model of psychiatric rehabilitation could improve the self-esteem of participants as we mentioned above and none of the included studies reported the effect of the clubhouse model of psychiatric rehabilitation on personal meaning. Fifth, as fidelity to clubhouse standards was not reported, fidelity of the studied clubhouses cannot be confirmed. More high-quality randomized controlled studies about the treatment effects of the clubhouse model of psychiatric rehabilitation are needed.

CONCLUSIONS

The clubhouse model of psychiatric rehabilitation has a significant effect on promoting the remission of psychiatric symptoms, social functioning recovery, reducing the family burden, improving the quality of life, and promoting the remission of depressive and anxiety symptoms of Chinese with schizophrenia. This model may be suitable to address the urgent need for better mental health services in China. Aside from following the International Clubhouse Standards, clubhouses need to make adaptations according to national and local contexts.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

HY designed the study and created the first draft of the manuscript. WG, YD, and HY conducted the literature search, study selection, quality assessment, and statistical analysis. WG and YD made improvements of the manuscript. All of the authors contributed to the final work.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2021.730552/full#supplementary-material

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Long-Term Effects of the Individual Placement and Support Intervention on Employment Status: 6-Year Follow-Up of a Randomized Controlled Trial

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People with mental illness often experience difficulties with reintegration into the workplace, although employment is known to assist these individuals in their recovery process. Traditional approaches of "first train, then place" have been recently replaced by supported employment (SE) methods that carry strategy of "first place, then train." Individual placement and support (IPS) is one of the best-studied methods of SE, which core principles are individualized assistance in rapid job search with consequent placement in a paid employment position. A considerable amount of high-quality evidence supported the superiority of IPS over conventional methods in providing improved employment rates, longer job tenure, as well as higher salaries in competitive job markets. Nonetheless, our knowledge about the IPS-mediated long-term effects is limited. This non-interventional follow-up study of a previously published randomized controlled trial (RCT) called ZhEPP aimed to understand the long-term impact of IPS after 6 years since the initial intervention. Participants from the ZhEPP trial, where 250 disability pensioners with mental illnesses were randomized into either IPS intervention group or treatment as usual group (TAU), were invited to face-to-face interviews, during which employment status, job tenure, workload, and salaries were assessed. One hundred and fourteen individuals agreed to participate in this follow-up study. Although during the first 2 years post-intervention, the IPS group had higher employment rates (40% (IPS) vs. 28% (TAU), $p < 0.05$ at 24 months), these differences disappeared by the time of follow-up assessments (72 months). The results indicated no substantial differences in primary outcome measures between IPS and TAU groups: employment rate (36 vs. 33%), workload (10.57 vs. 10.07 h per week), job tenure (29 vs. 28 months), and salary (20.21CHF vs. 25.02 CHF). These findings provide important insights regarding the long-term effects of IPS among individuals with mental health illnesses. Further research is required to advance the current knowledge about IPS intervention and its years-long impact.

Keywords: individual placement and support (IPS), supported employment (SE), vocational rehabilitation (VR), serious mental disease, social security disability insurance, job sustainability

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INTRODUCTION

Problems with mental health may cause an enormous burden to affected people, their beloved ones, and society in general. According to the Global Burden of Disease Study, 19% of all years lived with disability are caused by mental and addictive disorders affecting over 1 billion people worldwide as of 2016 (1). Mental illness can be disabling and diminish the ability to work in the competitive employment market. Poor health and diminished productivity due to mental problems amount to 3% of Swiss GDP and could lead to $6 trillion in annual loss globally (2, 3). Once work has been suspended, reintegration may be difficult and lead to long-term unemployment and chronic disability.

Nonetheless, the reintroduction of people with mental illness into the workforce holds medical, personal, and economic benefits both from an individual and societal perspectives (4–8). More recent evidence supports the assumption that employment benefits prevail for people with and without mental illness (8–11). Conversely, the negative effects of unemployment may be particularly profound for people with mental illness (12, 13).

Different approaches exist for the rehabilitation and reintegration of people with mental illness into the employment market. Following the pre-vocational rehabilitation (PVR) approach, the first step of reintegration involves training in protected work environments to instill habits that align with employer expectations and increase chances of successful integration into the competitive employment market (14). This stepwise approach is called "first train, then place" assuming that stabilization is a prerequisite to successful reintegration (15). However, high-level work overload as well as inability to integrate into the competitive job market limited the applicability of PVR, leading to stigmatization and social isolation of affected persons (16).

Following changes in the perception of people with mental illness and their ability to reintegrate, novel alternative rehabilitation approaches have begun to emerge, including the model of supported employment (SE). The latter aims to support affected individuals in seeking employment in the competitive market and receive coaching during their initial employment phase; thus, having a "first place, then train" approach (17). The superiority of the SE model over the PVR approach has been confirmed by a large number of studies (18, 19).

The individual placement and support (IPS) model represents the best described SE approach and has been developed based on empirical data, following defined principles and targets (18, 19). These include direct and rapid employment in the competitive market, under consideration of patient preferences, with unlimited duration of individual coaching in a non-institutional environment. Reintegration into the employment market and building a social network is the central aspect of patient management, integrating work and therapy, which is led by an interdisciplinary team (18, 19). A considerable amount of high-quality evidence from randomized controlled trials (RCT) supports the efficacy of this approach in providing improved employment, which has been validated in a number of countries and slowly becoming a standard of practice (18, 20–24). As such, aside from higher income and improved employment status, IPS was demonstrated to lead to enhanced job tenure, which is a key employment outcome for unemployed populations (18, 25–27).

Individuals who had undergone IPS show substantially high job tenure rates (i.e., the duration of the longest-held competitive employment job) ranging from as short as 7 weeks up to over 51 weeks in studies with a follow-up period of 12 to 24 months (27–36). This considerable variation in job tenure rates refers to distinct study populations and their specific characteristics (e.g., age, type of mental illness, level of education) (18, 37). The most frequently implemented strategies to address issues of job tenure among IPS service users include work-related skills training (e.g., social competencies, general skills) (28, 29). Nonetheless, cognitive training (e.g., cognitive remediation or errorless learning), psychological interventions, and supported education have also been described as potential tools of improvement (38–41). Moreover, support from peers, family members, or friends may enhance the effects of IPS on job tenure. In contrast, mobile apps to support task management, self-management programs, workplace accommodations, and working alliance between employee and employer can also be promising adjustments (42).

Nonetheless, the data on the long-term impact of IPS is still lacking. The latter is of particular concern, as one of the main challenges for work reintegration is the employment sustainability among people with mental disorder since it tends to be lower compared to individuals that were unemployed due to other reasons (43). Thus, there is a need to assess the durability of the positive effects of the intervention.

Another important aspect of IPS intervention is fidelity, which refers to the quality and success of the program implementation. Studies showed that higher IPS fidelity was associated with higher job tenures and increased employment rates (44, 45).

The return-to-work is hindered by important individual factors, such as somatic disorder, older age, higher levels of impairment, limited activity, increased work demands (46–48), as well as external barriers, such as stigmatization, unavailability of suitable jobs, lack of social support, and absence of financial incentives or subsidies for the promotion of integration (3, 48, 49). Poor information and knowledge about employment benefits and opportunities among healthcare providers and affected people can also contribute to the existing problem (3).

Switzerland provides people who are unfit to work due to injury or disease with a partial (25% of the total) or full (75% from the total) invalidity pension (IV, Invalidenversicherung), which is currently drawn by 4% of the total population. Nearly half of these pensions (49%) are provided to people with mental illness. Since 2012, incentives are offered to reintegrate IV beneficiaries into the employment market, following the PVR and IPS approach (50).

The present work is a follow-up study of the previous randomized controlled trial (RCT), which demonstrated higher efficacy of IPS compared to the standard approach during 46-months of the study period in achieving competitive employment acquisition among Swiss disability pensioners with mental illness (32 vs. 12%, $p < 0.0001$) (51). Thus, this study aimed to investigate the long-term effects of IPS intervention on job tenure and the factors influencing it by performing follow-up interviews of participants from the ZhEPP trial 6 years since the start of the original intervention.

METHODS

Study Design and Participants

This study is an observational follow-up of the previously published RCT (51). The Zurich Integration Pilot Project (ZhEPP, *German*: Zürcher Eingliederungs Pilot Projekt) was conducted between January 2011 and September 2014 in order to investigate the efficacy of the IPS approach in reintegrating pensioners with mental illness into the competitive employment market (52). The ZhEPP was a collaboration between the Psychiatric University Hospital of Zürich (PUK, Psychiatrische Universitätsklinik) and the IV authority in Zürich. It was carried out at the PUK among 250 newly assigned IV beneficiaries who were disability pensioners with mental health problems. Individuals of working age, who had been IV beneficiaries for a maximum of 1 year due to a mental illness, and wished to return to regular employment, were included. Those with intellectual disabilities and organic mental disorders were excluded. The enrolled participants were randomized to either IPS (intervention group) or treatment as usual (TAU or control) group. Upon allocation, participants were interviewed every 6 months over the course of 2 years, with a total of five interviews regarding their employment status and additional job-related parameters. Each interview involved face-to-face conversations conducted by the research team and took half a day for each participant. Further details can be found in the published study protocol (52).

Our follow-up was conducted from November 2017 to February 2018 and did not involve any further interventions except for single timepoint interviews aiming to assess the long-term impact of IPS. Two psychologists of our research team carried out face-to-face interviews, identical to the ones from the original RCT. Only a single interview was conducted per participant during the follow-up period.

Procedures

Intervention and Control Group (Original ZhEPP-RCT)

During the preceding RCT, participants in the intervention group received free job coaching from one of the four psychologists of the research team (51). Job coaches followed the IPS principles and were requested to support patients during their job search and employment following patient preferences, emphasizing patient independence. They also provided assistance and support during the application process, during actual employment, as well as when a participant lost the job. Participants from the TAU group were free to choose other vocational services aimed to improve employment status; however, they were not supported by a job coach during the period of the original RCT. Implementation of the IPS approach was assessed every 3 months by an amended version of the 15-point fidelity scale (53). After the end of the ZhEPP trial, participants had an option to continue using IPS and TAU services, respectively, voluntarily.

Follow-Up Interviews

The follow-up interviews took place between November 2017 and February 2018 and are to be regarded as a non-interventional randomized controlled study. All original participants were contacted by phone and email. Those who could not be reached via these two means of contact were also asked to participate again by post, in which questionnaires were delivered and received in an enclosed envelope free of charge. For most participants, interview appointments lasting about half a day were set upon consent to participate. The effort of each participant in the follow-up interviews was reimbursed with a shopping voucher worth CHF 50 (∼$55). The primary outcome for the follow-up interview was assessing job sustainability for IPS compared to TAU based on the employment status 6 years post-intervention. The secondary outcome was the long-term impact of two approaches on job tenure and salary by assessing study participants' employment duration and wages.

Material

Questionnaires for the ZhEPP were modeled based on the multicenter EQOLISE study (54). Several sections from the original trial were used for this study. For the employment assessment, Job Status Questionnaire was used, in which participants were requested to indicate whether they gained employment through their effort (1), the IPS coach (2), or other means (3). Participants could also answer in an open response format (i.e., using their own words) about the current employer, the job, the start of the job, and the reason for possible interruptions in employment. Follow-up questions included information about current employers, project details, the start of employment, and potential breaks in employment. For the follow-up interviews, the questionnaire used was amended to fit the aim of the study. Participants were asked whether they were employed in the first (competitive) or second (protected) employment market, were in training, unemployed, or retired. The protected type of employment market lacks competition among applicants and employees and is characterized by a state-subsidized nature of relationships, which are usually not remunerated at market rates. If employed, further requested information included employer details, nature of work, working hours, and weekly salary. Participants were asked to indicate the number of vacancies (i.e., acquired job positions) and months worked for the year prior to the interviews. Regarding the period of 6 years, specific questions were only addressed about the number of positions acquired and months worked in the primary labor market (i.e., not in training).

The IPS fidelity scale was also used to evaluate the efficacy of IPS implementation on employment status by measuring the adherence to the core principles of this approach (55).

Patient demographics were recorded using the Client Sociodemographic and Service Receipt Inventory (CSSRI-EU), which was translated into German, and a user manual with definitions and instructions for understanding was provided (56). The questionnaire was divided into five areas. In the part of socio-demographic information, the variables age, gender, marital status, school education, and vocational training are recorded. In the section on the living situation, questions addressed the lifestyle and housing, as well as possible changes during the observation period. In the third part, the employment status, the occupation, the days of work absence, and the type and amount of social support benefits were recorded. In the fourth section, for the use of care services, information on possible inpatient, partial inpatient, outpatient, and complementary care services, as well as contact with the police and the judiciary, was collected. The fifth section on medication was used to document the type, name, dosage, and frequency of the medication taken. The third section on the employment situation was shortened, as the information could already be collected through the job status questionnaire.

Data Analysis

Data analysis was performed using IBM SPSS version 24 (Armonk, NY, USA). The normal distribution of the variables was examined visually by histograms and Q-Q-plots and confirmed by Shapiro-Wilk tests. Differences in-between groups on continuous variables were analyzed by t-tests for independent samples. In the case of the non-normal distribution of a variable, analysis was performed using the Mann-Whitney-U test. In-between group differences of categorical variables were examined using the Pearson Chi-squared test. In the case of expected cell frequencies of <5, variables were analyzed using Fisher's exact test. A p-value of ≤ 0.05 was considered statistically significant.

Longitudinal inter-group differences were analyzed using a generalized estimated equation (GEE) model, which is perfectly suited for examining dichotomous data over time, taking into account dependencies of repeated measurements of a participant and the time course in the model (57). GEE was squared to allow more flexibility in handling possible fluctuations regarding the primary outcome during different measurement points.

For identification of factors influencing the effects of job coaching on employment status in the competitive market, only participants in the intervention group ($n = 127$) were analyzed by means of logistic regression models (**Supplementary Table 1**) (58). As the selection of potential predictors of employment in the competitive market was based on theoretical assumptions, the inclusion method was used.

Ethical Considerations

The ZhEPP and the follow-up study were approved by the local ethics committee (approval number *2016-01636*) and were carried out in line with the Helsinki declaration. Data confidentiality was ensured by providing each participant with a unique participant ID by the interviewers, which was henceforth used for data collection and analysis of both ZhEPP and the follow-up study.

RESULTS

Representativeness

The representativeness of the study population was counted from the start of the trial to the end of the follow-up period considering the present work as a continuation of the ZhEPP. Out of the 250 participants enrolled in the original ZhEPP study, two did not show up for the first appointment and were excluded from the baseline assessment, reducing the original sample size of the ZhEPP to 248 (36). For the follow-up interviews, 25 out of the 248 participants (10.1%) could not be contacted due to missing valid contact information. Further, 68 participants (27.4%) were excluded as they could not be reached or did not respond. Twenty-four participants (9.7%) had no interest in participating in the study, 15 people (6%) decided against participation after receiving the questionnaire, and 3 people (1.2%) had died. In total, 114 people (46% of the baseline sample) participated in the follow-up interviews. The difference in dropouts between the study groups (18% (IPS) vs. 14% (TAU)) was not significant (data not shown).

Most of the participants were lost in the first part of the ZhEPP trial (16%, $n = 40$). In order to assess representativeness, we compared the data set (follow-up time point, $n = 114$) to those participants of ZhEPP who did not take part in the follow-up interviews ($n = 134$). Comparison of the data sets reveals a significantly higher percentage of people with the affective disorder as the primary diagnosis ($\chi^2(1) = 7.73$, $p = 0.005$, Cramers $V = 0.189$), as well as a significantly lower percentage of people with the primary school as their highest level of education ($\chi^2(1) = 4.04$, $p = 0.04$, Cramers $V = -0.138$) in the group evaluated in the follow-up study, compared to those who did not participate. No further differences were noticed (see **Supplementary Table 2**). The analysis was not controlled for the dropout time or the number of completed questionnaires pursuing the intention-to-treat analysis approach, which most closely corresponds to clinical practice.

Patient Demographics

A comparison of the patient demographics of the IPS coaching group to the TAU group revealed significant differences between the groups regarding primary school rates. In the IPS coaching group, significantly more attendees reported having only a primary school degree than TAU controls ($p = 0.04$, Cramers $V = 0.204$) (**Table 1**).

Employment Status

Out of the 114 participants of the study at a follow-up time point, 36 (31%) were not in employment, 52 (45.1%) were employed in the competitive (primary) job market, and 21 (18.6%) held a position in the protected (secondary) job market. Furthermore, 5 participants (4.4%) had retired (see **Table 2**). No significant differences were observed between the IPS coaching group and the TAU group.

Employment Duration and Wages

Further assessment of the employment situations and the employment history was conducted in order to evaluate differences in the quality of employment between the groups. Comparison of the number of acquired positions and the employment duration during the last 6 years revealed no differences between the study groups (see **Tables 3**, **4**). Participants with competitive and protected jobs in the IPS coaching group worked on average 29 months, whereas those

TABLE 1 | Participant characteristics Follow-up study ($n = 114$).

	IPS coaching $n = 62$	TAU control $n = 52$	*p*-value	Total
Women[ad]	32 (51.6%)	30 (54.4%)	0.516	62 (54.4%)
Age, yrs at follow-up time point (*M*±*SD*)[c]	47.32 ±10.44	50.68 ±10.62	0.953	48.75 ±10.59
Number of years between first contact with psychological care and begin of study[ac] (*M*±*SD*)	11.35 ±9.28	10.61 ±7.75	0.124	11.03 ±8.61
Clinical diagnosis[ad]				
Affective disorder	36 (58.1%)	30 (58.8%)	0.984	66 (58.9%)
Schizophrenia, schizoaffective disorder	8 (13.1%)	3 (5.9%)	0.200	11 (9.8%)
Personality disorder	7 (11.5%)	8 (15.7%)	0.515	15 (13.4%)
Other	10 (16.4%)	10 (19.6%)	0.658	20 (17.9%)
Comorbidities (yes)[ad]	26 (41.9%)	25 (48.1%)	0.511	51 (44.7%)
Hospitalizations at follow-up time point[ad]				
None	20 (37%)	17 (41.5%)	0.661	37 (38.9%)
1–5	28 (51.9%)	19 (36.5%)	0.591	47 (49.5%)
6–10	4 (7.4%)	5 (12.2%)	0.430	9 (9.5%)
11+	2 (3.2%)	0	0.213	2 (2.1%)
Highest Level of Education at follow-up time point[b]				
Primary School	33 (56.9%)	16 (35.5%)	0.040	49 (47.6%)
Secondary school diploma	8 (13.8%)	12 (26.7%)	0.089	20 (19.4%)
Another diploma	17 (29.3%)	16 (35.6%)	0.415	33 (32.0%)
Living situation at follow-up time point[bd]				
Single	34 (58.6%)	21 (47.7%)	0.274	55 (53.9%)
Living with partner/married	17 (29.3%)	19 (43.2%)	0.147	36 (35.3%)
Living with relatives	4 (6.9%)	4 (9.1%)	0.723	8 (7.8%)
Living with others	3 (5.2%)	0	0.257	3 (2.9%)

IPS, Individual Placement and Support; M, Mean; SD, standard deviation; TAU, treatment as usual. Data correlate with number (n) per group (valid percentage).

[a] *In relation to baseline.*

[b] *Smaller sample size due to lack of obtained information.*

[c] *Mann-Whitney-U-Test.*

[d] *Chi-Square Test using Fisher's exact test if cells had expected count <5.*

$p > 0.05$, no significant differences between the groups.

TABLE 2 | Employment status at the follow-up interviews.

	IPS Coaching $n = 62$	TAU Control $n = 52$	*p*-value	Total
Not employed	21 (33.9%)	15 (28.8%)	0.565	36 (31.9%)
Employed primary job market	27 (43.5%)	25 (48.1%)	0.629	52 (45.6%)
Employed secondary job market	12 (19.4%)	9 (17.3%)	0.779	21 (18.4%)
Retired	2 (3.2%)	3 (5.8%)	0.658	5 (4.4%)

Primary job market refers to employment in the competitive job market, secondary job market refers to protected employment.

IPS, Individual Placement and Support; TAU, treatment as usual.

Chi-Square test using Fisher's exact test if cells had expected count <5. $P > 0.05$, no significant differences between the groups.

TABLE 3 | Model estimate of the number of positions acquired in the primary work market over the various time points.

	Constant	SE	*p*-value	Exp (*B*)
Intercepts	−1.105	0.2118	0.000***	0.331
Group	0.116	0.288	0.688	1.123
Time	−0.091	0.1025	0.373	0.913
Time 2	0.034	0.0195	0.081	1.035
Group Time	0.571	0.1453	0.000***	1.770
Group Time 2	−0.114	0.0269	0.000***	0.892

*Group, IPS coaching group and control group; Time, six different time points; SE, standard error; Exp (B), effect size; df, 1; Goodness for fit (QIC) = 1857.096. ***$p < 0.001$.*

in the TAU group 28 months, with 1.17 and 1.23, acquired positions over the study duration, respectively. The workload was also comparable between the groups, with participants in the IPS coaching group working an average of 16.60 h per week in the competitive job market, compared to 17.31 h per week in the TAU group. Hourly At follow-up time points, hourly wages (for both types of jobs) at follow-up time points did not differ significantly between the groups (**Table 5**). Likewise, the analysis of employment rates at the selected follow-up time point showed no differences between TAU and the IPS approach (**Table 6**).

DISCUSSION

Main Findings

Our six-year observations from the ZhEPP-RCT data indicated that both IPS and traditional approaches effectively provide competitive job positions for individuals with mental illnesses in Switzerland. However, the positive effects of IPS implementation on employment seem to decrease over time. The difference in the effects from the IPS and TAU groups were prominent after the first 6 months post-intervention (36 vs. 24% in employment, respectively). The percentage of participants who received IPS with the protective or competitive type of job increased from the starting 26 to 44% by the second year, whereas no major changes were observed in the control group (25 to 26%, respectively). Nonetheless, the follow-up interviews conducted 6 years after the initial interventions demonstrated that the gap between the study groups diminished over the years and was not significant anymore due to a decrease in the employment rate in the IPS group. Only 36% of participants of the IPS group still held a job in either competitive or protected type of employment, while the TAU group had 33% employed participants. Comparison of the employment rates in the competitive job market at follow-up time point revealed no significant difference between the study groups. Nevertheless, at the end of the 6-year follow-up, the employment rates were significantly higher than the study's baseline. These findings provide important insights regarding the long-term effects of distinct intervention strategies aiming at personal and/or clinical rehabilitation from mental illness.

TABLE 4 | Positions and employment duration in the follow-up study.

	IPS coaching group (*n* = 62)	TAU group (*n* = 52)	Total	*p*-value	Effect size
Acquired positions over the last 6 years (*M*±*SD*)[a]	1.23 ± 1.33	1.1 ± 1.31	1.17 ± 1.32	0.261	−0.098
Months employed during the last 6 years (*M*±*SD*)[a,b]	28.78 ± 29.44	27.90 ± 28.67	28.38 ± 28.97	0.386	0.157

IPS, Individual Placement and Support; M, Mean; SD, standard deviation; TAU, treatment as usual.

[a]Mann-Whitney-U-Test, one-tailed, [b]Smaller sample size due to lack of obtained information.

$p > 0.05$, no significant differences between the groups.

Investigation of workload and remuneration also revealed no difference between the IPS coaching group and the TAU group. Approximately half of the participants employed in the competitive market worked part-time between 10 and 30 h. In comparison, a third worked <10 h, primarily corresponding to the preferences of a participant and the preferences of the job coach (received at the beginning of the coaching during the original RCT). The latter can potentially be a reason for longer job duration compared to other studies. However, there was a comparable distribution of employment in the primary and secondary markets in both groups. The average salary of participants of the IPS coaching group did not exceed the average income of the TAU group, again contradicting the findings from previous studies. One of the potential explanations of these findings could be the issue that the interventions (i.e., IPS and TAU) from the original ZhEPP study were not carried out continuously in all participants after the end of the trial. Since study groups showed similar results in primary endpoints (i.e., job tenure, employment rates, and workload), one may argue that the superiority of IPS over conventional methods tends to wean over the years, especially if not continuously supported. Nonetheless, it is important to keep in mind that a range of various factors could potentially impact employment outcomes. Thus, generalizability and interpretation of the

TABLE 5 | Workload and salary in the follow-up settings.

All employed participants	Total (*n* = 73)[c]	IPS (*n* = 39)[c]	TAU (*n* = 34)[c]	*p*-value	Cohens d
Workload (Hours/week)[a]	10.57 ±12.48	10.07 ±11.88	11.15 ±13.25	0.443	0.086
<10 h[b]	21 (28.76%)	12 (30.77%)	9 (26.47%)		
10–30 h[b]	0.40 (54.79%)	23 (58.98%)	17 (50%)		
>30 h[b]	8 (10.96%)	3 (7.69%)	5 (14.71%)		
Wages in CHF (±SD)[a]	22.30 ±13.28	20.21 ±13.22	25.02 ±13.12	0.101	0.365
Primary job market only	**Total (*n* = 52)[c]**	**IPS (*n* = 27)[c]**	**TAU (*n* = 25)[c]**	***p*-value**	**Cohens d**
Workload (Hours/week)[a]	15.73 ± 13.26	16.60 ± 12.84	17.31 ± 13.41	0.451	0.054
<10 h[b]	19 (36.5%)	11 (40.7%)	8 (32%)		
10–30 h[b]	25 (48.1%)	13 (48.1%)	12 (48%)		
>30 h[b]	7 (13.5%)	3 (11.1%)	4 (16%)		
Wages in CHF (±SD)[a]	25.98 ± 11.91	25.02 ± 11.39	27.06 ± 12.64	0.308	0.17

CHF, Swiss Francs; IPS, individual Placement and Support; SD, standard deviation; TAU, treatment as usual.

[a]Marry-Whitney U-test, one-sided; [b]Pearson Chi-squared test, one-sided; [c]small sample size due to missing values.

$p > 0.05$: no significant differences between study groups were founded.

TABLE 6 | Employment rate across the time points ($n = 248$).

	IPS Coaching Group		TAU Group			
TP	**Number**	**% in M1**[b]	**Number**	**% in M1**[b]	***p*-value**	**Cramers *V***
0	34	26.8	30	24.8	0.833	0.023
1	46	36.2	29	24.0	0.05*	0.133
2	52	40.9	29	24.0	0.007**	0.181
3	56	44.1	31	25.6	0.004**	0.194
4	51	40.2	34	28.1	0.062*	0.127
Follow-up[a]	46	36.2	40	33.1	0.595	0.041

IPS, Individual Placement and Support; M1, primary job market; TAU, treatment as usual; TP, time point. Analysis based on intention-to-treat, LOCF.

[a] *For participants retired at follow up time point, the values obtained at time point 4 were carried over.*

[b] *Valid percentage indicated.* $^{*}p < 0.05$, $^{**}p < 0.01$. *Pearson Chi-squared test, two-tailed, with Yates correction (continuity correction), df = 1.*

presented findings require vigilance and careful consideration of the context and details of settings.

Comparison With Findings From Previous Studies

Implementation of the IPS leads to higher rates of employment and job tenure and improved salary (18, 23). The overwhelming amount of evidence supported the superiority of IPS compared to traditional methods of interventions changing the standards of practice in many countries (23, 59–62). For example, in the Netherlands, the number of individuals involved in IPS programs doubled from 2016 to 2017 primarily due to national funding of such services (63).

The findings from our study are partially comparable to and somewhat distinguished from the previously published literature results. The employment outcomes (i.e., job tenure and employment rates) may range depending on participants' study characteristics and individual features and applied interventions (64). For example, an RCT of 162 participants with schizophrenia receiving IPS showed that 50% of employment rate with 25.47 weeks in job tenure after 1 year of follow-up (65). Throughout the 18-month follow-up period, IPS-supported employment led to 68.6% of job acquisition among 541 unemployed US-veterans with post-traumatic stress disorder in a multi-site RCT (66). Meanwhile, in an RCT of 85 participants with severe mental illness and justice involvement, 31% of people who received IPS acquired a competitive type of job compared to only 7% in the control group at 1-year of follow-up ($p < 0.01$) (67). The trends observed in the first two years after intervention (as described in the ZhEPP trial) (51) are similar to the ones described in the literature (68–70), in which the between-group differences became significant after a half of year of the intervention and may continue to rise or stay stable up to 1 or 2 years (27, 71, 72). As in our study, the likelihood of acquiring a job position diminishes over time among individuals with IPS, despite overall higher employment rates (73). These findings may serve as an important clue for practitioners regarding recovery and rehabilitation planning and outcome anticipation for patients and clinicians (68).

The data on the long-term impact of IPS is, however, limited. Among 151 individuals with severe mental diseases demonstrated higher employment rates in those receiving IPS strategy compared to people managed with the traditional methods (44 vs. 25%) were found in a 30-month multi-site RCT from the Netherlands (74). A study of 95 persons with mental disorders from Italy demonstrated steadily rising rates in competitive employment for almost up to 4 years of follow-up, claiming the sustainability of IPS effects (75). In contrast to our data, 41% of participants of this study had a competitive type of job by the fourth year of observations (75). Our results also contradict the findings from a study with a similar methodological design by Hoffmann et al., in which 100 Swiss residents with mental disorders receiving IPS had higher rates of competitive employment 5-years after the intervention compared to those with conventional approach (65.2 vs 33.3%, $p < 0.002$) (76). The advantage of IPS in various employment outcomes was similar during the first 2 years of the follow-up and remained significant afterwards, indicating that the positive and sustainable effects of IPS on work over the 5-year follow-up period (76).

One of the factors possibly explaining the differences of our study findings is the fact that most of the participants reported the initial time point of seeking psychological care on average as 10 years ago, even though all of the participants had qualified to obtain IV pension within the last year before the beginning of the study. This indicates that many of the survey participants had been affected by their disorder long-term. Furthermore, we found a significantly higher proportion of participants from the IPS group having primary school as the highest academic degree, which could have impacted the outcomes. The observed assimilation in the employment rate of the IPS coaching and the TAU group at the follow-up time point may be based on changes in legislation during the study period. In 2012, a revision of measures to support the reintegration of people with disabilities came into effect, providing increased support during the job search. Therefore, participants of the TAU group may have benefitted from this revision, which may have caused a steady increase in the employment rate observed in the TAU group over time. It was beyond the scope of this study to investigate the impact of the revised legislation on the results. Nonetheless, the IPS strategy resulted in a continuous level of employment of 36% (**Figure 1**) of participants in the competitive job market across study duration, thereby showing similar results to other long-term studies (76).

In addition, ethical considerations could not prevent participants of the TAU group from joining other support programs. Participants of the TAU group were free to use other services for employment acquisition. However, this data was not recorded and therefore not considered in the analysis, possibly masking a more pronounced difference between the groups.

Barriers and Facilitators of Successful IPS Implementation and Employment

Aside from methodological differences, the distinction in employment sustainability as well as in the magnitude of the

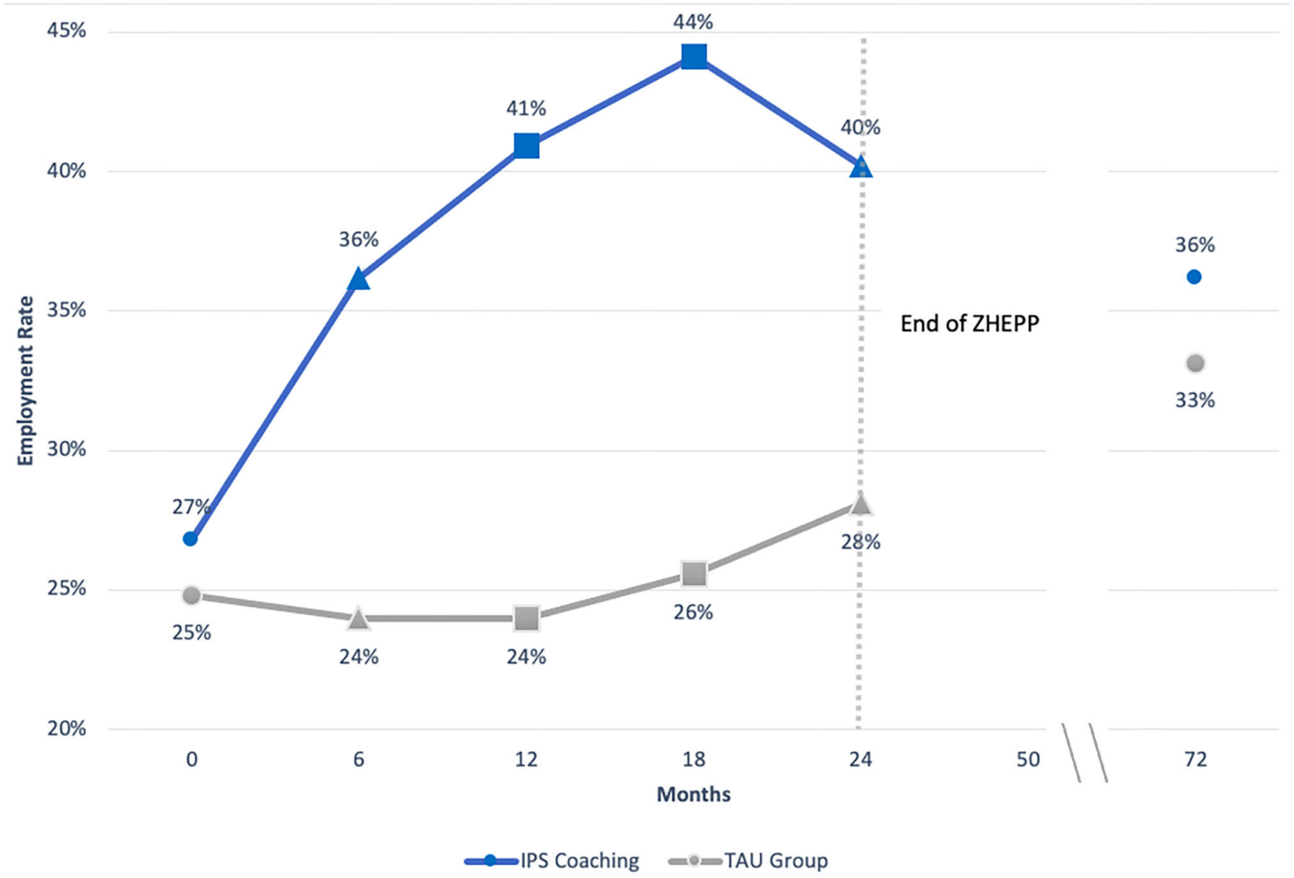

FIGURE 1 | Employment rate in ZhEPP and its follow-up based on *intention-to-treat*, LOCF analysis. IPS=Individual Placement and Support, M1 = primary job market, TAU = treatment as usual. For participants retired at follow-up time point (72 months after start of study), the values obtained at time point 4 were carried over.

effects among the study results may correspond to several important factors that either enhance the impact of an intervention or hinder it. Multiple studies cited lack of disability benefits cited lack of disability benefits cited lack of disability benefits as a key environmental barrier for employment (49).

Another critical obstacle for people with mental disorders is motivation to acquire a job, which refers to practical steps and strategic efforts required for potential employment (49). Individual perception of multiple impediments can lead to hesitance and inaction, which can be combated with the person's empowerment (39). Individualized support is perceived by people with mental illnesses seeking employment as an important facilitating factor, which is a challenging task for social workers and clinicians involved in IPS programs (77, 78). The type of mental disorder can also affect program's efficacy for different outcomes (21). External emotional support from peers and family members is critical for rehabilitation and recovery (42, 79). Cognitive and psychological interventions along with supported education were shown to be important contributors to enhancing employment status (42, 80).

The relationship between the employer and an employee with mental illness can play a crucial role, which can depend on the individual internal barriers of the person (e.g., disease nature, severity of impairment), as well as competencies of the employment specialist (34). Therefore, not only people with mental disabilities should receive training to increase job tenure and employment sustainability, but also employers to help to solve the common problem (81–83).

Type of the mental issue is also critical as it seems to be more effective in some disorders and less and in others (21, 84). A systematic review of studies assessing IPS efficacy in individuals with substance use disorders found that episodic treatment of the disease and risk of relapse of the mental disease were among important barriers in implementing IPS (22). Often, the ethical part of the mental disease is not considered. Qualitative analysis by de Greef showed that the risk of disclosure of the medical diagnosis might represent a potential issue for people with mental conditions seeking employment (85). Lastly, since the spread of the IPS model, different variants and types were invented to fit the needs of specific population groups (50, 86, 87), explaining the individualistic approach to the implementation of this strategy and an opportunity for further development improvements and developments (88).

Limitations and Strengths

The results of this study should be interpreted carefully, as our study has several important limitations. One of the key limitations is the differences in the level of education between study groups. Significantly more participants of the IPS group had primary school as the highest achieved academic level, compared to the controls, which could be reflected in their qualification and remuneration. This could have further affected the long-term outcomes of the duration of employment, workload, or salary for the IPS group, which did not differ from the TAU group. Furthermore, we could not provide longitudinal associations between interventions and outcomes; thus, limiting the interpretation of trends because of interruption in the timeline. The number of people with affective disorders was slightly higher in the participants of the follow-up survey (58.9%) than in those who did not participate (40%), the impact of which on main outcomes cannot be ruled out completely. Recall bias is another potential limitation of the presented work, a common drawback of observation-based studies. Moreover, a lack of information regarding the intensity of IPS and TAU services use between the end of the ZhEPP trial, and follow-up interviews (i.e., from September 2014 to November 2017) in our study limits the interpretation of these findings, as some participants could have continued with IPS, while others might have dropped out. Lastly, we were unable to collect data about alternative support that participants of the TAU group may have received, which may have impacted our findings.

These drawbacks are, however, balanced by the strengths of this work. The findings of this study provide an essential perspective to the body of research on the long-term efficacy of the IPS based on the firm methodological approach and statistical analysis. Our outcome assessment was identical to the one used in the original trial, involving face-to-face interviews; thus, limiting variability in evaluation and outcome reports. To our best knowledge, this is one of the first studies to assess the effectiveness of IPS beyond 5 years of follow-up after intervention compared to conventional methods. Evaluation of the representativity of the respondent participants of the follow-up study revealed only minor differences between the groups, making the sample representative of the group of people who enrolled in the ZhEPP project. The results highlight the importance of continuous monitoring and/or intervention for people with mental disorders.

Future studies with a robust statistical approach, larger sample size, and comprehensive longitudinal follow-up are required to clarify the differences found between our study and others in the long-term impact of IPS.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Swiss Association of Research Ethics Committees Kantonale Ethikkommission Zürich Stampfenbachstrasse 121 8090 Zürich. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

WK designed the follow up study and served the principal investigator. E-MP contributed to design of study. NS, LW, and SH did the statistical analysis. BW contributed to statistical analyses. E-MP drafted the manuscript. All authors participated considerably in writing of this manuscript and critically revised the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2021.709732/full#supplementary-material

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The Case for Co-production in Singapore's Mental Healthcare

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For better or worse, there exists a power differential between psychiatrists and their patients in mental healthcare. Co-production was proposed to be the "third space" to offer truce between the professional-patient tension in mental healthcare. In Singapore, co-production is a new, but growing, approach to mental healthcare service delivery. In this commentary, we argue that co-production is not just a novel way to provide service, but a moral imperative. Recovery Colleges and its adoption in Singapore is discussed in some detail to highlight how co-production may be applied in practice.

Keywords: psychosis, co-production, psychosocial treatment, participatory, collaboration

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INTRODUCTION

I was inducted to the mental healthcare system under unfortunate circumstances in 2013. My family sought help for me at a tertiary psychiatric hospital because I was experiencing symptoms of paranoia, delusions and disorganized thoughts and behaviors. Eventually, I was diagnosed with schizophrenia. Experiencing psychosis took away my autonomy and rights as a human being in some ways. One of which was the loss of my mental capacity to seek medical treatment. For better or for worse, there exists a power differential between psychiatrists and their patients in mental healthcare. Psychiatrists wield a certain power over their patients as healthcare providers by having the power to legally mandate treatment on their patients. For instance, psychiatry is the only medical specialty that is empowered by the law to mandate treatment on its patients (1, 2). Even though the decision to invoke the Mental Health (Care and Treatment) Act for involuntary admission is based on a thorough assessment and criteria, treatment can include enforced hospital admissions, injections of sedative and/or psychiatric medications, and in some cases, physical and/or chemical restraints. Of course, I would like to believe that all psychiatrists exercise such power with care, and only in some cases. In Singapore, doctors are held in great esteem and they enjoy a high social status as members of a highly regarded profession (3). As a result, local patients very often treat their doctor's advice and instructions with great reverence. Hence, even when a patient seeking psychiatric help is in remission, such a power differential can loom over—unseen, unheard, subtly influencing the doctor-patient dynamics.

Besides gaining medical remission and functioning, my journey of recovery included rebuilding my sense of self and autonomy as an active citizen of my community. I had an excellent care team, which included case managers and psychiatrists, who always took my values and goals into consideration when providing care for me. In fact, we got along so well that I got invited to join their multidisciplinary team as a peer support specialist. After a 2-year stint with them, I joined Institute of Mental Health's (IMH) research department. Despite the power differential between psychiatrists and their patients, there are efforts to level the playing field. In the landmark Salzburg Statement on Shared Decision Making (2011), a group of professionals and patients agreed on a statement that called on both patients and clinicians to be co-producers of health. It described a shifting boundary between expert and non-expert, where patients were called on to play a more active role in the decisions regarding their healthcare needs and increasing involvement of patients and the public as key stakeholders in public healthcare. In the same vein, the IMH's senior management, in collaboration with its staff, has come up with seven aspirations to shape the future of local mental healthcare services. One of them is to collaborate and co-create with patients, caregivers, and partners for care delivery. By leveraging the unique experience of patients, caregivers, and partners to bolster current services, we hope to develop more person-centric and innovative care models. As this initiative only started in 2021, the champions of the co-creation workgroup has been working with our senior leaders and Corporate Development team to identify best practices for the development of new care models. It helps to address the power differential between healthcare providers and patients. Benefits of addressing the issues of power between healthcare provider and patients include promotion of shared decision-making during consultations. Shared decision-making has been linked with better health outcomes (4), higher patient satisfaction, and patient adherence to treatment (5).

One of the latest offerings in the mental healthcare landscape beyond our shores is co-production. Co-production and co-creation are often used interchangeably when referring to service user involvement in the development and delivery of public services. However, it was suggested that co-production and co-creation are distinct processes in the cycle of service user involvement (6). Co-creation was defined as user involvement at the strategic level, during the planning and designing of services, while co-production was defined as user involvement at the implementation level, during the delivery of services (6). The integration of peer support services within IMH is an effort to promote more co-production in mental healthcare delivery locally (7).

WHAT IS CO-PRODUCTION?

Co-production has been heralded as the "third space" to offer truce between the professional-patient tension in mental healthcare (2). This term was first coined by Nobel laureate Elinor Ostrom et al., and later operationalized by law professor Edgar Cahn. First introduced to solve the skyrocketing youth crime rates during the 1970s in the Chicago area, this concept has evolved into a key working principle in the UK's mental healthcare system (8). Today, a working definition of co-production is "delivering public services in an equal and reciprocal relationship between professionals, people using services, their families and their neighbors" (8). Co-production fosters reciprocal relationships between mental healthcare professionals, the recipients of their services, and others in the social network via collaborations and partnerships. There is an element of power and knowledge sharing between professionals and the layperson stakeholders. A useful way to describe co-production is to draw upon Arnstein's Ladder of Participation (9). At the lowest level, there are services that are "doing to" recipients of care, where recipients are not given a choice. In the second level, there are services that are "doing for" recipients of care, where recipients are engaged in care. In the third level, there are services that are "doing with," where recipients are co-designing and co-delivering services (10).

There are four main tenets in co-production, as advocated by Cahn (11). Firstly, it is to recognize people as assets because people themselves are the true wealth of the society. Secondly, it is to recognize that work and productivity may look different for different people. For example, a mental health advocate, who may not be holding a full-time job, "work" may not always be directly translated into economic gains. Thirdly, promoting reciprocity by giving and receiving, because it builds trust between people and fosters mutual respect. Fourthly, it is building social networks because people's physical and mental well-being depends on strong enduring relationships. We would argue that co-production is not just a novel way of producing and delivering mental healthcare services, it is a moral imperative. The challenges posed by mental health issues are quite unlike other physical illnesses because of its unique socioeconomic consequences. Persons in recovery from mental health issues in Singapore face tremendous stigma and discrimination from the public and the workplace (12, 13). These studies on the level of stigma against persons with mental health issues in Singapore consistently suggest that they were excluded from social circles and denied work opportunities because of their conditions. As a result, the quality of life for this group of people suffers, possibly due to the systemic social and occupational discrimination (14). Co-production can be an approach where the knowledge of lived experiences can be harnessed to co-create a more humane and empathetic mental healthcare system in Singapore. The marriage between the expertise of professionals and experiences of patients could provide medically informed services that are sensitive to the struggles of its recipients.

CO-PRODUCTION IN ACTION: THE EMERGENCE OF RECOVERY COLLEGES

Recovery Colleges are emerging as platforms for co-production in mental healthcare worldwide (15, 16). The idea was first mooted in the US, and then manualized in the UK (15). Since the emergence of the first Recovery College in London in 2008, it has spread to regions like Australia, Hong Kong, and Singapore (16). Recovery Colleges provide an alternative form of intervention for the recovery of persons with mental illness. Defining features of a Recovery College included, but are not limited to, (1) a focus on co-production, where classes are co-produced and co-delivered by professionals and persons in recovery, (2) open for everyone in the mental health community, to promote interactions between mental health professionals and persons in recovery on a level playing field, and (3) operates on college principles, where students register for classes, plan their own timetables, and classes are educational in nature (15). Modeling after UK's Recovery College, four non-profit organizations, with support from Jardine Matheson Group MINDSET, came together to establish the Mindset College in Hong Kong. With co-production as its bedrock value and mode of operation, they have created educational courses for persons in recovery from mental health issues (17).

Although co-production is a growing trend in mental healthcare service designing and delivery in the UK (18, 19), there is a dearth of evidence base from Singapore. To the authors' best knowledge, only one paper was published by two local authors based in Singapore on the theoretical principles of collaborations, co-productions and network (20). From a public policy perspective, they delved into the definitions of collaboration, co-production and created networks based on four case studies in the local context. The authors (20) cautioned that co-production in its local context may lose its original intent of encouraging active citizen participation to become a form of cost-efficient volunteer management model. In Hong Kong, recovery in mental healthcare is a burgeoning field. A small but vocal group of mental health professionals are rallying service users to be involved in their care, and are advocating on their behalf on the international stage for the value and challenge of co-production in an Asian society (21–23).

Recovery Colleges in Singapore is in its infancy now. Resilience Collective, a local social service agency, was set up in 2018 to emulate the Recovery Colleges model in the UK (24). Co-managed by staff who are persons in recovery, Resilience Collective co-produced workshops on topics that explores recovery from mental illness, managing anxiety, art of friendship, and managing self-stigma to support members in the mental health community. School of Ability and Recovery (SOAR) was started in 2018 as a ground up initiative modeled after Recovery Colleges. With the support of Youth Corps Singapore and like-minded volunteers, SOAR ran two workshop series in 2019, totaling to 10 workshops on topics like mindfulness, self-care, what is psychosis and dealing with workplace stigma (25).

A challenge faced when sourcing for funding for Recovery Colleges in Singapore is the lack of evidence to support the efficacy of such co-production efforts on patient outcomes locally. Even though quantitative and qualitative evidence for co-production from Europe is growing (26, 27), the import of new ideas across continents is sometimes met with a level of skepticism in Singapore, especially of its transferability to the local context and culture. However, the lessons learnt by our European colleagues may serve as foresight for us. For instance, when conducting co-production trainings, considering into its long-term efficacy is crucial. Continuous training and long-term supervision may benefit practitioners of co-production (26). Moreover, due to the flexible nature of co-production, the context in which co-production is implemented must be considered when one performs evaluation projects on co-production (27).

As frustrating as the power differential between psychiatrists and patients can be for some, change is gradually making its way into the mental healthcare system. Efforts to co-create a collaborative mental healthcare landscape is currently underway. In fact, the National Healthcare Group has approved a pilot grant to evaluate the outcomes of co-producing and co-delivering educational workshops for persons with first episode psychosis in November 2020. Various stakeholders, like patients, caregivers, members of public and mental health professionals, were invited to join sessions to brainstorm and co-create educational workshops. To date, we have run 9 hours of co-produced online workshops (called *Striking Matches*) in collaboration with the Early Psychosis Intervention Programme in Singapore. Preliminary results indicate that there was a modest increase in mental well-being, personal recovery, and social inclusion in participants with first episode psychosis. This project is the first of its kind in Singapore. A long-term goal of this project is to build the evidence base for co-production in the local mental health community.

In the UK, the presence of Recovery Colleges impacts more than just patients in recovery from mental health issues, it was also reported that they change the way staff and society view persons in recovery (28). As a result, the mental health services in the UK changed in a fundamental way. No longer are patients viewed as disabled, passive recipients of services, but they are enabled, active members making contributions to the mental health community. We believe that there is something for Singapore's mental healthcare system to learn from our English counterparts. Co-production may be part of the solution in the recovery of our mental healthcare system.

CONCLUSION

Experiencing psychosis can be dehumanizing in some ways. The existing power differential between psychiatrists and patients does not always help to promote recovery and shared decision-making in mental healthcare services. Co-production, an emerging approach to mental healthcare, may be a candidate to address issues brought about by power differential in mental healthcare services. Recovery College is a novel approach to mental healthcare intervention that is an epitome of co-production. While Recovery Colleges are common in the UK, it is still on its way to be fully supported by healthcare professionals, funders and policymakers in Singapore. Yet, there is a growing number of programs and services adopting co-production in its workflow locally. In Singapore, there is Resilience Collective and the SOAR initiative. More recently, there is also a funded pilot project on co-producing workshops for persons with psychosis going on at the IMH since March 2021. Seeing how co-production has changed the UK mental health services in fundamental ways, some practitioners in Singapore are holding the hope that this approach to mental healthcare can transform our mental healthcare services to a more empowering one for our patients.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

YYL conceptualized and wrote the first draft of the paper. SA and CT gave intellectual feedback to the manuscript based on their clinical and professional expertise. All authors contributed to the article and approved the submitted version.

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BRIEF RESEARCH REPORT
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Implementing an Exercise Physiology Clinic for Consumers Within a Community Mental Health Service: A Real-World Evaluation

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Background: Physical activity significantly improves mental illness symptoms and physical health for people living with mental illness. Mental health services do not routinely provide their consumers with access to exercise professionals for physical activity engagement. Barriers exist to integrating physical activity as part of standard care including staff culture, finance, and resources. This study examines the feasibility of newly established exercise physiology clinic within a mental health service in Sydney, Australia.

Methods: A single site, open trial was conducted in a community centre within a large mental health district. A meeting room was converted into a part-time exercise physiology clinic where individualised physical activity interventions were delivered by an accredited exercise physiologist. Outcome measures including BMI, cardiovascular fitness, and self-reported physical activity were collected.

Results: A total of 84 mental health consumers (17% of eligible consumers within the mental health service) participated in the clinic on average for one exercise session weekly. Moderate-to-vigorous physical activity significantly increased and sedentary time significantly decreased ($p < 0.001$).

Conclusions: Exercise physiology clinics are feasible within mental health services and should be incorporated as part of standard care.

Keywords: physical activity, exercise, mental illness, interventions, exercise specialists, exercise physiologists, mental health

INTRODUCTION

People with severe mental illness face a reduced life expectancy of 15–20 years compared to the general population (1); this is overwhelmingly attributed to chronic physical illnesses such as cardiovascular disease and diabetes (2). While side effects from antipsychotic medications contribute largely to this higher incidence of cardiometabolic disease (3), modifiable lifestyle risk factors also impact significantly. High rates of tobacco smoking (4), physical inactivity (5), poor nutrition (6) and low cardiorespiratory fitness (7) are prevalent for people with severe mental illness and influence the widening life-expectancy gap (1) while contributing to the global burden of disease (8).

Lifestyle interventions, incorporating nutrition and physical activity, are beneficial in reducing cardiometabolic risk (5, 6, 9) whilst also having positive effects on mental health symptomatology, cognition and psychosocial functioning for people with severe mental illness (10, 11). Evidence suggests that such lifestyle interventions are most effective when delivered by experts in the relevant fields, including dietitians and exercise physiologists, as they can adopt evidence-based practises and utilise behaviour change techniques to maximise long term adherence in people with severe mental illness (6, 12–14). For instance, dropout rates are lower and adherence is improved when exercise professionals deliver physical activity interventions to people with mental illness (15, 16).

A 2019 Lancet commission called for mental health services to include lifestyle interventions, including physical activity, to protect the physical health of people with severe mental illness (17). Calls to action for implementation and integration of lifestyle programs in routine mental health care have been made by Australian and international peak exercise professional and psychiatric organisations (12, 18–20). It is important to establish the feasibility of lifestyle interventions in community mental health settings, with a focus on real-world conditions (21–23). Evaluating such novel strategies would increase widespread adoption of these programs by mental healthcare systems (24).

In this paper we evaluated the feasibility of a novel exercise physiology clinic delivered as routine care to people living with severe mental illness receiving treatment in a community mental health centre. With a focus on delivering physical activity interventions within real-world conditions, a newly created exercise physiology clinic was conceived, implemented, and adopted as part of standard mental health care.

METHODS

The study was assessed by the South Eastern Sydney Local Health District (SESLHD) Human Research Ethics Committee and was determined to be a quality improvement or quality assurance activity not requiring independent ethics review [17/298(LNR/17/POWH/580)].

Study Design

A single site, open trial was conducted in a community centre located within a large public health district providing mental health services to ∼600 people living with severe mental illness. The community centre, while linked to a major teaching hospital, is sited in the local community, and comprised a waiting room, consumer appointment rooms, staff offices, and a large meeting room. People living with severe mental illness who access this centre are provided a package of care consisting of support by a multidisciplinary team. This team includes psychiatrists, mental health nurse specialists, occupational therapists, clinical psychologists, and social workers. Collectively, the mental health team supported consumers through a combination of pharmacotherapy and psychosocial interventions which utilise person-centred and recovery-oriented practises. In addition to the mental health team, the community centre has a physical health team. The *Keeping the Body in Mind* team was comprised of a clinical nurse consultant, accredited practising dietitian, accredited exercise physiologist, and a peer worker with lived experience of mental illness. *Keeping the Body in Mind* initially was established as a pilot programme and demonstrated antipsychotic-related weight gain in first episode psychosis in those aged 14–25 could be attenuated through lifestyle interventions (25, 26). Following this, *Keeping the Body in Mind* teams were deployed by the mental health service to address the physical health needs of youth and adult consumers through a combination of individualised and group-based lifestyle interventions.

When the *Keeping the Body in Mind* team began working at the community health centre, no exercise facilities existed, and physical activity interventions could not be performed on-site, significantly limiting the scope of exercise physiology services. Consumers accessed individual consultations with the accredited exercise physiologist to discuss their physical activity as well as engaging in motivational interviewing and goal setting. Following an allocation of funding from the mental health service to purchase small items of equipment, and discussions with centre management, the large meeting room was converted to a "make-shift" exercise physiology clinic during times when meetings did not occur.

All adult community case managed consumers were eligible for the exercise physiology clinic. Recruitment to the clinic occurred via referrals from staff members who managed the mental health services provided to consumers.

Evolution of the Clinic and Physical Activity Intervention

Under the direction of the accredited exercise physiologist, mental health consumers were initially able to attend the clinic (located within the staff meeting room) one day each week which increased to three days a week as awareness and interest from both consumers and staff increased. Due to limited funding, only a small amount of equipment could be purchased, including a stationary bicycle and a set of dumbbells. Over the next three months, more equipment was acquired with additional funding from the mental health service, including a rowing machine, and boxing and bench-press equipment.

Upon referral, consumers had an initial consultation with the accredited exercise physiologist, to obtain baseline measures, discuss physical activity goals and engage in motivational interviewing. An initial physical activity program and plan was developed in this session. Consultations with the accredited exercise physiologist were subsequently provided as required, typically monthly, with outcomes measures repeated every three months. More frequent consultations could occur if requested.

To align exercise physiology interventions with recovery-oriented mental health treatment approaches and to support engagement in the clinic, the physical activity programs were client-centred, i.e., tailored to the consumers' interests, goals, level of motivation, readiness to change, and physical capabilities. Consumers could engage in a range of activities including, but not limited to, aerobic exercise on machines, strength training or boxing for fitness. Yoga sessions and Zumba dance classes directed by "YouTube" instructional videos, and supervised by the accredited exercise physiologist, were also offered. Mental health peer workers employed by the mental health service were engaged in the referral process and ongoing to assist participating consumers in navigating the exercise service.

Consumers could attend the clinic as often they wished during business hours, typically booking in to 30–60-min timeslots. As clinic attendance increased, final year university exercise physiology students on clinical placement were incorporated into the clinic, assisting those attending with exercise prescription, including modifying the program, providing instruction, demonstration, and feedback.

Outcome Measures

Baseline measures were collected during the initial consultation with the accredited exercise physiologist and repeated at least on a 3-monthly basis for the duration of the consumer engagement in the service. Outcome measures included:

Anthropometry

Height and weight, were used to calculate Body Mass Index (BMI) using standardised procedures. Participants were weighed without shoes and wearing light clothing on the OMRON HN-283 digital scale to the nearest 0.1 kg. Height was measured with shoes off, using a wall-mounted stadiometer to the nearest 0.1 cm. BMI was calculated as weight (kg)/height $(m)^2$ with participants characterised as normal weight (18.5–24.9 kg/m^2), overweight (25–29.9 kg/m^2), obese (30–39.9 kg/m^2) and morbidly obese ($\geq$40 kg/m^2) according to World Health Organisation criteria (27).

Cardiorespiratory Fitness

This was assessed via the Astrand Rhyming submaximal test (28). The test involves 6-min of cycling on a cycle ergometer (Monark 828E Ergomedic bike) at a specified resistance whilst measuring heart rate response. The average heart rate of the final two min of exercise is recorded and used via the Astrand-Rhyming gender-sensitive nomogram to estimate the participants' VO_2max, or maximum rate of oxygen consumption, an indicator of cardiorespiratory fitness. Results were then normalised to age using the Astrand-Rhyming age-correction factor (29).

Self-Reported Physical Activity

This was assessed using questions taken from the short-form International Physical Activity Questionnaire (30). Questions refer to activity performed over the previous seven days and categorises activity according to vigorous activities, moderate activities, walking and sedentary time. Vigorous and moderate physical activity levels were combined for analysis to reflect current Australian physical activity guidelines (31).

Statistical Analysis

Data analysis was conducted using the Statistical Package for the Social Science, Version 27.0. Outcome measures were assessed using paired sample *t*-tests with a Bonferroni's correction applied for multiple statistical tests. For paired sample *t*-tests using a Bonferroni's correction results were significant if $p \leq 0.01$.

TABLE 1 | Participant demographics, clinic attendance ($n = 84$).

Age Categories	n (%)	
18–25		6 (7.1)
26–35		12 (14.3)
36–45		23 (27.4)
46–55		28 (33.3)
55+		15 (17.9)
Mental Health Diagnosis	n (%)	
Schizophrenia		51 (60.7)
Schizoaffective Disorder		24 (28.6)
Bipolar Disorder		7 (8.3)
First Episode Psychosis		1 (1.2)
Major Depressive Disorder		1 (1.2)
Number of Exercise Physiology Clinic Sessions Attended	n (%)	
1 session		13 (15.5)
2–5 sessions		22 (26.2)
6–10 sessions		17 (20.2)
11–20 sessions		10 (11.9)
>20 sessions		22 (26.2)
Time spent in the Exercise Physiology Clinic	n (%)	
<1 month		16 (19.0)
1–3 months		18 (21.4)
3–6 months		11 (13.1)
>6 months		39 (46.4)

RESULTS

Participant demographic information and clinic attendance data is presented in **Table 1**. During the period the exercise physiology clinic was operating, there were 483 individuals who were eligible for referral. In total, $n = 84$ consumers (17% of eligible consumers) attended the exercise physiology clinic between May 2018 and March 2020. Just over half of participants were male ($n = 43$, 51%) and the largest cohort were between the ages of 46 and 55 ($n = 28$, 33%). The majority had a diagnosis of schizophrenia or schizoaffective disorder ($n = 75$, 89.3%) and almost all had been prescribed antipsychotic medication ($n = 86$, 98%). Of the consumers prescribed antipsychotic medication, 47 (56%) took one form of oral antipsychotic medication and 11 (13%) took more than one type of oral antipsychotic medications. There were 9 (11%) consumers who received one type of antipsychotic medication via a depot injection and 15 (18%) were prescribed both an oral and a depot injection antipsychotic medication. Of the consumers who were taking oral antipsychotic medication, 31 were prescribed Clozapine (35.2) 7 (8%) were prescribed Olanzapine.

In total, $n = 39$ (46%) of participants attended the exercise physiology clinic for a period of 6 months or more and the mean number of sessions attended was 17 (SD ± 22.9). Participants attended the clinic on average one session a week (SD ± 1.3). There were 16 participants (19%) that engaged with the clinic for <1 month.

Results of the statistical analysis of outcome measures are presented in **Table 2**. Upon commencement of the clinic, participants had a mean baseline BMI of 30.9 (SD ± 7.1), placing the average participant in the "obese" BMI category.

TABLE 2 | Pre- and post-outcome measures.

	N	Baseline mean (SD)	Post mean (SD)	Mean difference (95% CI)	T value	df	*P* value (two-tailed)
MVPA (min/week)	29	88.1 (108.8)	162.3 (139.7)	74.2 (31.92, 116.57)	3.59	28	0.001
Walking (min/week)	29	163.8 (245.8)	205.2 (205.7)	41.4 (−16.73, 99.49)	1.50	28	0.156
Sitting (min/day)	29	5.9 (2.1)	4.4 (2.3)	−1.6 (−2.4, 0.71)	−3.72	28	0.001
BMI	55	30.92 (7.1)	30.90 (7.2)	−0.01 (−0.8, 0.9)	0.03	54	0.977
Vo2max	32	23.8 (6.9)	25.5 (8.2)	1.7 (−0.4, 3.8)	−1.61	31	0.117

In total, physical activity data was collected for $n = 61$ (73%) of participants on commencement at the clinic. Of these participants, the mean self-reported weekly moderate to vigorous physical activity level was 71 min (SD ± 100.7) and as such, $n = 49$ participants (81% of participants with completed physical activity follow-up data) did not meet the Australian recommended guidelines for physical activity of at least 150 min of moderate to vigorous intensity exercise per week (31).

In total, $n = 55$ participants (65%) completed follow-up anthropometry measurements. Weight neutrality was observed with no statistically significant changes to participants' BMI during the program (mean change = −0.01, 95% CI −0.88, 0.86; $t = -0.03$, $p = 0.98$).

Follow-up cardiovascular fitness measures were collected for $n = 32$ participants (38%) and follow-up self-reported physical activity measures were collected for $n = 29$ participants (35%). The mean time between baseline and follow-up fitness and physical activity measures was 333 days (SD ± 180, range = 42–581) and 347 days (SD ± 178, range = 42–623) respectively. A mean increase to moderate-to-vigorous physical activity of 74-min per week occurred for participants during their involvement in the service which represented statistically significant changes (95% CI 31.9, 116.6; $t = 3.6$, $p < 0.001$). Of the $n = 29$ participants who completed follow-up measures, the number that met the Australian recommended guidelines for physical activity of at least 150 min of moderate to vigorous intensity exercise per week, increased from 7 (24.1%) to 14 (48.3%). A mean decrease to daily sedentary time of 1.6 h occurred which represented statistically significant changes (95% CI −2.4, 0.71; $t = -3.7$, $p < 0.001$). No statistically significant changes occurred for cardiovascular fitness and time spent walking (both p values > 0.01). Individual changes to participant's moderate to vigorous physical activity levels and sedentary time is represented graphically in **Figures 1**, **2**, respectively.

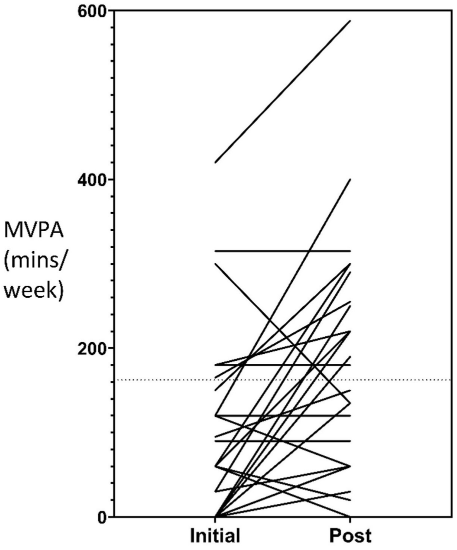

FIGURE 1 | Moderate-vigorous physical activity pre- and post-values.

DISCUSSION

Our findings demonstrated that a new mental health exercise physiology clinic conducted under real-world conditions was feasible for people living with severe mental illness. Feasibility of an exercise physiology service in a recent study for youth at risk of mental illness and attendance was deemed "well-attended" at ∼1 session per week (32). In addition to the clinic in our study being well-attended, engagement in higher levels of moderate-to-vigorous physical activity and a decrease in sedentary time occurred for participants following their involvement. Despite this, no significant improvements were evident in cardiovascular fitness or BMI throughout the program. In the absence of a control comparison group, inferences regarding the association between changes in outcome measures and clinic attendance should be made with caution.

Given the non-significant changes to fitness and anthropometry measures despite regular clinic attendance, it is important to consider the possible reasons underpinning these findings. Perhaps the weekly exercise sessions did not produce substantial physiological changes in fitness measures, without participants also engaging in additional home-based exercise. Additionally, as body weight is predominantly impacted by nutrition, the lack of nutritional counselling for the participants attending the clinic was a significant barrier to weight decrease. A similar behavioural weight-loss intervention conducted as an RCT demonstrated significantly reduced weight in overweight

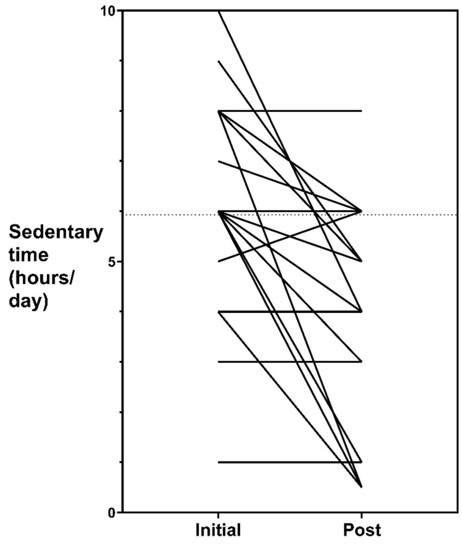

FIGURE 2 | Sedentary time pre- and post-values.

and obese adults with serious mental illness (33), and included the addition of a dietietic service. While participants in the mental health exercise physiology clinic in this study had access to a dietitian, it was not compulsory and not all participants took up this option.

The implementation of a mental health exercise physiology clinic in a routine community health centre provides real-world evidence to for the feasibility and acceptability of such clinics in other mental health services. Australia has clear policy directives and guidelines supporting the implementation of physical health programs for people living with mental illness (18, 20, 34), however there has so far not been wide-spread adoption of such programs by community mental health services (35). When people with mental illness engage in physical activity it results in beneficial effects on mental health, physical health, and quality of life (36). Given regular attendance by people living with mental illness, the low-cost nature of implementation, and successful integration into a busy community mental health centre, the positive findings should encourage mental health services to create their own exercise physiology clinics, building on the framework outlined here, whilst considering the challenges encountered and the recommendations that arise from this evaluation.

Challenges of the Service

Consistent with other reporting in this area, the main challenges associated with establishing the service were centred around financial aspects, staff culture, physical space, and negotiations with management (19). Given that a fully-equipped gym was not possible to implement due to physical limitations of the building and the associated costs, utilising less-frequently used spaces in the community centre was essential. To procure equipment, grant funding and applications for small allocations of funds through the mental health service was necessary. The benefits of accredited exercise physiologists prescribing physical activity and leading interventions for people with mental illness extends beyond clinical relevance, with examples of economic benefits emerging. Deloitte Access Economics reported exercise physiology services within the Australian mental health sector were cost-effective; with each depressive episode prevented through physical activity services delivered by an accredited exercise physiologist resulting in public savings of AUD$10,062 (∼USD$7,400) through improvements to productivity and health system expenditures. Emerging analyses show that mental health interventions incorporating physical activity interventions are cost-effective for health services (37–39) and may help to secure funding needed to implement such programs.

Limitations of the Study

Results should be interpreted considering several methodological limitations. A lack of control group limits the generalisability of the findings. Establishing the clinic under real-world conditions was critical so that as many mental health consumers as possible could participate. The high volume of clients seen in the community mental health centre, lack of physical space and resources, and embedding the clinic within the service over many months, meant that conducting a pragmatic randomised control trial was not possible. Given the need to formally evaluate the success of similar programs in mental health services, future studies should consider more rigorous evaluation methodologies.

Furthermore, the exercise physiology clinic operated under real world conditions, and clinicians needed to ensure that mental health consumers were not unduly inconvenienced, such that outcome measures were not always able to be obtained. This contributed to the numbers of participants that did not have follow-up outcome measures and reduced the data available for analysis. Due to the clinic operating under real-world conditions with consumer-focused clinical services the primary focus, conditions usually implemented within clinical research studies were not strictly adhered to within this evaluation. For example, the mean time between baseline and follow-up measurements were widely variable, and as such additional factors may have influenced changes in outcome measures such as medical illness, medication changes, clinical input from other medical professionals, among others. Such limitations should be considered in future evaluations of real-world clinical services with wide varying follow-up timepoints.

Recommendations for Future Practise

When implementing physical activity programs in mental health settings best-practise, evidence- based principles should be applied (17, 35). The clinic in this study implemented many evidence-based elements, including individualised programs tailored to participant needs and goals, expert supervision provided by exercise professionals specialising in mental health, routine metabolic monitoring, and regular sessions focused on behaviour change strategies (12, 13). Future studies implementing an exercise physiology clinic for community-based people living with severe mental illness should consider options for improving the rigour of the outcome assessment methodology, collaboration with mental health services and participant retention. Additionally, future services should incorporate well-structured mental health dietetic components alongside exercise physiology services in addition to other interventions such as metformin which have proven successful for weight loss in similar population groups (40, 41). Future studies would also benefit from examining other factors which may be associated with physical activity improvements including psychological well-being, adherence to treatment, reduction in emergency department presentations, and improvements in mental state.

CONCLUSION

The implementation of an exercise physiology clinic for consumers within a community-based mental health service was feasible. Such services can improve moderate-to-vigorous physical activity levels and sedentary time for people living with severe mental illness, however further research is needed to determine whether weight reduction and increased fitness levels can also be achieved. When implementing an exercise physiology clinic, programs should be designed in a collaborative approach considering the individual needs of mental health consumers. Given the high level of consumer engagement, potential to improve the physical and mental health of consumers, and cost-effectiveness of physical activity programs, community-based mental health services should consider developing physical activity services lead by exercise professionals as part of routine care.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by South Eastern Sydney Local Health District (SESLHD) Human Research Ethics Committee. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

HF, LE, and OL delivered the intervention. HF, RM, OL, and PW performed data analysis. All authors contributed to the development of the publication.

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BRIEF RESEARCH REPORT
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The Implementation and Review of Cognitive Remediation Training for First Episode Psychosis in Singapore

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Objective: Early intervention in patients with first episode psychosis (FEP) can improve cognitive abilities, with both short- and long-term benefits. In this paper, we describe the implementation and review of cognitive remediation training (CRT) in an Asian FEP population. The outcomes of the training are also evaluated and discussed.

Methods: This naturalistic paper describes in detail the real-life implementation and conduct of CRT in an early psychosis intervention service. One hundred and nine patients with FEP underwent a 24-session CRT programme, using Cogpack and Neuropsychological Educational Approach to Remediation. The program is evaluated with pre- and post-CRT assessment scores which included Montreal Cognitive Assessment and Brief Assessment of Cognition in Schizophrenia. The rates of improvement on these cognitive assessments were evaluated using paired *t*-tests, with statistical significance set at $p \leq 0.05$.

Results: Of the 109 patients who underwent CRT, a total of 92 (84.4%) completed all 24 sessions. Paired *t*-tests between pre- and post-CRT assessments scores revealed that participants significantly improved on majority of the measures, including verbal memory, digit sequencing, and symbol coding.

Conclusion: As with other cognitive remediation programmes, CRT has shown to improve cognitive functioning in patients with FEP. The results support the use of CRT in an Asian context and may serve as guidance for the implementation of similar training programmes in other Asian early psychosis intervention services.

Keywords: schizophrenia, first-episode psychosis, early intervention programmes, cognitive remediation, cognition

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INTRODUCTION

Schizophrenia and other psychotic disorders belong to a spectrum of primary psychotic disorders in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (1), and patients with psychosis present with neuropsychiatric disturbances including hallucinations, delusions, thought disorders, abnormal psychomotor behaviours, negative symptoms, cognitive impairments, and emotional disturbance (2). In the most recent Singapore Mental Health Study, Subramaniam and colleagues found that the lifetime prevalence of schizophrenia and other psychotic disorders in Singapore's adult population stands relatively low at 2.3% (3). However, schizophrenia is a chronic and severe mental disorder that has a profound impact on the individual and society. Although treatment has greatly advanced and outcomes may not be as uniformly negative as previously believed, over half of individuals with schizophrenia have intermittent but long-term psychiatric problems, and about 20% have chronic symptoms and disability (4). Following psychotic episodes, negative symptoms are commonly present and associated with cognitive impairments (5) and psychosocial disabilities. Therefore, it is not surprising to find unemployment at staggeringly high rates of 80–90% in some populations (6, 7). Furthermore, life expectancy is reduced by 10–20 years as compared to the general population (8, 9), largely due to increased cardiovascular-related morbidity and mortality (10), and contributed in part by an increased risk of suicide (11) and violence (12). These are the main reasons why this relatively infrequent disorder is responsible for the 6th largest share of disability adjusted life years (DALYs) in adults in Europe, and the 3rd largest of all brain disorders worldwide (13). In Europe, the total cost to society was 93.9 billion euros in 2010, and only the cost for mood disorders and dementia were higher amongst all brain disorders (13). In England, schizophrenia was found to cost society 11.8 billion pounds per year, equating to an average annual cost to society of about 60 thousand pounds per person (14).

Even on its first presentation, schizophrenia can lead to cognitive deficits similar to those found in chronic schizophrenia (15). Domains of cognition found to be affected include attention, working memory, verbal memory, and verbal fluency information processing (16). If left untreated, first episode psychosis (FEP) may result in poorer clinical and treatment outcomes (17), such as prolonged positive symptoms at 3, 6, and 12 months of treatment (18), lower rates of employment, and poorer global functioning (19).

While the severity of psychosis is concerning, appropriate interventions such as cognitive remediation (CR) can improve patients' cognitive abilities. Medalia and Choi described CR as an evidenced-based non-pharmacological intervention for cognitive deficits present in schizophrenia, encompassing cognitive drills or compensatory interventions to improve cognition (20). A randomised clinical trial conducted by Christensen studied the use of CR in conjunction with early intervention programmes, and showed that the addition of CR brought both short- and long-term improvements in both cognition and symptomology (21). With regard to symptomology, CR has been shown to exert greater effects in terms of negative symptoms (22, 23). CR has also shown improvement in functional outcomes (24), albeit with varying results (25).

To date, most of the publications on cognitive remediation training (CRT) in psychosis have been from Western countries, and literature from Asian societies have been limited. In a 2016 review by Tan and Liu (26) examining eight original papers on the research and clinical practice of CRT in China, the authors concluded that all papers reported some beneficial effects on cognitive functions, with three of them showing benefits on social functions. This study aimed to describe the conduct of CRT in an Asian early psychosis intervention service and evaluate the outcomes of CRT on individuals with FEP, by comparing pre- and post-CRT cognitive assessment scores.

METHOD

The Singapore Early Psychosis Intervention Programme (EPIP) is a nationwide programme, which was launched in 2001 at the Institute of Mental Health (IMH), the only state psychiatric hospital in Singapore. Patients accepted into EPIP fulfil the following criteria: (a) age between 12 and 40 years old inclusive, (b) first-episode psychotic disorder with no prior or minimal treatment, and (c) psychotic disorder that is not secondary to a general medical condition or substance use. Psychotic Disorder is defined as meeting the Diagnostic and Statistical Manual of Mental Disorders IV-TR (DSM-IV-TR) (27) criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief psychotic disorder, psychotic disorder not otherwise specified, or mood disorders with psychotic features. Intensive multidisciplinary care for patients presenting with first episode psychotic disorders is provided by EPIP in the initial 3 years, following which patients are transferred to other psychiatric services for continued care. Psychopharmacological treatment is based on a treatment algorithm that emphasises the use of antipsychotic monotherapy. Clozapine is considered in treatment-resistant patients who have failed at least 2 adequate trials of different antipsychotics, of which one should be a non-clozapine atypical antipsychotic. Depot medications are considered when medication non-adherence is identified. Adjunct medications such as antidepressants and mood stabilisers are used to treat comorbid anxiety and mood symptoms. Each patient has a case manager who provides supportive counselling, psychoeducation, and coordination of various services, while also ensuring continuity of care through the different phases of the illness. If required, patients are also referred for individual or group interventions with a psychologist, family therapist, occupational therapist (OT), or peer support specialist.

EPIP maintains an on-going database registered with the Singapore National Healthcare Group (NHG), capturing clinico-demographic data prospectively and maintaining data integrity through stringent and regular quality cheques. Ethics approval was obtained for the maintenance of this database. Patients are informed that routine data collected will be used for research and service evaluation purposes and those who disagree will still receive the relevant clinical services but not have their data collected. Each patient's duration of untreated psychosis (DUP) and diagnosis according to the DSM-IV-TR are assessed by their treating psychiatrist at baseline. Other rating scales are also administered at fixed time points (baseline, 3, 6, 12, 24, and 36 months). The Positive and Negative Syndrome Scale (PANSS) (28) is rated by the treating psychiatrist, and is a 30-item instrument consisting of three subscales—positive, negative, and general psychopathology. Each item is rated on a seven-point Likert scale, on which a higher score indicates a higher level of psychopathology. The Global Assessment of Functioning (GAF) scale (27) is rated by the treating psychiatrist, and consists of three subscales as well—total, symptom, and disability. Each subscale has a range of 0 to 100, on which the patient's level of functioning is rated, where higher scores indicate higher functioning.

CRT is offered as part of the programme to all suitable patients who have cognitive difficulties. CRT in EPIP makes use of the Cogpack (Marker Software®) (29) program and components from Neurocognitive Educational Approach to Remediation (NEAR), with the inclusion of group sessions to encourage social interactions and synthesise learning. Cogpack has shown to effectively improve cognitive functioning in several international randomised controlled trials (30–32), which contains structured neurocognitive exercises grouped into themes, such as attention, memory, speed of apprehension, visual motor, and reaction. These exercises are targeted at training certain domains of cognition that are typically hindered in schizophrenia (attention, working memory, verbal memory, verbal fluency, psychomotor speed, and executive function). NEAR takes on CR as a type of education (33), with stresses on short- and long-term goals that require patients to be insightful and motivated (34). There is also emphasis on patients to recognise the socio-emotional context of this approach and how it affects cognitive function (34). This can be done by organising group sessions that allow patients to interact with others and hone cognitive skills collectively (35). NEAR has shown to improve cognitive functions, namely processing speed (36), attention (37), and immediate learning and memory (38). The OTs running CRT have been trained in NEAR. As identified by Bowie et al. (39), Cogpack and NEAR are considered to be cognitive exercises, one out of the four core techniques in CR. Another core technique identified in the same study is the active involvement of a therapist, which would bring greater benefits for patients. This is practised in EPIP, with the help of experienced OTs, tailoring CRT sessions to each patient's progress and needs.

CRT in EPIP is an individualised 24-session programme that is delivered over a period of 3 months, with two sessions per week and each session lasting 1.5 h. It is delivered in a group with a maximum of five clients in a session. The same five clients are grouped together for all the 24 sessions. Through this, OTs were able to facilitate social skills norms and this helped to facilitate social communication, bonding and friendships amongst the group participants. A combination approach of both drill and practise as well as strategy coaching is adopted in the sessions. CRT initially starts out using Cogpack, making use of its repetitive drilling exercises. Cogpack is a software constituted by 64 exercises classifiable as domain-specific exercises and non-domain-specific exercises. The former act on individual skills such as verbal memory, verbal fluency, motor coordination, sustained attention, selective attention, working memory, and executive functions. The non-domain-specific exercises do not focus on one specific cognitive domain, but require the use and simultaneous involvement of aspects such as language, culture, and basic logical and mathematical skills. The exercises may be administered randomly and have their difficulty level adjusted by the computer on the basis of the performance in the course of sessions, so as to prevent the patient carrying out exercises that are too simple or excessively difficult (40). Exercises are selected by OTs to train individual domains of cognition, or combined exercises involving the use of multiple domains at once can be selected as well. OTs had gone through all the exercises in Cogpack and those that were not culturally relevant to the Singapore context were skipped but these were minimal. At times teaching of new words in relation to pictures were also facilitated by the OTs during the session as this promoted learning and facilitated recall which is linked to memory. OTs assess patients and tailor CRT in collaboration with the patient, by increasing or lowering the difficulty in accordance with each patient's progress. The exercises are built in a hierarchical manner starting with attention, processing speed, and reaction, and moving on to memory and problem solving. Cogpack displays the results after each exercise, showing patients their performance thus far. Encouragement and support are provided to patients. NEAR principles emphasise that the clients have a positive learning experience, they have a positive attitude about learning and that the games promote optimal cognitive functioning. Some of the NEAR games are Carmen Sandiego, Hot dog stand and Fripple Place. At EPIP commercial computer, board, or card Games using NEAR principles are brought in for patients who are assessed to have made sufficient progress. Bridging sessions are also a core component where patients discuss about the game and strategies they employ, and these are contextualised to their role and real-life situations. This not only facilitates social interaction amongst patients and the OT, but also transferability of skills learnt in sessions to real life situations (35). During and after each session, patients are required to record their own progress, by noting down what the activity involved and how they performed. They also set targets which serve as motivation for subsequent sessions. Individual review sessions are also conducted once a month with patients to highlight their progress, get feedback on how they are feeling and how they view the sessions and goals set for themselves.

Participants in the present study were receiving EPIP services and assessed to be suitable for CRT by their treating psychiatrist. Prior to commencement of CRT, level of participation in other psychosocial groups and source of motivation (whether the participation was of the patient's own volition, i.e., "self," or if it was imposed upon by their caregiver, i.e., "enforced") was also noted for each patient. There were no external rewards, monetary or otherwise, provided to incentivise patients to complete CRT. Pre- and post-CRT assessments, including the Montreal Cognitive Assessment (MoCA) (41) and Brief Assessment of Cognition in Schizophrenia (BACS) (42), were conducted by trained OTs and documented as well. In our naturalistic study, all consecutive patients who had presented to EPIP with FEP and underwent CRT, from February 2012–December 2019 inclusive, were included for analysis.

Statistical analyses were performed using IBM Statistical Package for Social Sciences (SPSS) 23. Continuous variables include age, DUP, PANSS positive, negative, and general psychopathology scores, and GAF symptom and disability scores. Categorical variables include gender, ethnicity, highest educational level, level of participation in other groups, source of motivation, baseline functioning status, and baseline DSM-IV diagnosis. Outcome measures include pre- and post-CRT

TABLE 1 | Baseline sociodemographic and clinical characteristics of patients who participated in CRT.

	CRT completed		Total ($n = 109$)	*P*-value
	Yes ($n = 92$)	No ($n = 17$)		
Age – years, mean (SD)	24.8 (5.7)	24.7 (4.9)	24.8 (5.6)	0.916
Gender – no. (%)				
Female	44 (47.8)	10 (58.8)	54 (49.5)	0.405
Male	48 (52.2)	7 (41.2)	55 (50.5)	
Ethnicity – no. (%)				
Chinese	72 (78.3)	12 (70.6)	84 (77.1)	0.032*
Malay	13 (14.1)	0 (0.0)	13 (11.9)	
Indian	6 (6.5)	4 (23.5)	10 (9.2)	
Others	1 (1.1)	1 (5.9)	2 (1.8)	
Highest education – no. (%)				
Primary	1 (1.1)	1 (5.9)	2 (1.8)	0.390
Secondary	37 (40.2)	7 (41.2)	44 (40.4)	
Tertiary	54 (58.7)	9 (52.9)	63 (57.8)	
Participation in other groups – no. (%)				
Yes	53 (57.6)	4 (23.5)	57 (52.3)	0.010**
No	39 (42.4)	13 (76.5)	52 (47.7)	
Motivation – no. (%)				
Self	64 (69.6)	2 (11.8)	66 (60.6)	<0.001**
Enforced	28 (30.4)	15 (88.2)	43 (39.4)	
Baseline functioning status – no. (%)				
Age-appropriate role or employment	8 (8.7)	2 (11.8)	10 (9.2)	0.844
In training	1 (1.1)	0 (0.0)	1 (0.9)	
Unemployed	83 (90.2)	15 (88.2)	98 (89.9)	
Baseline DSM-IV diagnosis – no. (%)				
Schizophrenia spectrum	58 (64.4)	12 (70.6)	70 (65.4)	0.769
Mood disorders with psychotic features	6 (6.7)	0 (0.0)	6 (5.6)	
Delusional disorder	2 (2.2)	0 (0.0)	2 (1.9)	
Brief psychotic disorder and psychotic disorder not otherwise specified	17 (18.9)	4 (23.5)	21 (19.6)	
Others	7 (7.8)	1 (5.9)	8 (7.5)	
DUP – months, mean (SD)	9.3 (18.8)	4.7 (5.0)	8.5 (17.3)	0.324
PANSS – mean (SD)				
Total	82.2 (26.0)	85.9 (20.4)	82.8 (25.1)	0.578
Positive	20.5 (7.5)	22.2 (4.9)	20.8 (7.1)	0.380
Negative	18.9 (9.1)	18.8 (8.9)	18.9 (9.0)	0.967
General psychopathology	42.7 (14.0)	44.9 (12.2)	43.1 (13.7)	0.555
GAF – mean (SD)				
Total	40.9 (13.0)	39.9 (11.2)	40.8 (12.7)	0.774
Symptom	41.6 (13.4)	40.2 (10.6)	41.4 (13.0)	0.682
Disability	42.7 (12.1)	41.0 (11.1)	42.4 (11.9)	0.587

*$p \leq 0.05$; **$p \leq 0.01$.

assessments scores (including the MoCA and BACS). The rates of improvement on CRT assessments were evaluated using paired t-tests. Statistical significance was set at $p \leq 0.05$.

RESULTS

The mean (SD) age for the overall study sample was 24.8 (5.6), of which nearly half (49.5%) were female and majority (77.1%) were Chinese. Out of the 109 patients who participated in CRT from 2012 to 2019, a total of 92 (84.4%) completed the full 24-session therapy. The baseline sociodemographic and clinical information of the sample, comparing between the groups who did and did not complete CRT, is presented in **Table 1**. Of note, the two groups differed significantly on their participation in other groups and source of motivation. Although the two groups also appeared to differ in terms of ethnicity, this is likely because for the Malay participants, all 13 of them had successfully completed CRT, as compared to the other ethnicities.

TABLE 2 | Paired *t*-test results for CRT assessments scores.

	Mean difference	95% CI	*P*-value
MoCA	2.02	1.41–2.63	<0.001*
Verbal memory	6.57	4.68–8.45	<0.001*
Digit sequencing	1.86	1.15–2.56	<0.001*
Token motor task	3.64	1.05–6.23	0.006*
Semantic fluency	1.28	−0.07 to 2.64	0.063
Symbol coding	3.95	2.18–5.71	<0.001*
Tower of london	1.65	0.84–2.47	<0.001*
BACS composite *z*-score	0.76	0.59–0.93	<0.001*
BACS composite *t*-score	7.60	5.92–9.28	<0.001*
Trail making test A	−4.88	−8.10 to −1.66	0.003*
Trail making test B	−15.94	−27.29 to −4.59	0.007*

*$p \leq 0.01$.

Normality was assumed due to the sample size, and paired *t*-tests (**Table 2**) between pre- and post-CRT assessments scores revealed that participants significantly improved on majority of the measures, except on the Semantic Fluency item. As the scores for the Trail Making Tests are operationalised by time taken to complete the task, the negative mean difference represents a positive result.

DISCUSSION

Four core features of CR were identified in a white paper by Bowie and colleagues: a trained therapist, cognitive exercise trainings, attention to the development of strategies, and procedures to facilitate transfer to real world functioning (39). The current paper detailed the implementation of CRT in EPIP and illustrated how these four core components were fulfilled. The CRT sessions were held twice a week with a total training duration of 36 h, meeting the effective intensity and durations found by Bowie et al. (39), whereby effective programmes call for two to three sessions per week, with total training durations ranging from 20 to over 40 h. Our duration surpassed recommendations by Hooker et al. (43) that 25–30 h of cognitive training is required for cognitive benefits. A mixed approach of drill and practise with strategy coaching was utilised. The bridging sessions facilitated transferability of skills taught in the classroom-like setting to the real world. This contextualisation increased patients' interest, enabling them to make connections and linkages to their everyday functioning, and aided them in forward planning and goal setting.

A major strength of our study was that we naturalistically examined a large cohort of patients with FEP who underwent CRT, looking at data collected over a span of seven years. We were able to utilise data from the EPIP database, which is an on-going registry capturing information prospectively. The variables collected are clearly defined and objectified using standard psychiatric rating instruments; and data integrity is subjected to stringent and regular quality cheques by the nation's relevant governing body. However, as with naturalistic studies, the OTs running the sessions were the ones who conducted the pre and post assessments. As such, there could have been potential for bias, even though this was minimised by ensuring that well-established, standardised and validated test instruments were used, and the OTs conducting the cognitive assessments had the necessary prerequisite training.

Our results were consistent with existing literature which indicates that CRT has beneficial effects on the cognitive abilities of patients with early psychosis. A limitation to our study was that there was no follow up data to see if the cognitive changes were sustained after completion of CRT. A study conducted by Buonocore et al. (44) demonstrated stable cognitive abilities 5 years after treatment completion, with the exception of psychomotor speed and coordination. Buonocore made use of Cogpack, similar to our CRT, which provides some assurance of its long-term results. It was interesting to note that participants who completed CRT had significant improvements on all measures except for semantic fluency. For semantic fluency, participants are required to generate as many words as possible from a given semantic category within a limited time. The role of executive functioning increases with the degree of retrieval difficulty, and more strategic planning is required. Impairments in semantic fluency are typically either related to blunt executive functioning (lack of sustained retrieval management), or to a breakdown of semantic knowledge (associated with semantic/conceptual memory disruption or/and storage shrinkage) (45). Our findings appeared to differ from other studies where improvements in semantic fluency were noted post-CRT (46). It is possible that the MoCA was not sensitive enough to pick up changes in an Asian FEP population where albeit being English-literate, English may not be the main conversational language. It is certainly worthwhile exploring this further in a controlled trial with a larger sample size.

There was a high completion rate of CRT, and amongst those who completed CRT, a significant majority were self-motivated and participated in other psychosocial group activities. Although this may indicate an intrinsic motivation which naturally leads to better outcomes, it is noteworthy that motivation was the only significant factor associated with completion of CRT, and suggests that services should place emphasis on increasing both intrinsic and extrinsic motivation during the course of CRT, and examine this relationship further with more robust methodologies. In a meta-analysis by Medalia and Saperstein (47), outcomes of NEAR have strong correlations to participants' motivation. As NEAR is part of CRT, EPIP has adopted various methods to raise the motivation of participants. Patients can voice their opinions and wishes, and are actively involved in goal-setting and decision-making for each session. Having autonomy and being empowered to share their thoughts and feelings have shown to raise participants' intrinsic motivation (48), as well as promote interest (49), thereby keeping them engaged with CRT. Each session is also facilitated by an actively involved OT, who adjusts sessions according to each patient's individualised progress, and utilises an appropriate scaffolding approach as the patients advance through the sessions and cognitive tasks (49). The sessions are contextualised and personalised for each patient, engaging and allowing patients to have a sense of control over their learning process. The level of difficulty is adjusted accordingly for "just enough" challenge to be presented to the patients for every session and this helps to promote self-perceived competence which increases their motivation in the sessions.

A systemic review by Reser et al. (50) had indicated that CRT improved working memory in younger but not older participants. It was also mentioned that reasoning, problem solving, and working memory were strongly predictive of within-domain improvement, and that training task progress was a strong cross-domain predictor of cognitive outcome. A meta-analysis on computer-assisted CR (CACR) by Grynszpan et al. (51) noted significant effect sizes on processing speed, attention, working memory, and verbal learning and memory. A more recent multi-outcome meta-analysis by Kambeitz-Ilankovic et al. (52) studied outcomes of CACR alone and CACR with supplementary human guidance, which demonstrated similar outcomes to Grynszpan, with the addition of social cognition, reasoning, and global cognition. Looking to an Asian population, an evaluation on CACR was conducted in Hong Kong and found that CACR improves neurocognition (53).

What aids the efficacy of CRT, which patient characteristics would ideally benefit from it, and its long-term effects is still being explored and debated upon (54). While our study has demonstrated how CRT can be implemented in an Asian early intervention service and adds to the limited body of literature assessing CRT in an Asian FEP population, further studies will need to be conducted to maximise the gains from CRT.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

NC: writing–original draft. YM: conceptualisation, methodology, investigation, writing–review & editing, and supervision. YC: formal analysis, data curation, and writing–review & editing. CT: conceptualisation, methodology, writing–review & editing, and supervision. All authors contributed to the article and approved the submitted version.

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STUDY PROTOCOL
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Volunteering *via* Smart-Phone for People With Psychosis—Protocol of a Feasibility Trial

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The literature suggests that volunteering can be used to address social isolation and support patients with psychosis in the community. However, many expect in person meetings, requiring a greater effort of availability and commitment. There is therefore a need for more flexible, easily accessible support. Volunteering *via* smart-phone could be a useful intervention for people with psychosis. One patient and one volunteer have been matched for a duration of 12 weeks, and participants have been encouraged to communicate through a variety of communication methods (audio calls, video calls, text messages, WhatsApp messages and e-mails). The Phone Pal study aimed to investigate the feasibility of recruitment, participant retention, data collection procedures, intervention usage of the methods of communication and changes in outcome data. At baseline and follow-up outcome measures collected from patients and volunteers included their quality of life, physical activity, self-esteem and social comparison. Additional outcomes assessed patients' attachment, social contacts and symptoms; for volunteers, their social distance was evaluated. At follow-up both patients and volunteers rank their perception of their relationship with each other. This mixed method feasibility study has been conducted in two phases, the first stage evaluating a smaller sample of patients and volunteers recruited in London, and then a second phase with a larger sample of volunteers recruited from across the United Kingdom.

Trial registration: ISRCTN17586238.

Keywords: volunteering, smart-phones, remote, communication, digital mental health, psychosis, intervention, trial

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INTRODUCTION

Health-promotion interventions that increase engagement in lifestyle changes can offer potential health benefits across the lifespan, including to people with severe mental illness (SMI) (1). Amongst such interventions, one-to-one face-to-face volunteering in mental health, which already exists in the community, can be a way to promote social relationships in patients and positive attitudes toward people with SMI in volunteers (2, 3). Current evidence indicates improvements in patients' and volunteers' physical and mental health (4, 5). In spite of this, existing volunteering programmes seem to be inflexible (6) and disregard people's preferences and the challenges they encounter to physically meet (e.g., long distances and busy agendas); how modern technology is integrated into everyday life is overlooked.

A study investigating the choice of technology-based communication tools (e.g., e-mail, phone or face-to-face modalities used by the general population to communicate with their closest ties) described it as dependent on their skills, modality availability and location of their contacts (7). Patients with psychosis increasingly own technological devices such as mobile phones (8) and are using them to digitally connect (9). A meta-analysis of people with symptoms of psychosis revealed that the prevalence of phone ownership was rapidly increasing, with 81.4% ownership amongst those surveyed in 2014 and 2015 (10). Digital tools may enhance how patients and volunteers establish and maintain a relationship in a volunteering programme. This may have a positive effect in the level of community involvement, connecting people with SMI with others, such as volunteers. For people with psychosis, who often fear and avoid social interaction, speaking to a volunteer they do not know over the phone and engaging in mutual support toward a healthy lifestyle may encourage them to find new ways to interact, be reciprocal, establish more secure attachments and become more physically active. Volunteering provided remotely over smart-phones could be a route to these improvements.

To explore this, the "Phone Pal" intervention has been designed following the person-based approach and the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (11). The "Phone Pal" enables patients to use a smart-phone to communicate with a volunteer through text, WhatsApp messages, e-mails, audio or video calls, thus enabling the participant to conduct informal conversations and promoting mutual encouragement toward a healthy lifestyle for a duration of up to 12 weeks (12).

According to the MRC guidelines, a feasibility study should be the next step to elucidate how the intervention works in practice. It is typical for feasibility studies to use more flexible methodology, such as an observational design, since the aims focus on evaluating acceptability and feasibility of intervention and study procedures (13). It is therefore unnecessary to use control groups and to randomize participants at this early stage in the intervention development process, although this may be necessary in a later pilot study (13) that precedes the randomized controlled trial (RCT). It is therefore important to establish the perceived acceptability of this intervention, and to evaluate the feasibility of conducting a trial.

Aim and Objectives

The aim of this mixed methods feasibility study has been to address the uncertainties regarding the feasibility of the intervention and the study procedures.

The specific objectives have been as follows:

- To evaluate the feasibility of the following study procedures:
  - recruitment, including time to recruit
  - eligibility criteria and resulting sample characteristics
  - matching patients and volunteers
  - study retention and follow-up
  - data collection procedures and outcome measures, including missing data.
- To explore the usage of the intervention in terms of:
  - acceptability of, and adherence to, the intervention
  - patterns of intervention use.
- To investigate the acceptability of, and participants' response to the intervention by assessment of:
  - changes in outcome data and estimate of the variability of outcome measurement
  - participants' views and experiences of the intervention relating to the initial training received, access to support throughout the study, and the wider study procedures.

METHODS

Design

A single center, pre-post, single arm, mixed methods feasibility study with two phases. The first with a small sample of patients and volunteers recruited in London; the second phase incorporating a larger sample with volunteers recruited nationwide.

A pre-post design with some process measures was chosen as the most appropriate method for addressing the study objectives. Since this has been within the initial stage of intervention development and testing, a single center was deemed as the most practicable setting. The follow-up involved quantitative assessments, data usage analysis and in-depth qualitative interviews. This evaluation planned to cover the perspective of the participants (i.e., patients and volunteers), and a system analysis of smart-phone data usage collected by two apps "mspy" and "accupedo pedometer—step counter". The utilization of multiple methods allows for a more complete and thorough understanding of feasibility questions in the target population (14, 15), using a combination of self-reported and observed behavioral measures (16).

The first phase included 6 participants ($n = 3$ patients, $n = 3$ volunteers). If feasible, and allowing for further refinements provided by participants' feedback, a subsequent full study with another 30 participants ($n = 15$ patients, $n = 15$ volunteers) would be carried out.

Study Materials

The study title "Phone Pal" was incorporated throughout all materials relating to the study. The researcher's goal was to use attractive and relevant imagery for the logo and study materials, which the lead author designed personally and with the objective of approximating the principle of similarity (17). The patients' and volunteers' advisory groups provided feedback to the study advert design, i.e., to make them interesting and appealing, and advised on the wording of the participant facing documents to ensure that the information was clear and understandable.

Ethical Approval

The regulatory approvals to conduct this study were required by the lead author in her role as Chief Investigator (CI) and local Principal Investigator (PI), with the Health Research Authority (HRA) and local governance office of East London NHS Foundation Trust (ELFT).

The lead author presented the study to the East of England—Cambridgeshire and Hertfordshire Research Ethics Committee (REC reference: 18/EE/0196) on 12 June 2018. HRA approval was received on 7 September 2018. The study was then registered in the International Standard RCT Number (ISRCTN) database (ISRCTN17586238).

Further to the first stage of this study, and given the wide expression of interests received from volunteers from outside London, a minor amendment was requested on 20 February 2019 and approved on 1 March 2019 to recruit volunteers across the country, and to have support from other researchers to undertake participants' assessments.

Recruitment and Sampling

Owing to the nature of the intervention, aiming to connect people in the community, it was most appropriate to recruit people with psychosis who are followed in outpatient community services, together with community volunteers. A range of recruitment strategies have been used (**Figure 1**). All patients have been recruited from ELFT. Volunteers have been recruited in London for the first phase of the study, and across the country for the subsequent phase.

Study Set-Up

General Procedures

Preparations were made well in advance, recruitment activities were discussed with the NHS Trust and the volunteering associations at the development stage of this work.

Researchers' Training

Scripts were developed containing key instructions for approaching potential patient participants, and for training them on the intervention usage. The lead author provided these to the two researchers trained by the lead author to provide support with patient assessments.

In addition, all researchers received training in the Brief Psychiatric Rating Scale (BPRS) in order to be able to assess patients. The training consisted of: (i) formal teaching with the support of PowerPoint presentations that introduced the BPRS rationale, interview characteristics, description and scoring items, and (ii) video-training comprising four video-taped BPRS clinical case interviews with reference "standard" ratings previously defined. For quality assurance each BPRS interview was discussed with the lead author.

Patient Participants

The study was set up in ELFT, with the lead author as local Principal Investigator (PI). The lead author attained approvals through NOCLOR research support (www.noclor.nhs.uk) from three separate local boroughs, i.e., City and Hackney, Tower Hamlets and Newham to recruit people with psychosis followed in these community mental health teams (CMHTs).

Study adverts were given in person or sent by e-mail to clinicians and clinical study officers and were also placed in the waiting areas of clinical settings in CMHTs in ELFT.

Volunteer Participants

The study was disseminated through adverts, mailing lists and social media. Study adverts were placed in East London through flyers, posters displayed in public spaces in community venues, e.g., local libraries, charities, community centers and universities. The study was also advertised by e-mail *via* mailing lists or e-newsletters of volunteering organizations or universities or distributed online *via* social media including Twitter and Facebook.

In the first and second phases of this study, volunteers were recruited in London and from across the country, respectively.

Eligibility Criteria

Inclusion Criteria

Patient Participants

- 18 years or over
- Clinical diagnosis of schizophrenia or a related psychotic disorder (ICD 10: F20-29)
- Interested in having a volunteer with whom they would be in contact primarily through a smart-phone for 12 weeks
- Receiving care in secondary NHS mental health services
- Have the capacity to provide informed consent
- Sufficient command of English to complete the measures.

Volunteer Participants

- 18 years or over
- Interested in having a patient with whom they would be in contact primarily through a smart-phone for 12 weeks
- Have the capacity to provide informed consent
- Sufficient command of English to complete the measures.

Exclusion Criteria

Patient and Volunteer Participants

- Failure to meet any of the inclusion criteria
- Unable to use smart-phones even if provided with appropriate assistive technology.

Screening and Initial Approach

A screening log has been maintained throughout the study, using Microsoft Excel 2010, to monitor participants' progress and the feasibility of recruitment and retention.

Patient Participants

Potential patient participants have been identified by the clinical team, the clinical study officers and the researchers or could self-refer.

- Clinicians have been provided with the study information sheet containing the contact details of the researcher and have been encouraged to approach patients with psychosis directly. Clinicians informed patients about the study during routine clinical meetings and invited patients to take part.
- Clinical study officers screened RiO, the electronic patient record system used at ELFT, for patients with psychosis. On meeting these patients in person in CMHTs, they invited them to take part in the study. Clinicians and clinical study officers could pass on patient details to the researcher or could encourage patients to self-refer.

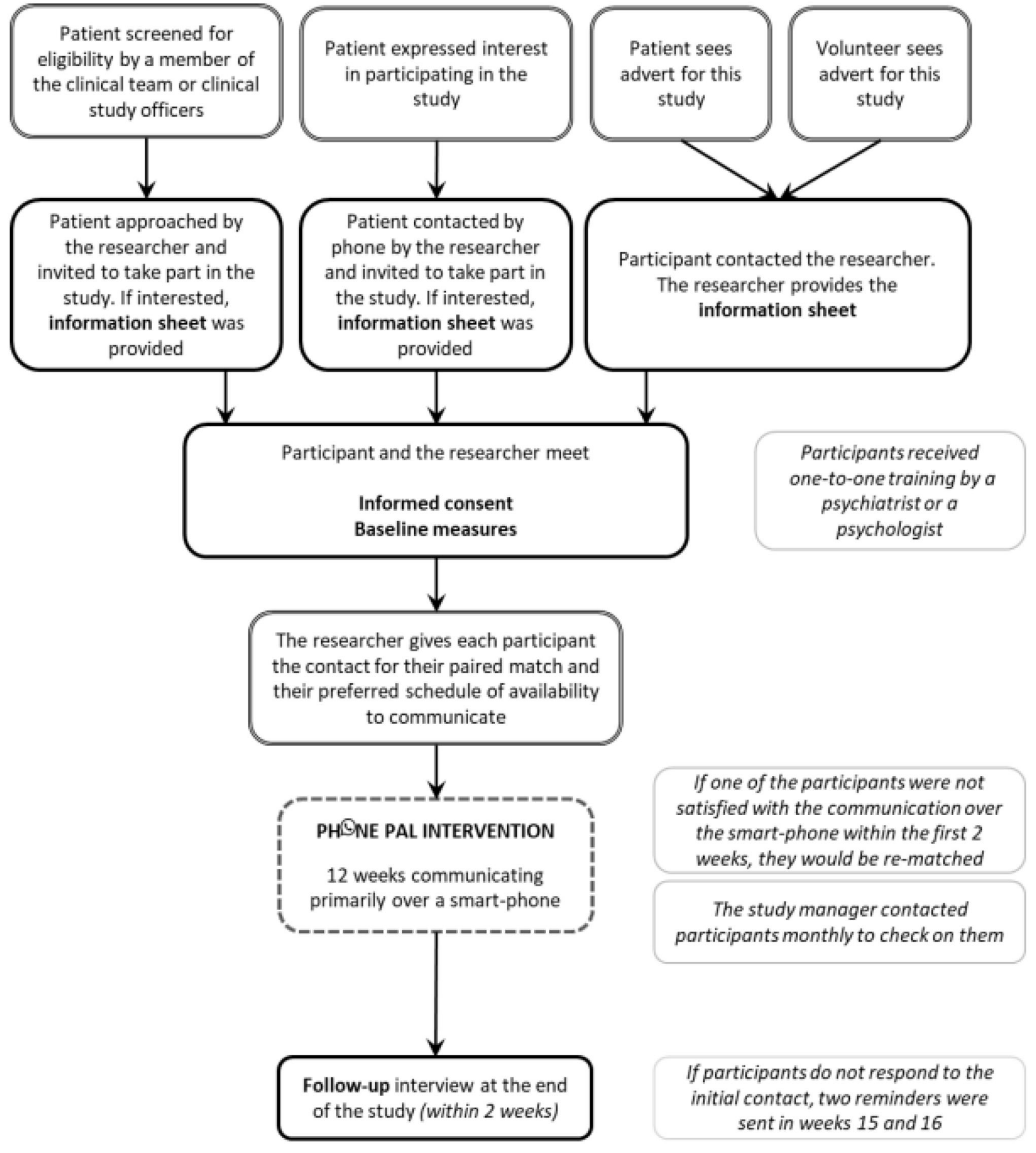

FIGURE 1 | Diagram of study procedures.

- A purposive sample of patients from ELFT outpatient services who had already expressed willingness for future contact in future research were contacted over the phone by the lead author and invited to take part in the Phone Pal study.
- Patients that saw the advert in the CMHT could also self-refer to the study. After speaking with the patients over the phone, the researcher would check in RiO to establish whether the patient met the study inclusion criteria, and then contact patients back to confirm.

Over the phone, the researcher explained the content of the study, covering the information described in the information sheet. Patients were invited to take part and were provided with an opportunity to discuss the study and to ask questions. Patients that were interested in the study were then invited to meet the researcher in person.

Volunteer Participants

- Potential volunteer participants that saw the advert and were interested in the study have been able to self-refer and to contact the researcher over the phone or *via* e-mail to express their interest.

Over the phone, the researcher explained the content of the Phone Pal study, covering the information described in the information sheet. Potential volunteers were invited to participate and were provided with an opportunity to discuss the study and ask questions. Information sheets were sent *via* e-mail. Individuals that met the inclusion criteria and maintained interest in the study were invited to meet the researcher in person.

Consent and Enrolment

Patient Participants

In the face-to-face interview with the researcher, the patient was taken through the study information sheet and received detailed explanations about the intervention. It was ensured that they understood what their participation involved and that they agreed that their study-provided smart-phone communication with the volunteer was going to be checked (i.e., for patterns and frequency of the audio and video calls, and the content of any written messages).

At this initial face-to-face meeting, which occurred at ELFT facilities or other location of their convenience, participants also provided written informed consent. As further described, this was followed by the collection of baseline measures including communication usage and preferences, training and receiving £10 as a token of appreciation. The patient participant was then enrolled in the study and paired with their matched volunteer.

Volunteer Participants

In the face-to-face interview with the researcher, each individual was taken through the study information sheet, and received detailed explanations about the intervention and their role as a volunteer. They were also assessed for their suitability to participate. It was ensured that they understood what their participation involved and that their study-provided smart-phone communication with the patient was going to be checked (i.e., for patterns and frequency of the audio and video calls, and the content in any written messages).

At this initial face-to-face meeting, which occurred in the facilities of ELFT, Queen Mary University of London (QMUL), or other location of their convenience, participants provided written informed consent. This was followed by the collection of baseline measures, including communication usage and preferences, training and receiving £10 as a token of appreciation. The volunteer participant was then enrolled in the study and paired with their matched patient.

Training

Patient Participants

In the first phase of the study, the lead author provided individual one-to-one face-to-face training for all patient participants, which lasted between 1 and 2 h, responding to the individual queries of each patient participant. In the full study, two researchers supported the lead author in enrolling the patients, conducting baseline measures, providing them training and performing the follow-up measures and interviews.

Patients' training covered an overview of the study, the intervention and its aims, the role and responsibilities of the volunteer, and guidance to engage and interact with their paired volunteer. It also included communication and listening skills, suggestions for the conversation content, confidentiality and when this could be breached, relationship boundaries, and contact information for them to have access to support and help in an emergency. The printed handouts of this training presentation were given to patient participants to keep.

On completion, patients received a smart-phone, and were trained and guided in its use by sending a text message, a WhatsApp message and an e-mail to the lead author's study phone. Patient participants were provided with the details of the Gmail account that was created for them.

Volunteer Participants

Volunteers' training covered an overview of the study, the intervention and its aims, the role and responsibilities of the volunteer, and guidance to engage and interact with their paired patient. It also included communication and listening skills, suggestions for the conversation content, confidentiality and when this should be breached, relationship boundaries, the potential communication and behavior problems of patients with psychosis, procedures to assess risk and to safeguard vulnerable people and report abuse, and contact information to have access to support and help in an emergency. The printed handouts of this training presentation were given to volunteer participants to keep.

This training was provided individually to all volunteers by the lead author and lasted between 1 and 2 h; all individual queries were answered. At the end of the training the volunteers were asked to sign a confidentiality agreement.

On completion, volunteers received a smart-phone, and were trained and guided in its use, testing it in the same way as the patients (see above). Volunteer participants were provided with the details of the Gmail account that was created for them.

Matching Patients and Volunteers

The lead author matched patients and volunteers in a pragmatic way, matching the first patient with the first volunteer available throughout the recruitment period. Each volunteer only had one assigned patient.

Once they were matched, participants were sent a text message in which they were given their match contact details, i.e., study phone contact number and e-mail account details. They also received information about the general availability of their paired match in a typical week, with their preferred hours to communicate.

Participants were matched on the same day as the face-to-face meeting with the researcher, or as soon as possible and within a maximum of 2 weeks. If in the first 2 weeks after being matched, one of the participants was not satisfied with the communication with their match, the lead author would re-match those participants within a further 2 weeks.

Access to Support and Supervision

All participants were given the study contact phone number and e-mail of the lead author. Throughout the study, the researchers followed the "ELFT Policy for Safeguarding Vulnerable Adults" and the department's "Lone Workers Policy".

The lead author proactively contacted all participants once per month to check on them. In addition, during the course of the study, participants had access to support and supervision from the lead author for any questions or concerns; they could also book a face-to-face appointment with the lead author if required on weekdays during working hours. This could be useful if during the communication with their match, participants had heard or read something that they found emotionally distressing. Participants were informed about the mental health crisis and emergency contacts that they could call in case they had a mental health emergency, when they could be placing themselves or others at risk.

Follow-Up

At the end of the 12 weeks, participants were telephoned to arrange a follow-up interview and asked to meet the researcher within a 2 week interval. If participants did not respond to the phone call, they were sent an SMS. In order to acknowledge participants' time, £10 was provided for completion of each assessment, i.e., at baseline and follow-up in alignment with research suggesting that this level of compensation can increase follow-up rates in digital trials (18).

Withdrawals

Participants could decide to drop out of the study at any time. Participants who wanted to withdraw from the intervention would be asked if they also wanted to withdraw from follow-up data collection. Those that refused to take part in further data collection would be withdrawn, but their existing data would be included in the analysis unless they requested otherwise. Reasons for withdrawal would be documented.

Sample Size

A formal sample size calculation was not conducted since the guidance on sample sizes for feasibility studies is diverse (19), although commonly adopting a figure of 30 (20). The lead author aimed to recruit 6 participants ($n = 3$ patients and $n = 3$ volunteers) in the first phase, and an additional 30 participants ($n = 15$ patients and $n = 15$ volunteers) in the second phase. These numbers were based on a pragmatic assessment; a sample of 36 participants was deemed still manageable for the lead author, whilst allowing for estimates of variability in outcome measurements and trial parameters. Of note is that this feasibility study was not designed for testing effectiveness of the intervention with a pre-determined effect size (20, 21).

TABLE 1 | Measures used at baseline and follow-up.

Assessment	Baseline (T1 = week 0)	Follow-up (T2 = week 12)
All participants		
Socio-demographics	✓	
Smart-phone preferences usage	✓	✓
Availability	✓	
Quality of life (MANSA)	✓	✓
International Physical Activity Questionnaire (IPAQ)	✓	✓
Self Esteem Rating Scale—short form	✓	✓
Social Comparison Scale	✓	✓
Interviews		✓
Patients		
Revised Adult Attachment Scale (RAAS)	✓	✓
7-days Social Contacts Assessment	✓	✓
Brief Psychiatric Rating Scale (BPRS)	✓	✓
Scale to Assess Therapeutic Relationships—Patient Version (STAR-P)		✓
Volunteers		
Social Distance Questionnaire	✓	✓
Scale to Assess Therapeutic Relationships—Volunteer Version (STAR-V)		✓

Intervention

The intervention has been described in detail elsewhere (11). Briefly, the intervention consists of a patient-volunteer pair conducting informal conversation with each other over a smart-phone through SMS, WhatsApp messages, e-mails, audio or video calls. The intervention was delivered as being flexible and low-intensity, whereby each patient-volunteer pair could determine the extent to which they would communicate, and through which smart-phone communication methods. Participants were encouraged to make contact at least once a week for a period of 12 weeks.

Measures

Table 1 outlines the measures used in the Phone Pal study. All the questions and measures queried at baseline and follow-up are contained in the patients' and volunteers' Case Report Forms (CRFs).

The following scales were used in both patients and volunteers:

- *Subjective quality of life* has been assessed by the Manchester Short Assessment of Quality of Life (MANSA) (22), which is a 16-item scale. The instrument assesses satisfaction with life as a whole and additionally in 11 specific domains, i.e., employment, financial situation, friendships, leisure activities, accommodation, personal safety, people living in household/living alone, sex life, relationship with family, physical and mental health. Satisfaction is rated on a 7-point rating scale where 1 = could not be worse and 7 = could not be better. The mean of the 12 subjective satisfaction items is taken as the subjective quality of life score; total values can range from 12 to 84. The higher the score the better the quality of life. In addition, MANSA has 4 yes/no questions related to objective aspects of social life, i.e., having a close friend or seen a friend or safety, i.e., been accused of a crime or a victim of physical violence. The satisfaction ratings of the scale have adequate reliability with a Cronbach's α of 0.74.

- *Physical activity* has been measured with the International Physical Activity Questionnaire (IPAQ) Short-Form (23). This is a 7-item scale that assesses the types of physical activity, i.e., vigorous activities, such as aerobics; moderate activities, such as leisure cycling; walking and sitting over the last 7 days. The values of the physical activity have a maximum range of 960 min (16 h) where higher values should be excluded from the analysis, and a minimum range of 10 min where lower values should be recoded to zero. The total weekly physical activity is estimated by weighting time spent in each activity intensity with its estimated metabolic equivalent (MET) energy expenditure (24) yielding 'metabolic equivalent minutes' per week (MET minutes/week). The IPAQ scoring protocol assigns the following MET values to walking, moderate, and vigorous intensity activity: 3.3 METs, 4.0 METs, and 8.0 METs, respectively, to report it as a continuous variable (24) (www.ipaq.ki.se). Reliability and validity, calculated in a sample of outpatients with the clinical diagnosis of schizophrenia, reported correlation coefficients of 0.68 and 0.37 for criterion validity of the reported minutes of physical activity (25).
- *Self-esteem* has been measured with the Self-Esteem Rating Scale Short-Form (SERS-SF) (26), which was adapted from the Self-Esteem Rating Scale (27) and covers different aspects such as competence, perceived self-worth and social relations. This scale consists of 20 items rated on a 7-point rating scale (1 = never to 7 = always), of which 10 items are scored positively and 20 negatively. The scale offers both positive and negative scores as well as global self-esteem scores. Positive scores correspond to a more positive self-esteem, and negative scores are indicative of more negative levels of self-esteem. SERS-SF has an internal consistency alpha coefficient of 0.91 for positive self-esteem and 0.87 for the negative scale (26).
- *Self-perceptions of social rank and relative social standing* has been assessed through the Social Comparison Scale (28). This is an 11-item scale where participants are required to make a global comparison of themselves in relation to other people and to rate themselves along a 10-point scale. Scores are obtained as a sum of all items and range from 11 to 110. Low scores point to feelings of inferiority and low rank self-perceptions. The scale has been found to have good reliability, with Cronbach alphas of 0.88 and 0.96 with clinical populations and 0.91 and 0.90 with student populations (28).

In addition, the following scales have been used for patients:

- *Close interpersonal relationships* have been assessed through the Revised Adult Attachment Scale—Close Relationships Version (RAAS) (29). This is an 18-item scale ranked on 5 points where 1 = not at all characteristic of me, and 5 = very characteristic of me. This scale measures three subscales: closeness, dependency and anxiety, each one with six items. Close refers to comfort with intimacy and emotional closeness, e.g., "I find it relatively easy to get close to people". Depend reflects the extent to which one trusts and relies on others, e.g., "I am comfortable depending on others." Anxiety relates to fears of rejection and abandonment, e.g., "I often worry that other people don't really love me." A secure person should score high on the close and low on the dependency and anxiety dimensions (30). The internal consistency of the subscales has been proven using both non-clinical and clinical samples with Cronbach's α of 0.81 and 0.84 for closeness, 0.78 and 0.76 for dependency, and 0.85 and 0.90 for anxiety, respectively (29, 31).
- *Social contacts* in the past week have been assessed through the 7 days Social Contacts Assessment (32). This scale measures the number of social contacts in the past week, face-to-face or remotely, e.g., audio call, video call, e-mail, text messages or social networking, excluding people with whom participants live or mental health professionals or work contacts. The overall score reported is the number of social contacts that each patient had in the last 7 days. The psychometric properties of this scale have not been examined, although it has been widely used in other research studies with patients with psychosis (6, 33, 34).
- *Symptomatology* has been assessed through the Brief Psychiatric Rating Scale (BPRS) utilizing the 24-item version (35). The existence and severity of each of the 24 symptoms were rated on a scale where 1 = not present and 7 = extremely severe. The sum score of all 24 items reflects the symptom level, with total scores ranging from 24 to 168 and where higher scores reflect more severe psychopathology. In this study a four component analysis was chosen with four subscales: (i) depression (with the items: anxiety, depression, suicidality, guilt), (ii) manic symptoms (with the items: motor hyperactivity, elevated mood, excitement, distractibility and grandiosity), (iii) negative symptoms (blunted affect, motor retardation, emotional withdrawal and self-neglect), and (iv) positive symptoms (bizarre behavior, unusual though content, disorientation, hallucinations and suspiciousness) (36). Psychometric investigations of different BPRS versions provided evidence for satisfactory to excellent inter-rater reliability (35). There is also evidence for satisfactory validity based on score correlations with other rating scales (37) and longitudinal sensitivity to changes in psychiatric symptoms (38).
- *Character of the relationship with the volunteer* through the Scale to Assess Therapeutic Relationship—Patients Version (STAR-P). This was an adaptation of the STAR scale (39) which was developed to assess the clinician-patient therapeutic relationship in community mental health care and has patient (STAR-P) and clinician versions (STAR-C). In this study, the same items are used, but applied to characterize the relationship between patient and volunteer in order to capture relevant concepts of this relationship, e.g., trust, respect, openness and commitment. This is a 12-item scale with 5 Likert items, i.e., 1 = Never, 5 = Always. In STAR-P there are three subscale scores of positive collaboration, positive

volunteer input and non-supportive volunteer input, (items that should be reversed). The total score is obtained by the sum of all items and ranges from 0 to 48, with higher scores indicating a stronger relationship between each pair. The test–retest reliability for the original scale of STAR-P was r = 0.76 with an acceptable internal consistency, i.e., Cronbach's $\alpha > 0.65$ (39).

For volunteers, the following scales have been used:

- *Attitudes toward people with mental illness* through the Social Distance Questionnaire (40), a modified version of the Bogardus Social Distance Questionnaire (41). This assesses 7 areas, i.e., renting a room, being a worker, a neighbor, caretaker of the children, marrying their children, introducing to a young woman they are friendly with, recommending for a job working for a friend. It uses a 4-item Likert scale, i.e., 0 = definitely willing, 1 = probably willing, 2 = probably unwilling, 3 = definitely unwilling. The total score is obtained by the sum of all items. Higher scores represent greater desire to distance oneself from people with mental illness. The internal consistency reliability Cronbach's α of this measure was 0.92 (40).
- *Character of the relationship with the patient* through the Scale to Assess Therapeutic Relationship—Volunteer Version. This was an adaptation of the STAR scale (39) from the clinician version (STAR—C). This is a 12-item scale with 5 Likert items (1 = Never, 5 = Always). In the Volunteers version (STAR-V) there are three subscale scores: positive collaboration, emotional difficulties (items that should be reversed) and positive volunteer input. The total score is obtained by the sum of all items and ranges from 0 to 48, with higher scores indicating a stronger relationship between each pair. Test–retest reliability was $r = 0.68$ for the clinician version STAR-C, with an acceptable internal consistency, i.e., Cronbach's $\alpha > 0.65$ (39).

Socio-Demographics

At baseline, patients were asked about their socio-demographic data and clinical information. Patients were questioned about their age, gender, marital status, country of birth, nationality, first language, ethnic background, years of education, highest level of education achieved, employment status, occupation, monthly income, who they lived with, type of accommodation, if they had children and if they had any religious or spiritual beliefs. Clinical information concerning their psychiatric treatment, i.e., clinical diagnosis, number of years with the diagnosis, hospitalisations in the past year, was also collected.

At baseline, volunteers were asked about their socio-demographics, previous experience in volunteering as well as whether they had lived experience of mental illness. The same personal socio-demographic data was then collected as for the patients. Volunteers were also questioned about their previous experience of volunteering, and if present, whether it was in mental health. In addition, volunteers were asked if they had mental health lived experience, and if so, if they had ever received any mental health treatment and hospitalisations.

Smart-Phone Preferences Usage

At baseline, patients and volunteers were questioned about their former smart-phone usage, and whether they had used or owned a smart-phone before. They were asked about which communication methods they most frequently used or would like to use, e.g., audio calls, video calls, text, Facebook or WhatsApp messages, e-mails or others.

At follow-up, both patients and volunteers were questioned about the communication methods they had used the study smart-phone most often for, i.e., audio calls, video calls, text messages, WhatsApp messages or e-mails, and in particular, utilized to communicate with their match.

Availability

In the baseline assessment, patients and volunteers were questioned about their usual availability to get into smart-phone contact with their match according to a weekly schedule.

Smart-Phone Usage Data

The smart-phones provided had two apps installed: "mspy", to monitor communication and "accupedo" to monitor step count. The former aimed to collect the date and time of participants' communications through the smart-phone, to look at written message content and the frequency and duration of the audio communication. The latter aimed to collect the number of steps as recorded *via* the smart-phone pedometer app.

A database in Microsoft Excel in 2010 was used to organize participants' details of the communications retrieved and the step count number.

Risk Assessment and Adverse Events

The patients' assessment included a health outcome symptom rating scale (BPRS) measured at baseline and follow-up. If some of the clinical features were present that would be classified as risk, e.g., suicidality, this would be addressed accordingly in line with ELFT clinical safeguarding and incident procedures. If patients endorsed this item or if the researchers were made aware of any risk during the initial assessment, patients would be advised to contact a health professional immediately and would be followed-up with a telephone call, which is in keeping with recommendations for when suicidal ideation is expressed (42).

If an adverse event (AE) would arise during smart-phone communication, it was the participant's responsibility to contact the lead author. She would then follow up the AE with the participant, establishing whether the AE had been resolved or continued, and record the event in the AE log. When the AE occurred or was identified during the assessment, then it was the researcher's responsibility to follow the same procedure. The AE would be assessed to establish whether or not it should be classified as a serious adverse event (SAE).

A SAE would be classified as: (i) "related", when it resulted from the administration of any of the research procedures, and (ii) "unexpected", when the type of event is not listed in the protocol as an expected occurrence. A SAE that is considered to be related and unexpected would be reported to the sponsor within 24 h of learning of the event and to the main REC within 15 days in line with the required timeframe.

Data Analysis

The quantitative data would be analyzed through descriptive analysis for participants who completed the baseline and follow-up measures, regardless of whether they completed the intervention or withdrew ("intention to treat" analysis). Outcome measures would be assessed for completeness and the percentage of missing responses reported. To enable the calculation of the overall scales, individual mean imputation would be performed, imputing the calculated mean for a participant to the responses to the other questions (43).

Normally, in a single-group feasibility study, only a within-group estimate is possible (44), reporting the mean and standard deviation. Owing to the design of the study and the small number of participants, it is not appropriate to test for differences of effect of the intervention in the different measures. The secondary outcomes should be reported with the participants' mean scores and standard deviations in the different time points, i.e., baseline and follow-up or the median and the interquartile ranges, where appropriate.

The qualitative data from the semi-structured interviews would be analyzed through thematic analysis (45).

DISCUSSION

This is the first study to investigate volunteering *via* smartphone for people with psychosis, exploring the feasibility of recruitment, retention and data collection procedures, the usage of the intervention, and the acceptability of, and participants response to the intervention.

Wide inclusion criteria were employed in line with one of the study objectives, which was to assess how acceptable the intervention was. No pre-defined stop-go criteria were set, since the purpose has been to identify any potential barriers and facilitators to performing a larger trial relating to this intervention. Commonly, progression criteria can range and encompass figures of recruitment, retention, programme implementation, achieved measures, fidelity, factors affecting protocol adherence and acceptability (46).

Importantly, this study uses only two discrete temporal assessments, at the beginning and end of the study. Only one follow-up limits understanding of how participants' outcomes may change with time and whether those changes are sustained. Future research should consider additional time points for follow-ups.

Other studies reported unplanned absences from volunteers and high levels of volunteer attrition (47, 48). It has been suggested that volunteers may drop out when there are discrepancies between "ought" and "actual experiences". When these discrepancies between expectations and reality arise, feelings of anger and disappointment may set in, and to preserve their positive self-feeling, devoted volunteers may drop out (49). The importance of the self-regulation between volunteers and the organization in the decision to drop out or persevere has been previously recognized (49).

The lead author aimed to develop a team mind-set of the "Phone Pal study" with the two researchers that have been helping in the study. A team-based approach is important in establishing a cohesive longitudinal research framework (50, 51). Some have argued that successful follow-up is both top-down and bottom-up driven, requiring efforts from all staff, including the PI (52), which has a key role in modeling professional communication and perseverance (53), and is commonly in a position to empower staff to improve team effectiveness (54).

It has been raised that during intervention development, new measures may need to be designed that align with the theoretical perspectives and hypothesized mechanisms of change reflected in the intervention. If researchers move too soon to adopt an outcome measure in an RCT and the trial is not effective, the main problem may be the selection of an outcome measure that is insensitive to change or incongruent with the logic model of the intervention. Performance of feasibility studies to assess measures prior to larger trials is recommended to improve subsequent RCT data interpretation (55).

In the Phone Pal study, a range of observer rated (i.e., BPRS and self-reported outcomes) have been utilized, some of them concerning behavioral outcomes (e.g., social contacts and physical activity).

The publication of the quantitative and qualitative data of the Phone Pal study will shed light on volunteering *via* smartphone for people with psychosis as an intervention, and whether a future trial should be conducted to explore its effectiveness and cost-effectiveness.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

This study was reviewed and approved by the Research Ethics Committee East of England—Cambridgeshire and Hertfordshire (REC reference: 18/EE/0196) and the Health Research Authority in the UK. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MPC wrote the protocol, sought ethical approval of the study and has been the Chief Investigator and the Principal Investigator of the Phone Pal study. The Phone Pal Advisory Groups provided advice to the Chief Investigator. The authors contributed to the article and approved the submitted version.

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BRIEF RESEARCH REPORT
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Multi-Family Therapy for First Episode Psychosis: Experiences of Families in Singapore

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Aim: This qualitative study examined the experiences of families with Multi-Family Therapy (MFT) provided by the Early Psychosis Intervention Programme (EPIP) in Singapore. The MFT was piloted over a period of 2 years and findings from this study were used to further refine the MFT to better meet the needs of Singaporean families in the service.

Methods: Families who completed the MFT were invited to participate in the study. Nine clients and ten carers who consented to participate in the study were allocated to two client and two carer Focus Group Discussions (FGDs) respectively. A semi-structured interview schedule was used to facilitate the discussions. The FGDs were audio recorded, transcribed, and anonymised. The data was analysed using thematic analysis.

Results: Four main themes emerged from the analysis: (1) therapeutic processes of MFT, (2) positive changes in family relationships, (3) improvements in coping with psychosis, and (4) suggestions for improvement in MFT. The families suggested some structural changes to the MFT, and more carers than clients would prefer therapists to offer more expert advice.

Conclusions: Findings suggest that a Western-based MFT can be adapted to work with Singaporean families. This study sheds light on the therapeutic processes that may be related to the changes in family relationships and coping with psychosis. In addition, it suggests that therapists taking an expert and authoritative approach may not fit with the needs of younger generations in Singapore. It advocates for therapists to take a flexible and fluid stance to work with Singaporean families.

Keywords: psychosis, first episode psychosis, multi-family therapy (MFT), multiple family group therapy, multiple family group programme, early intervention in psychosis, culturally sensitive adaptation

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INTRODUCTION

Multi-Family Therapy (MFT) is a Western-based model that combines the theory and practise of group and family therapies, and its key therapeutic aim is to foster mutual support and learning between families who face similar difficulties (1). Over the last seven decades, MFT has been applied across the world in various settings such as psychosis (2–6), mood disorders (7), eating disorders (8), child and adolescent mental health (9–11), family separation and divorce (12), physical health and educational settings (13). The wide range of MFT models and settings makes it difficult to establish a solid evidence base. A narrative review suggested that MFT has the strongest evidence base for psychosis in comparison to other settings (14). By and large, MFT in psychosis was based on the earlier psychoeducation model developed by McFarlane (15). Over the years, MFT in the field of psychosis has evolved into two different strands: one that preserves a strong psychoeducational component (16, 17), and the other that focuses on therapeutic activities (1, 18). Most adaptations of MFT to work with Asian families draw on a psychoeducational model (3–6) and it was only recently that a MFT based on therapeutic activities was developed in Singapore by same group of authors in this current study (19).

More broadly, family-based interventions—albeit different in their theoretical approach, method, and techniques—share similar aims to support engagement with service, treatment adherence, symptoms reduction, relapse prevention, and improvement in carer's well-being (20, 21). Previous MFT studies found that this particular family-based intervention helped to improve the patients' quality of life and carers' knowledge of illness (6), reduce carer burden (4, 5), reduce hospitalisation rate, and support better engagement with mental health services (3). Although the benefits of MFT are well-documented in the field of psychosis, a systematic review highlighted the wide range of variations in this particular therapeutic intervention (22). For instance, Kung et al. (6) piloted a MFT specifically for Chinese-American patients with schizophrenia. This model adopted a psychoeducational and problem-solving approach using a combination of multi-family groups for carers only (without the clients) and single family therapy sessions. Chien and Wong (5) described a MFT which comprised 18 2-h sessions that were conducted on a fortnightly basis over four key stages: (1) three sessions of orientation and engagement, (2) six sessions of educational workshop, (3) seven sessions that focussed on therapeutic family role and strength building and (4) two sessions on termination. Whilst different forms of MFT to work with Asian families continue to develop in the field of psychosis, it is imperative for therapists to be sensitive to the cultural nuances when applying a Western model to the local context (23–25). Although incompatibilities exist between Western-based treatment models and Asian cultures, Bentelspacher et al. (26) indicated that multi-family psychoeducational groups could be beneficial to Singaporean families when adjustments were made to the process of facilitation to suit the local cultural norms and values. Chinese Singaporean clients' aetiology and treatment beliefs about psychological problems are eclectic, deriving from both Western and traditional therapies (27). Therefore, counselling and psychotherapy approaches combining both Western and traditional therapies would more likely fit with the needs of Chinese Singaporeans (28).

Prior to this study, the MFT undergone a 2-year pilot phase to establish the structure and content of the programme as well as understand the facilitation process that would best meet the needs of Singaporean families. Preliminary results from the pilot study were promising (19). This MFT was an activity-based programme grounded in psychotherapeutic principles which comprised 4 weekly sessions and a follow up session. The therapeutic activities included "Image of Psychosis," "Multi-family Group Discussion," "Family Tree," "Sculpting," "Letter to Psychosis," "Family Life River," and "Self-Psychoeducation and Consolidation of Work" [see (19) for further details of the MFT]. The objectives of the MFT were: (1) to improve understanding of psychosis and its impact on clients and their families, (2) to provide a space for families to learn from one another about new ways of managing psychosis, (3) to provide opportunities for families with similar experiences to expand their support network, and (4) to help families draw on their resources to manage psychosis. This qualitative study aimed to explore the experiences of Singaporean families with MFT in EPIP. The position of this study was influenced by several concerns: (a) there is a need to understand more about the processes rather than outcomes of MFT, (b) it is crucial to look into the finer details of adapting a Western-based model to a specific localised context (in this case Singapore) and (c) there is an interest to "research with" rather than "research on" the families who were coping with psychosis. The study served to generate rather than test hypotheses. The hypotheses generated may be tested in future research to further understand the use of MFT in Singapore. In addition, findings from the study will be used for service evaluation and development.

METHODS

The study was approved by the National Healthcare Group (NHG) Domain Specific Review Board (DSRB) and the Institute of Mental Health (IMH) Institutional Research Review Committee (IRRC) in Singapore. A total of 16 families took part in a course of the MFT and three families dropped out which gave an 81.25% of completion rate.

Participants

This single site study utilised a purposeful sampling method whereby participants were recruited *via* the MFT in EPIP over a period of a year. A researcher introduced the study in the first MFT session and gave a follow up call to the clients and carers after 2 weeks to ask if they would like to take part in the study. Written informed consent was obtained from clients and carers who consented to take part in the study. The inclusion criteria for clients were: (1) EPIP client who presented with first episode psychosis, (2) between the age of 16 and 40, (3) Singaporean or Singapore Permanent Resident, (4) clinically stable, (5) English speaking and (6) completed a course of MFT. The inclusion criteria for carers were: (i) family member of an EPIP client, (ii) aged 21 and above, (iii) Singaporean or Singapore Permanent Resident, (iv) English speaking and (v) completed a course of MFT. The exclusion criteria for both clients and carers were: (a) client/carer who was not fluent in English and (b) not willing for the interview to be audio recorded. For younger EPIP clients aged 16 to 20, parental consent was obtained.

A total of nine clients and 10 carers participated in a Focus Group Discussion (FGD). The participants' demographics are summarised in **Table 1**. The proportion of participants' ethnicity was representative of Singapore (and EPIP) population which

TABLE 1 | Participants' demographics.

	N	%
Gender		
Male	11	57.9
Female	8	42.1
Ethnicity		
Chinese	15	78.9
Malay	4	21.1
Age of the clients (mean, SD)	(21.1, 2.85)	
Relationship of carer with the clients		
Mother	6	60
Father	3	30
Brother	1	10

consists of 74.2% Chinese, 13.7% Malays, 8.9% Indians and 3.2 other ethnicities (29). All clients had a family member (i.e., their carer) who took part in this study. Only one carer did not have a family member (i.e., the client) participating together with them as the client declined the invitation. Each participant was given a small monetary remuneration upon completing the FGD.

Data Collection

The FGDs were conducted by a facilitator with a note taker who were part of the EPIP team and not blinded to the study. The FGDs took place immediately after the final session of MFT. The discussions were facilitated using a semi-structured interview schedule (see **Appendix 1**). Four FGDs were organised for two different groups of participants: one for clients and the other for carers. The clients and carers were grouped separately with the purpose to facilitate more open discussion. Each FGD lasted ∼1 h and comprised 4–5 participants. The FGDs were audio recorded and transcribed to anonymised verbatim reports, and the researchers checked the transcripts for consistency.

Data Analysis

The data was analysed using thematic analysis which involved identifying, analysing, and reporting patterns (themes) (30). The analysis was conducted manually by using an excel sheet to label, organise and sort the codes and themes accordingly. Data analysis commenced with two researchers familiarising themselves by reading and re-reading of the transcripts and generating a list of ideas for coding. Next, the raw data was organised into units of analysis and each unit was summarised to create a list of initial codes. The list of initial codes was then organised into meaningful groups (themes). Due to the exploratory nature of the study, coding of the data was done using a data-driven approach (31) where two researchers approached the data with no specific questions in mind to allow themes to emerge. A codebook was developed and applied to a sub-sample (20%) of the data to verify its applicability by the two researchers. Throughout this process, a third researcher was involved when there were discrepancies in the coding process. The three researchers considered how the overarching themes were related to one another and how they fitted with the overall purpose of the study. When the analysis was satisfactory, a thematic map was produced to reflect the meaning of the data as a whole.

RESULTS

The emerging themes from the FGDs were categorised into four overarching themes: (1) therapeutic processes of MFT, (2) positive changes in family relationships, (3) improvements in coping with psychosis and (4) suggestions for improvement in MFT. These overarching themes were found in both clients' and carers' groups which reflected the similar experiences shared between both clients and carers.

Therapeutic Processes of MFT

This theme sheds light on the mechanisms of MFT. Participants felt validated and comforted by others who were in similar situation; they felt that they were not alone. They reported feeling safe which helped them to share openly with each other.

> *Carer08: "I think it's basically a programme which provides us with a great opportunity to actually meet with fellow parents who have got children going through this condition itself, otherwise you would feel kind of alone."*
>
> *Carer04: "From their stories similar to my daughter, and I know that I am not alone here, and there is somebody with me."*
>
> *Client02: "Basically what I feel is it is a place where we do not judge each other, help our relationships to be better... and basically help us to enable... be a bit more frank about things such [as] psychosis. . . "*
>
> *Client06: "Maybe more... more people can tell more about their condition without hiding."*

Some participants reported that MFT created the opportunity for them to connect with others and expand their support network, which they were keen to maintain beyond the sessions.

> *Client03: "I see this as a way to build a community of people who have similar experiences . . . "*
>
> *Carer05: "But later on we meet up again, and we have a common call. So, this actually helped in a progressive manner."*

Participants also felt that there was mutual learning amongst themselves.

> *Client06: "Because there is also other families, so we can learn from each other even though different people have different type of illness."*
>
> *Client04: "We shared a lot of experience and learn from each other. But I think by talking about the issues, I think we have more like self-aware[ness], like [knowing] what's going on you know."*

Positive Changes in Family Relationship

Participants reported that there was more empathy and understanding towards each other within the family unit.

> *Client09: "For me I think it would be good if our family knows that we are getting improve in our sickness. So they understand us well."*
>
> *Carer02: ". . . like as a family, it really helps us to realign our expectations . . . "*

Some participants noticed that there was more communication and positive interactions with their family members. It encouraged them to have conversations which they would not otherwise have in the context of home. Some of them also reported increased family cohesion and unity.

> *Carer05:* "*First it gives me the opportunity to present my thoughts to my son. On one to one basis we normally don't talk about this but in this set up itself, the presentation itself give me opportunity to say a bit more about myself, what I am thinking of to my son.*"
>
> *Carer05:* "*We change our habit and we are more united on what we see.*"
>
> *Carer03:* "*I think more closer now especially to the dad …*"

Improvements in Coping With Psychosis

Besides the interpersonal gains as mentioned above, there were accounts of intrapersonal gains in terms of improving one's capacity in dealing with psychosis. Participants reported gaining a better understanding of and coming to terms with the illness.

> *Carer07:* "*… he is also frustrated why he has this illness. So, after going through all these, slowly he understands more of it.*"
>
> *Client07:* "*It's more like ya just understanding of the illness itself, and kind of explaining your own symptoms to your own parents… not just to other families.*"

Participants also reported acquiring new skills to cope with psychosis on a day-to-day basis through MFT.

> *Client07:* "*… it kind of brought the awareness to me… like I am aware of this now so how can I like… start to cope with it.*"
>
> *Client08:* "*It would help us in our everyday … it will help us to learn how to cope better with our everyday tasks with our condition...*"

Suggestions for Improvements

There were constructive suggestions to make some structural changes to the programme.

> *Client01:* "*I think there should be some breakouts… more breakouts I would say, because certain things, you would see that in front of the loved ones, I think caregivers are also holding back certain things.*"
>
> *Client08:* "*I think maybe they can let us do some exercises together like as a family or like [in] pair[s] to learn more about other people also.*"

Participants who were mostly carers also expressed their preference for more professional advice during MFT.

> *Carer02:* "*I feel that certain topics need that expertise to just tell us at the end are we on the right track and is this the right way.*"
>
> *Carer03:* "*What are people in the field talking about it? Like what is this illness about? I would like to know more reliable information.*"

DISCUSSION

The current article explores the experiences of families with MFT in the context of EPIP in Singapore. Findings from this study provide insights to the processes of MFT that may account for the changes in the families. Constructive feedback from participants may be of direct clinical relevance for service development to better suit the needs of Singaporean families.

Processes of MFT

A safe environment is the foundation for therapeutic work to take place in any forms of therapy. Clients and carers in the current study felt that they were not alone in the situation. This reflects the connection between the group participants and the sense of safety in the group that was established over the course of MFT. The process of creating a safe space in MFT is a joint effort between participants and therapists as illustrated in a study (11). The essence of MFT is to draw on the resources in the group whereby therapists "de-center"—that is becoming less active—over time and enable participants to take more lead in the work (1). In working with EPIP clients and their families, the notion of therapists de-centering looked different in that therapists still took a fairly active role, alongside holding an expert and authoritative stance, throughout the course of MFT.

It is well-documented that mutual support and learning are key therapeutic factors of MFT in working with Asian families (6, 10, 26). Reports from clients and carers in the current study echo findings from these Asian studies. Mutual learning and support were only plausible when families participated openly in the group discussions. Both clients' and carers' accounts of mutual support and learning were particularly pertinent to working with Singaporean families as it challenged the view that they were unlikely to engage in such a group setting due to belief about "not washing your dirty linen in public." Furthermore, the clients' and carers' engagement throughout the MFT also challenged the view that Singaporean families were unlikely to seek help due to stigma of mental illness. The safe space that was co-created between participants and therapists warmed the context for open sharing and communication, which in turn may have facilitated support and learning in the group. As participants felt heard and validated, it may have positioned them to share more openly and, thereby, further fortified the sense of safety in the group.

Another key finding is the shared experience between clients and carers with the positive changes in familial relationships where there was more empathy, communication, and understanding. The safe therapeutic space could help families to have conversations that were otherwise difficult to have at home. Besides providing psychoeducation, MFT has the potential to strengthen relationships. It could also prevent the risk of relationship breakdown due to psychosis. Several studies in Asia has suggested on the use of MFT to enhance familial relationships (9–12). More importantly, there was a greater sense of family cohesion reported by clients and carers. The processes outlined above may be related to the shifts in the familial communication and relationships where there was, perhaps, a sense of esprit de corps in fighting psychosis as a family unit. Changes in relationship may also be linked to reduced carer burden as reported in some MFT studies in a psychosis setting in Hong Kong (4, 5); clients and their families carers are likely in a better place to work on their relationship when there is reduced carer burden. Expressed Emotion (EE) is associated with family burden in families of clients with first episode psychosis (32) and there is evidence to support the use of family-based interventions in reducing EE (33). Besides addressing carer burden, MFT may have the potential to alleviate EE in familial relationships. However, there is no universal norm in EE experience and thus it is important to be aware that care provision and care receiving behaviours differ across cultures (34).

In general, there was an improvement in subjective experience of coping with psychosis. Consistent with previous studies (6, 9), participants reported that MFT helped them to understand more about the illness. In addition, they acquired new cope skills and found themselves coming more to terms with psychosis. With increased confidence in coping and more acceptance of the illness, clients and carers may be more enabled to address the relational impact of psychosis.

Ideas for Service Development

Reports of clients and carers revealed some differences in the way the two groups preferred the MFT to be conducted. Clients would like to have more multi-family group activities to bond and have discussions with their families. Carers, on the contrary, expressed the need to have more discussions amongst themselves without the clients as they felt a need to hold back. A benefit of MFT is the ability to offer both multi-family group activities and separate group discussions that cater to the two reported preferences. MFT can served as a stepping stone for clients and carers to be signposted to other services to suit their needs. Clients and their families, for instance, can be referred for single family therapy after completion of MFT. The need for carers to have more discussions with other carers can be fulfilled *via* attending carers' support groups in the community. Furthermore, carers (and clients) can be encouraged to form their own support network beyond the MFT by keeping in touch on messenger group chat and social media. It is worthwhile to note that some MFT groups managed to do so and found such support network helpful.

In line with previous studies which advocated for taking an expert and authoritative stance in working with Asian families (19, 24, 26, 35, 36), participants (mostly carers) indicated that they would like more professional input. A unique finding in the current study is that this feedback came from the carers rather than the clients. It is worth to reiterate here that the clients were young adults (with a mean age of 21.1) and the difference in preference for therapist's approach may be related to the difference in generation between young adult clients and their carers. This difference may be influenced by the changing traditional values and mindset over the generations in Singapore. As Foo et al. (27) highlighted, Chinese Singaporean clients' understanding of psychological issues and treatment are influenced by Western models and traditional local beliefs. Therefore, therapists need to be flexible in their approaches and it is crucial not to assume that taking an expert and authoritative stance would fit with Singaporean families.

Self-Reflexivity

The four researchers are Singaporean Chinese in a life stage which was generally between that of the clients' and carers'. Two of them are men and two women. They were involved in the MFT in different ways. They were mindful of how their age, gender, ethnicity, and involvement in MFT may influence the way they understood and interpreted the participants' narratives. Thus, the authors met on many occasions to cross check with each other on their analyses with the aim to discuss any discrepancies as well as examine the influence of their potential biases on the study.

Limitations

Most carers in this study were parents which meant that experiences of spouses/partners and siblings were not represented. The clients were mostly young adults and likely shared similar life stage concerns. Therefore, findings from this study may not be applicable to clients who are older in age. The MFT was piloted in English (the official language in Singapore) and most of the participants were Chinese Singaporeans. This could mean that MFT may not fit the needs of non-English speaking families in Singapore. Future MFT could recruit spouses/partners and siblings as well as clients who are older in age. It would be useful to include more families from other ethnic backgrounds and possibly conduct the MFT in other languages. Concomitantly, future MFT research could explore the experiences of these groups of families which were not represented in the current study. Finally, the therapists' experiences of the MFT are missing in this study. Perhaps future studies could also look into this area to understand the challenges of conducting the MFT and, more importantly, support the service provider in sustaining this therapeutic intervention.

CONCLUSION

This project builds on the preliminary results from the pilot study on the use of MFT with EPIP clients and their families (19). Findings from this study support the argument that MFT can help families to cope better with psychosis and rebuild their relationships; they also endorse the view that a Western-based therapy model can be adapted to meet the needs of Singaporean families. What this study adds to the existing literature is that it highlights the therapeutic processes of MFT in helping Singaporean families in their recovery from psychosis. Interestingly, it also suggests that taking an expert and authoritative stance may not fit with the younger generations in Singapore as participants who expressed preference for this approach were carers but not young adult clients. Thus, the study calls for therapists to adopt a flexible and fluid stance that attends to different generations when working with Singaporean families.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by National Healthcare Group (NHG) Domain Specific Review Board (DSRB) and Institute of Mental Health (IMH) Institutional Research Review Committee (IRRC). Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

CL was the lead in the development of the MFT and this study. WL, HL, and AK supported the development of the MFT and all aspects of this study. All authors contributed to the article and approved the submitted version.

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Conflict of Interest: WL is employed by Cigna Europe Insurance Company S.A.-N.V.,.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

APPENDIX 1

MFT Focus Group Discussion

Interview Schedule

Main questions to answer in focus group discussion:

- What was the experience of young people/adults and their families with the MFT?
- How has the MFT impacted on the young people/adults and their families?
- What is a successful MFT to young people/adults and their families?

- *What was the experience of young people/adults and their families with the MFT?*

- What was your experience with the MFT Programme? [to elicit thoughts and feelings about the structure and content of the programme]
- Can you tell me about your experiences with the MFT Programme?
- Let's say you wanted to describe the programme to your friend, in your own words, how would you describe it?
- What do you think are some of the benefits of the programme? [Invite participants to list it out and discuss one benefit each. Slips can be collected later for text analysis]
- What would be some of your suggestions for improving the programme? [Invite participants to list it out and discuss one benefit each. Slips can be collected later for text analysis]
- Can you tell me what was the best part or experience in the programme?

- *How has the MFT impacted on the young people/adults and their families?*

- Have you noticed any effect the MFT has on you? [to elicit observations on the effects of the MFT and changes in selves]
- Do you think you have changed as a result of participating in the programme? Yes/No, can you tell me more about it?
- When you first joined the programme, what did you hope to get from the programme?
- Do you think the programme has met your needs? Yes/No, tell me more about it.
- Have you noticed any effect the MFT has on your family members who participated? [to elicit observations on the effects of the MFT and changes in family members].
- Do you think your family members have changed as a result of participating in the programme? Yes/No, can you tell me more about it?
- When your family members first joined the programme, what did they hope to get from the programme?
- Do you think the programme has met their needs? Yes/No, tell me more about it.

- *What is a successful MFT to young people/adults and their families?*

- How would you describe a MFT Programme that is successful? [to invite participants to define a successful programme]
- If your case manager said to you, the MFT Programme is a successful programme, what would it mean to you?
- How would you see a successful MFT Programme? What need to happen the MFT Programme?
- What would a successful MFT Programme do for you personally?
- What would a successful MFT Programme do for your family?

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Acceptability of Peer Support for People With Schizophrenia in Chennai, India: A Cross Sectional Study Amongst People With Lived Experience, Caregivers, and Mental Health Professionals

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Introduction: Establishing structured peer support in mental health, particularly for people with schizophrenia, as a psychosocial intervention is early in low and middle-income countries like India. Before implementing and understanding the effectiveness of peer support service and which mode of peer support delivery will be suitable for our culture, our study aimed to understand if peer support would be accepted by the different participants like persons with schizophrenia, caregivers and mental health professionals in a tertiary care center in Chennai, India.

Methods: The study was conducted at the outpatient department (OPD) of a tertiary psychiatric care facility in Chennai, India. A cross-sectional study method was used. Consecutive persons diagnosed with schizophrenia and caregivers of persons with schizophrenia, who attended the outpatient department, and mental health professionals within and outside the facility who met the inclusion and exclusion criteria participated in the study. A structured questionnaire purposefully developed for the study was administered to the different study participants. Descriptive statistics were used to analyze the data. Categorical variables were expressed as frequency and percentages, while the continuous variables were expressed as mean and standard deviation.

Results: A total of 155 participants (52 persons with schizophrenia, 50 caregivers and 53 mental health professionals) completed the survey. The majority of the participants (90.4% of persons with schizophrenia, 86% caregivers and all mental health professionals) welcomed peer support interventions. The participants wanted peers to help persons with schizophrenia achieve personal goals to enhance their mental health and day to day living with an emphasis on independent living and interpersonal and social relationships and help them achieve medication and treatment-related goals toward recovery. Understanding the role of a peer support volunteer and transitioning from a "person with schizophrenia" to a "peer support volunteer" by persons with schizophrenia was thought most challenging.

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Conclusion: The results highlight the potential acceptability of peer support across several stakeholders in the care of schizophrenia in a low and middle-income country context. The results may guide the implementation of a peer support volunteer programme as an essential mechanism of delivering psychosocial interventions for persons with schizophrenia.

Keywords: schizophrenia, peer support, peer support volunteer, psychosocial intervention, peer support program, acceptability

INTRODUCTION

Peer support can be broadly defined as a process through which people who have equal standing with another and share everyday experiences or face similar challenges come together as equals to give and receive help based on the knowledge that comes through shared experience (1). A Peer Support Volunteer (PSV) in a mental health setting would refer to a person who has a lived experience of mental ill health.

Peer support in mental health has been gaining focus, indicating that peer support has the potential to drive through recovery-focused changes in services and can transform both individuals and systems (2). Research on peer support across several populations in developed countries have demonstrated benefits in better coping with experiencing a sense of connectedness, or group belonging, positive opportunities of sharing personal stories (3), cordial relationship between peers and non-peer staff, self-efficacy resulting from the experience of helping others (4), increased wellness secondary to working (5) and earning money (6).

Peer support signifies the importance of personal interests and strengths as foundations to recovery, rather than psychopathology and treatment considerations (7). Studies have also reported several challenges and unforeseen risks, including exposure to misleading information, facing hostile or derogatory comments from others, or feeling more uncertain about one's health condition (3). Peer support workers can also face adverse experiences, which also include non-peer staff discrimination and prejudice, difficulty managing the transition from "patient" to "peer support worker" and having a poor understanding of the role of a "peer support worker." However, these potential risks can further be managed or controlled through training, supervision and attention given to solution-focused strategies (5).

The concept of peer support has received little attention in low- and middle-income countries (LMICs) such as India. Research on peer support workers' role in delivering evidence-based mental health interventions is still in the early stages (8). There are few efficacy and effectiveness studies on peer support and fewer policies to support personal recovery programmes (9). Peer support can be an asset for LMICs as it is less expensive and adds value to the mental health workforce (10).

There are very few studies on peer support in India, and have been from one part of the country only. As part of the Quality Rights project in Gujarat, India (11, 12), peer support volunteers (PSVs) were trained in recovery-oriented care and basic communication skills. In addition to working toward personal goals, they also created a professional employment space for peers (9). Other researchers who examined these trained PSVs in the mental health clinical setting reported that peer support had yielded positive outcomes (13). However, there is a need to explore this knowledge in other parts of the country to help develop peer-support programs localized to different Indian settings and cultures, as it will be complementary to the existing mental health services available to persons with mental illness disorders.

In keeping with this need, our research aimed to study the acceptability of peer support delivered by persons with schizophrenia (PWS) to other PWS by interviewing different stakeholders, including PWS, caregivers and Mental Health Professionals (MHP) in a tertiary care psychiatric facility.

The study objectives were to understand potential acceptability, the expectation of roles, feasibility of peer support and expected challenges from the different participant perspectives.

MATERIALS AND METHODS

Study Site and Context

The study was conducted at the outpatient department (OPD) of a tertiary psychiatric care facility in Chennai, India. This facility caters to persons with mental disorders from Chennai in the southern state of Tamil Nadu in India. The facility also receives referrals from surrounding areas, other districts of Tamil Nadu and nearby states. Comprehensive mental health services that include pharmacological, psychological and psychosocial treatments to persons with various mental illnesses are offered as part of the clinical services.

Psychosocial treatments and interventions are provided through the department of psychosocial rehabilitation by a dedicated and experienced team of MHP, including psychiatrists, psychologists, and psychiatric social workers. During the group training and enhancement programs, a naturally occurring informal peer support initiative between PWS has been observed, indicating the need to examine this phenomenon systematically.

Study Design

A cross-sectional study design was used. Institutional ethics committee (IEC) approval was obtained before the start of the study (SRF-CR/08/MAR-2020).

Abbreviations: PWS, Persons with Schizophrenia; PSV, Peer Support Volunteer; MHP, Mental Health Professionals; LMIC, Low- and Middle-Income Countries.

Study Participants

All persons with an established diagnosis of schizophrenia and clinically stable in the age group 18 years and above, caregivers (family members primarily responsible for caring for PWS) and MHP (with at least 3 years' experience in providing care to PWS) who were willing and able to provide written informed consent were included in the study. The exclusion criteria were PWS and caregivers on their first visit to the facility and those who refused to consent for the study.

Data Collection

Consecutive persons diagnosed with schizophrenia and caregivers of PWS who attended the outpatient department over 3 months, and MHP within and outside the facility, who met the inclusion and exclusion criteria, were included in the study. As the study period was interrupted by COVID second wave and lockdown restrictions, the data collection was extended for a further 4 month period to allow enough number of patients and caregivers to be included in the study. After obtaining written informed consent, the questionnaire was administered by the trained researchers. Data were collected between February and August 2021.

Assessments

A structured proforma was used to collect the essential sociodemographic variables such as age, gender, residential area, and others from the stakeholders.

For this study, the following operational definition of peer-support and peer-support volunteer was used while explaining peer-support among the participants. Peer support was defined as a system of giving and receiving help founded on fundamental principles of respect, shared responsibility and mutual agreement of what is helpful (14). Peer support volunteer was defined as "a person who has a living experience of schizophrenia and is willing to support persons with similar life experiences and challenges faced".

A structured survey questionnaire (version 1) was first developed for the study to explore the objectives of the study based on the review of literature and discussion amongst the research team. The questionnaire was then piloted amongst a small group of participants, and the items were modified based on feedback. The finalized questionnaire (version 2) consisted of 11 items (9 items were asked of all participants, one additional question was asked to PWS, and two additional questions were asked to MHP). **Supplementary Table 1**. This was used to collect data from the participants. The questions included acceptance of peer support, roles and services expected from a PSV, anticipated challenges and logistics of peer support service delivery. In addition, the MHP were asked for their opinion about supervision for the PSVs, and the PWS were asked if they would be interested in taking up the role of PSV. The questions had multiple options for the participant to choose from. "Other" option was provided for open ended responses that were not already covered in the multiple options.

TABLE 1 | The socio-demographic characteristics of the stakeholders.

	Persons with schizophrenia ($n = 52$)	**Caregivers ($n = 50$)**	**Mental health professionals ($n = 53$)**
Age Mean (sd)	43 (11.4)	50.1 (13.6)	34.3 (7.1)
Duration of illness			
Mean (sd)	13.4 (8.3)	NA	NA
Sex			
Males *n* (%)	31 (59.62%)	22 (44%)	16 (30.2%)
Females *n* (%)	21 (40.38%)	28 (56%)	37 (69.8%)
Place of stay			
Urban *n* (%)	45 (86.54%)	45(90%)	NA
Rural *n* (%)	7 (13.46%)	5(10%)	
Experience in working with PWS in years Mean (sd)	NA	NA	8.9 (6.3)

Data Analysis

The data analysis was done using SPSS 20.0.after cleaning and quality check and excluding missing data. Descriptive statistics were used to analyze the data. Categorical variables were expressed as frequency and percentages, while the continuous variables were expressed as mean and standard deviation.

RESULTS

One hundred and fifty-five participants (52 PWS, 50 caregivers, and 53 MHP) were interviewed for the study. Eight PWS refused to participate in the study. The open-ended responses to the questions were a very small number and hence they were not taken up for analysis.

Sociodemographic Profile of the Participants

Table 1 describes the sociodemographic characteristics of the participants.

The mean age of the PWS included in the study was 43 (sd 11.4) with an age range from 19 to 72 years. The mean duration of illness of PWS was 13.4 (sd 8.3). There were more male PWS 31(59.62%) who participated in the study. The majority [45(86.54%)] belonged to the urban background.

Caregivers were on an average −50.1(sd 13.6) years, and 32(64%) were either parents or spouses. There were more female 28(56%) than male 22(44%) caregivers, and 45(90%) of the caregivers were from an urban background.

The mean age of the MHP included in the study was 34.3 (sd 7.1). Most, 33(60%) of the MHP interviewed were psychiatric social workers. There were more female 37(69.8%) MHPs than males 16(30.2%).

Acceptance of Peer Support

Forty-seven (90.4%) PWS, 43(86%) caregivers, and 53(100%) MHP supported the idea of peer support, as shown in **Table 2**. Forty-four (84.6%) PWS were willing to share information

TABLE 2 | The acceptance of various stakeholders of peer support volunteers.

	Persons with schizophrenia (*n* = 52)	Caregiver of individuals with schizophrenia (*n* = 50)	Mental health professional (*n* = 53)
Acceptance toward peer support in dealing with problems			
YES *n* (%)	**47(90.4)**	**43(86)**	**53(100)**
NO *n* (%)	5(9.6)	7(14)	0(0)
Acceptance of sharing information with peers support volunteers			
YES *n* (%)	**44(84.6)**	**42(84)**	**52(98.1)**
NO *n* (%)	8(15.4)	8(16)	1(1.9)
Willing to be a peer support volunteer			
YES *n* (%)	**31(59.6)**	nil	
NO *n* (%)	21(40.4)		

The bold values represent highest values, highest preferences.

TABLE 3 | The types of support expected from peer support volunteers.

	Persons with schizophrenia (*n* = 52)	Caregiver of individuals with schizophrenia (*n* = 50)	Mental health professional (*n* = 53)
Better mental health *n* (%)	**37(71.2)**	**34(68)**	35(66)
Independent living *n* (%)	**35(67.3)**	32(64)	37(69.8)
Interpersonal and social relationships *n* (%)	30(57.7)	**34(68)**	**40(75.5)**
Achieve overall goals *n* (%)	30(57.7)	24(48)	25(47.2)
Medication and treatment support *n* (%)	29(55.8)	28(56)	**46(86.8)**
Employment *n* (%)	29(55.8)	25(50)	35(66)

The bold values represent highest values, highest preferences.

about their life events, illness, treatment, side effects, and personal information about themselves and their family with the PSV. Thirty-one (59.6%) PWS were willing to become PSV themselves. Forty-two (84%) caregivers were willing for PWS to share information to PSV regarding day-to-day happenings, challenges, and experiences faced. Fifty-two (98.1%) MHPs felt that PWS could share information regarding the illness and other aspects depending on their comfort level.

Those who did not want peer support stated reasons of being unsure of how one PWS can help another PWS as a peer support volunteer, and with good family support, there was no need for peer support. Those who did not want to share information with PSV cited confidentiality and privacy as the reasons.

Types of Support Expected From PSV

As shown in **Table 3**, more than two thirds, 37(71.2%) PWS wanted peers to help them achieve better mental health by providing them with emotional and psychological support when it is required, listen and understand problems, help them deal with day-to-day challenges and share positive experiences. 35(67.3%) PWS wanted peers to help them achieve independent living by providing them with motivation and encouragement to take responsibility toward a particular aspect of life, build a routine, and help them avail welfare benefits.

Caregivers stated expectations from peers in helping PWS achieve better mental health 34(68%) and good interpersonal and social relationships 34(68%) by providing them companionship and helping PWS socialize.

The majority of the MHPs 46(86.8%) wanted PSV to be involved in helping PWS in medication and treatment-related support where peers can educate PWS on illness and treatment, ensure adherence, accompany PWS to the clinic if required, build trust and help them feel accepted by helping them know that they are not alone in the struggle toward living with mental illness. MHP also had an expectation of peers helping PWS achieve interpersonal and social relationships 40(75.5%) and independent living 37(69.8%). All stakeholders, 29(55.8%) PWS, 25(50%) caregivers, 35(66%) MHPs, expected less support from peers in employment-related aspects.

Mode of Delivery of Peer Support

Around half the participants, 26(50%) PWS, 26(52%) caregivers, 27(50.9%) MHP reported that the peers could be of any gender. Thirty (57.7%) PWS, 28(56%) caregivers, 21(39.6%) MHP reported that peers could be of any age. Forty-four (88.6%) PWS, 40(80%) caregivers, 26(49.1%) MHP reported peers could be of any religion and 29(55.8%) PWS, 36(72%) caregivers, 46(86.8%) MHP stated that PSV should speak the same language as the PWS.

One to one peer support by meeting face to face was preferred by 42 (80.8%) PWS, 37 (74%) caregivers and 52 (98.1%) MHP and group peer support by meeting face to face was preferred by 31(59.6 %) PWS, 32(64%) caregivers and 46(86%) MHP. Participants were also open to other modes of interaction between PSV and PWS, such as telephonic contact, which was preferred by 26(50%) PWS, 26(52 %) caregivers and 37(69.8 %) MHP and text messaging was preferred by 18(34.6%) PWS, 17(34.7%) caregivers and 24(45.3%) MHP. Contact made through social media platforms was the least preferred mode of contact among all participants (6(11%) PWS, 4(8.2 %) caregivers, 5(9.4 %) MHP).

Most, 36(69.2%) PWS and 31(62%) caregivers stated that the frequency of contact should be as and when required, MHPs on the other hand, preferred planned contacts with the PSV on weekly 33(62.3%) or monthly 29(54.7%) basis.

The majority of the participants, 37(71.2 %) of PWS, 36(72%) caregivers, and 37(69%) MHP, preferred mental health professionals to choose the PSV for the PWS, followed by choices of PWS and peer volunteers. The involvement of caregivers in choosing the PSV for the PWS was comparatively less preferred amongst all the participants. Almost 51(96.2%) of the MHP stated that peers ought to be supervised by mental health professionals.

Potential Challenges in Delivering Peer-Support

Majority of the MHP [(43) 81.1%] stated that the patient's understanding of the role of a PSV can be difficult, and 35 (66%) also stated that transitioning from the role of a "person with schizophrenia" to a "peer support volunteer" may be most challenging. Several other challenges noted were poor sustainability 31(58.5%), the possibility of a negative relationship being created 31(58.5%), discrimination 30(56.6%), facing unfriendly critical comments 28(52.8%), and stigma 28(52.8%). Eleven (20.8%) MHPs stated other challenges such as over-familiarity, lack of boundaries, risk of transference between the PSV and PWS, caregiver interference, and the possibility of the PSV feeling burdened with the workload and having difficulty in coping with the stress, which could lead to a relapse.

Caregivers were concerned about PSV ability to understand the mental state of others, misguidance and unhealthy relationships being challenges. PWS stated that interpersonal issues such as disagreements, misunderstandings between peers and PWS, privacy and confidentiality could be challenging in peer support.

DISCUSSION

This study attempted to explore the attitudes and opinions toward peer support volunteer work in a tertiary mental health setting. The findings indicate that a majority of the interviewed participants, which included PWS, their caregivers and MHPs, were willing to accept peer support, could perceive its benefits and were willing to utilize such services. Participants' willingness to embrace the peer support program is crucial to implementing and integrating it within the existing clinical service (15). About half the PWS were unwilling to become PSVs themselves. This may have been due to poor confidence and lack of clarity on what being a PSV entails. Training and providing well-defined structure to roles of PSV may help the PSV get an understanding of the scope of their work (16) and provide them the confidence to take on this role.

Whilst the study in Gujarat has noted how peers had taken on roles that identified themselves as "service providers" (13), PWS and caregivers this study have expressed a consensus for PSV in taking up more informal roles as "companion," with whom PWS can feel connected, share information, be supported and motivated toward achieving personal goals such as better mental health, independent living and building up their interpersonal and social relationships.

This study has shown that majority of the MHP expect PSV to be involved in improving medication and treatment adherence of PWS. This is in keeping with the largely medical model of mental illness adopted by MHP both in training and practice (17).

All the participants do not expect support in the area of employment from PSV, the reasons for these needs to be explored further. The above expectations need to be kept in mind while developing a peer support programme that suits the local population. The needs of PWS should be matched to a peer's willingness to take on specific roles.

Paid peer work has emerged as an employment pathway for people in recovery (18). However, studies have also highlighted "issues of power" where there is a possibility of power imbalances in paid work. There is also the risk of peers over-professionalizing their work and the "dark side of peer support." Employed as a peer worker may cause a risk for future employment opportunities, tension around the workforce, risks regarding how peer workers access mental health services for their health, risk of peer workers experiencing trauma or re-traumatization through peer work and risks of bringing peer work and peer workers into the mainstream service system (19). Finding a steady funding source to support paid PSV can be an issue. Peer support is still in its early stages of development in India. No previous literature is available in the area of paid peer volunteers and their impact, but the Quality Rights project in Gujarat paid the PSVs a small honorarium to cover their travel and expenses (∼US$50 per month) supported by project funds initially followed by the provision of financial resources by the State Mental Health Authority, Government of Gujarat since June 2016 (9). It will be essential to educate the managers and policymakers and provide training at the service level to all the stakeholders to overcome these barriers. Future research needs to explore whether peers should be paid for the services they are willing to provide.

India being a diverse country, it was essential to understand the socio cultural factors that might be important when planning peer support. Interestingly all the participants emphasized language when matching PSV to PWS and placed lesser emphasis on socio cultural factors such as gender, age and religion.

While participants have stated that peers can connect with PWS using any mode of interaction, most participants preferred one-to-one, face-to-face interactions, followed by face-to-face group interactions. Participants felt that in-person interactions are more personal than teleconsultation, and it is much easier to observe emotional cues, talk about emotional issues and offer appropriate support, as noted in other literature (20). Technology is, however, increasingly being applied to deliver peer support to individuals with mental health conditions (21). Similarly, in the current study, participants were also open to telephonic contact. Social media was least preferred by all participants who stated that PWS might have less knowledge and usage of social media platforms, and it can be a risk to privacy and confidentiality. The majority of PWS and caregivers preferred frequency of contact to be as and when required as they felt PWS could communicate with peers based on need, crisis and urgency, but MHP preferred a more planned contact being established between peer and PWS so that there is a lesser chance of peers being overwhelmed or burdened. Future peer support programmes could focus on finding a middle ground between planned and anytime contact within a set of boundaries.

Even though peer support focuses on empowerment (22–24), the PWS and caregivers have stated preference toward the MHP to be the one to choose the PSV for the PWS. This reliance on MHP can be interpreted as lack of empowerment of PWS or a higher level of PWS and caregivers' trust in the MHP. It has been noted that MHP often select peers based upon their communication skills, understanding of mental illness, personal responsibility, compassion and level of clinical stability, and professionals are ones to supervise peers during the delivery of support services (25).

In keeping with earlier research (16) this study also shows that majority of the challenges perceived are concerning the PWS understanding of the role of the PSV and that PWS may have difficulty in transitioning from "PWS" to "peer," although this transition is seen as a gradual process. While developing a programme for PSV, it is vital to ensure that PSV has role clarity and training and supervision to ensure PWS can positively transform into a PSV and maintain the integrity of peer support, such that peer support workers are seen as peers and not para-professionals (26).

This study, establishes that PSV programme is acceptable and necessary in our setting. Further studies are needed to explore the benefits of peer support not only for the recipients of mental health services, but also for the PSV and the mental health care system as a whole. The feasibility and maintenance of a robust PSV programme in health care would only be possible through collaborative efforts and ongoing support and engagement from all stakeholders (27). PSV are more than professionally qualified at promoting recovery outcomes such as hope, empowerment, self-esteem and self-efficacy, social inclusion, and engagement (2, 9, 28).

Several limitations undermine the generalizability of the findings.

The small sample size and lack of a planned and justified sample size of each stakeholder group restricts meaningful comparison between the groups. The study participants are not representative of the geography of the country. The severity of the illness of the PWS, which could impact the decision-making capacity in taking part in peer support, was not explored. The study was conducted in a tertiary psychiatric setting by mental health professionals who possibly reinforced medical assumptions around peer support. Since this study is the first time exploring peer support volunteers undertaken in this part of the country and it is a relatively new concept that is yet to be introduced, a cross-sectional study design using a structured survey questionnaire was used. Future research could fill this gap and adopt a mixed-method design with qualitative exploration.

In conclusion, this study throws light on PSV being a potential resource for mental health delivery. The data provides evidence that training peers can add to the country's limited workforce resources for delivering mental health care. The future steps will be to explore in depth what existing peer support model would suit the local needs and adapt and implement a model that can then be evaluated for its effectiveness.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Ethics Committee of SCARF. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SS, SG, VR, LV, and RP contributed to the conception and design of the study. SS organized the database and wrote the first draft of the manuscript. VR performed the statistical analysis. SS, VR, SH, and JJ wrote sections of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.797427/full#supplementary-material

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Does Adding Social Cognitive Remediation Therapy to Neurocognitive Remediation Therapy Improve Outcomes in Young People With a Severe Mental Illness?—The Advantage Trial

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Introduction: Cognitive impairments are a common and significant issue for young people with a severe mental illness. Young people with schizophrenia, bipolar disorder and major depression all experience significant cognitive problems that impede their ability to return to work or study. These neurocognitive problems are frequently exacerbated by social cognitive deficits that interfere with their ability to integrate into the community and understand the social and emotional nuances about them. This study aimed to assess if the addition of a social cognitive remediation treatment to a neurocognitive remediation therapy improved functional outcome.

Methods: Five youth mental health services were trained in both the Neuropsychological Educational Approach to Remediation (NEAR) and the Social Cognition and Interaction Training (SCIT) treatments. Participants were randomised between receiving either NEAR + SCIT or NEAR + treatment as usual (TAU) over a 20-week period, with all participants receiving the NEAR treatment first. Symptoms, neurocognition, social cognition and functioning were examined at baseline, end of treatment and at 3 months follow-up and compared between the two arms of the study. The primary outcome was function.

Results: Thirty-nine participants were randomised to treatment (Schizophrenia spectrum = 28, Bipolar disorder = 7, Major Depression = 2). The trial was curtailed by Covid-related service restrictions. There was an overall significant improvement in function over time with a trend towards a greater improvement in the NEAR + SCIT arm. No changes in symptoms, neurocognitive or social cognitive measures were seen. While 74% completed treatment only 49% agreed to follow up at 3 months affecting our ability to interpret the findings. Attrition did not differ by arm.

Conclusions: In a pragmatic, service-based research project, treatment aimed at improving cognition enhanced functional outcome in young people with a range of severe mental illnesses. There was a trend towards improved function in young people who had a combined NEAR + SCIT approach.

Clinical Trial Registration: Identifier: ACTRN12622000192785.

Keywords: cognitive remediation, social cognition, schizophrenia, social cognition rehabilitation, bipolar disorder, youth mental health, outcome, community function

INTRODUCTION

Remission of psychotic symptoms is a common primary treatment metric used to assess treatment response in severe mental illnesses (SMI) such as schizophrenia, schizophreniform disorder or bipolar disorder, however functional recovery, a more important but frequently secondary outcome, remains elusive for many. A significant contributor to this failure to achieve functional recovery is the detrimental effects of neurocognitive and social cognitive deficits in SMI. Initially, investigations of neurocognitive and social cognitive deficits centred upon schizophrenia (1–3), however there is now a more holistic approach that these deficits are common to all SMI (4), albeit with different degrees of severity.

Neurocognition and social cognition are important because of their contribution to the ability of the individual to operate in a complex society, however their effects appear to be different though overlapping (5). While neurocognitive deficits are basic to the impact of cognition on function, both due to a direct effect and *via* its influence on social cognition, social cognition may have a greater effect on community functioning overall both by its direct effect and via moderating neurocognitive deficits (6). This suggests that targeting neurocognitive deficits alone is not sufficient to improve overall outcome. Unfortunately, the cognitive deficits in SMI are not ameliorated by standard antipsychotic therapies (7). This along with the recognition of the important role played by cognitive deficits in the outcome of SMI (6) has generated new treatment approaches such as cognitive remediation therapy (CRT) and more recently, social cognitive remediation therapy (SCRT). These treatments have a small to moderate effect upon cognitive function and this is noted to generalise to functional improvement (8, 9). This positive effect on functional recovery is helped by combining cognitive treatments with other psychosocial approaches such as supported employment (10), however, the effectiveness of combining the two approaches to cognitive remediation—therapy for neurocognitive as well as social cognitive deficits—is less frequently investigated. This is surprising given that neurocognition, at least in some analyses, appears to be a foundation for the mediating effect of social cognition upon eventual community functioning (6, 11, 12).

Of the studies that have examined the usefulness of combining neurocognitive and social cognitive remediation strategies, most have been in chronically unwell, predominantly male participants (13–16). While CRT clearly improved neurocognition (8), this effect was enhanced by the combination of neurocognitive and social cognitive remediation therapies (15). But improvement in social cognition required the specific treatment of that domain (13, 16). Treatment of cognition translated into better community function (15), though whether the combination of both treatments is necessary for this effect is not clear (13, 16). This study aimed to test the effectiveness of combining CRT with SCRT against CRT alone in improving community functioning in a group of young people with severe mental illness. In addition, it followed participants up over 3 months to see if any improvements were maintained longer term. We predicted that the combined treatment of neurocognitive and social cognitive remediation would have a superior effect on functional outcome over neurocognitive remediation alone.

METHOD

This trial was a single blind randomised controlled trial conducted in five youth mental health services across Sydney, Australia. All participants were aged between 17 and 25 years of age; had a diagnosis of a severe mental illness (first episode psychosis, schizophrenia, schizophreniform disorder, bipolar disorder, or major depressive disorder); neurocognitive or social cognitive deficits; were able to provide consent (and parent/guardian if required); and had reasonable English skills. Participants were excluded if they had a developmental delay (IQ < 75); current substance abuse or substance dependence other than caffeine or nicotine; a history of head injury (> 10 min unconsciousness); or had been treated with electroconvulsive therapy in the last 6 months.

Participants were randomised between two arms on a 1:1 ratio. Participants in the treatment arm were provided with a combination of Cognitive Remediation Therapy [using Neuropsychological Educational Approach to Remediation or NEAR (17)] and social cognitive remediation (using Social Cognition and Interaction Therapy or SCIT (18). This was compared to a control arm of CRT (NEAR) + the additional treatment available at the service where the treatment was provided.

NEAR (17) is a manualised CRT designed to address cognitive deficits by utilising commercially available educational software to create a rich learning environment that is intrinsically motivating and rewarding. The treatment was provided over 10

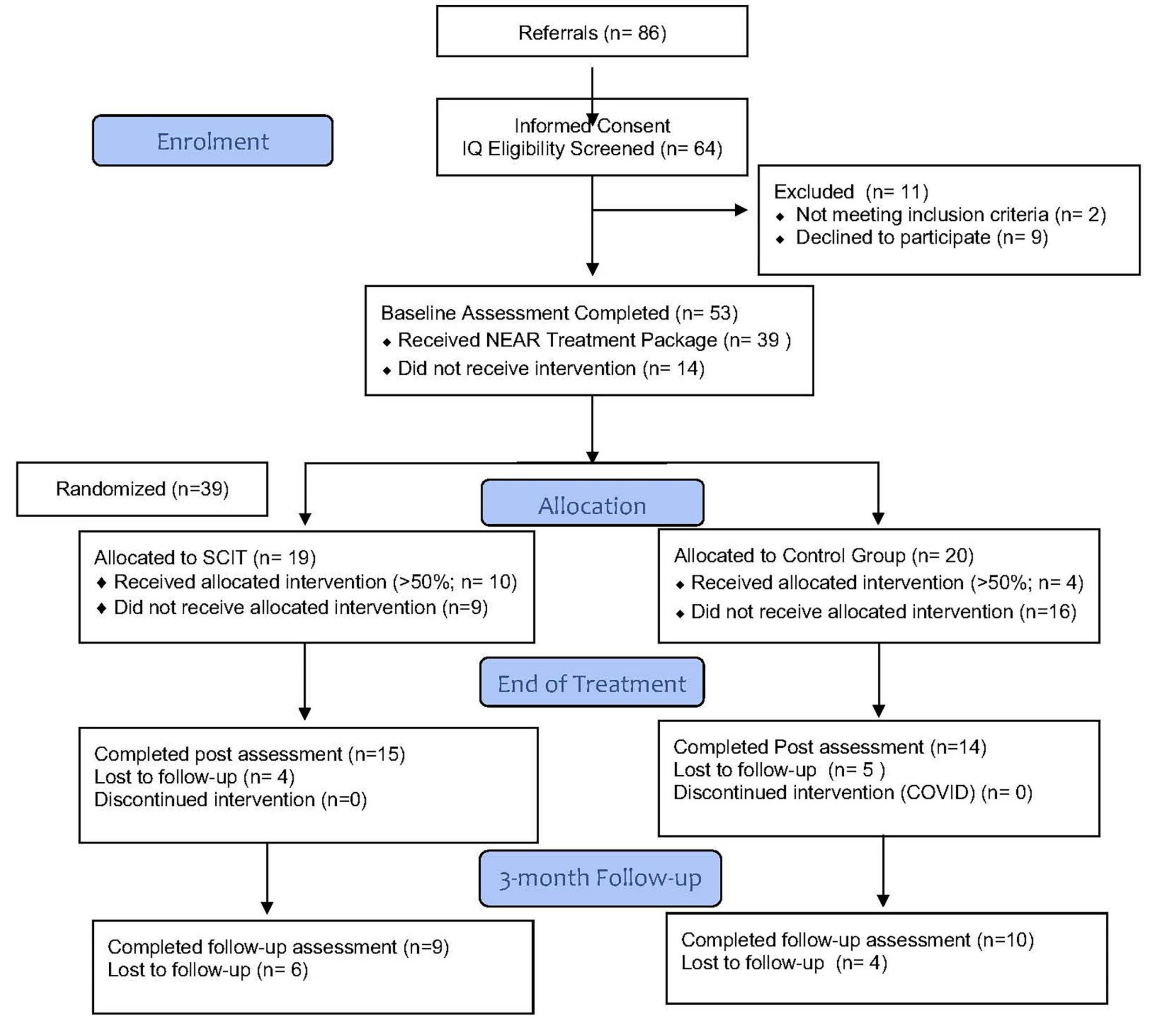

FIGURE 1 | CONSORT Diagram of the Advantage Trial.

weeks, two times per week to participants in groups averaging four people. All participants received NEAR.

SCIT (18) is a manualised treatment designed to address social cognitive deficits. It consisted of 20 1-h sessions over 10 weeks. Training was run in small groups of three to six people using a manual-driven suite of activities. The training approach of SCIT is such that participants receive repeated exposure and practise of the skills that underlie complex mental-state reasoning abilities. The CRT-only group had a range of additional active comparator treatments including physical exercise, social skills groups, individual therapy, or no additional treatment. Both arms received the same duration of treatment-—20 weeks of twice-weekly treatment. All therapists were trained and supervised for the duration of the study, however adherence to the manualised treatments was not formally audited.

Participants were randomised in blocks of four participants from a central register that was operated by administrative staff independent to the services involved. The randomisation sequence was stratified by site and was generated using an online randomisation generator (Sealed Envelope https://www.sealedenvelope.com/simple-randomiser/v1/lists) by a statistician affiliated with the University of Sydney and independent to the research team. Allocation was blind to the research psychologist performing all cognitive and clinical assessments. Allocation was revealed to the treating clinical team by the administrative staff after consent had been obtained and baseline measures taken.

Participants were assessed at baseline, at the completion of treatment and 3 months following the completion of treatment, on a broad range of clinical, cognitive, and functional measures by a psychologist blind to allocation. Initial demographic and clinical details was collected using a semi-structured interview that detailed age, duration of illness, age of onset of illness, treatment history, medication dose, years of education, past employment history, relationship history. Clinical psychopathology was rated using the Positive and Negative Syndrome Scale-—6 items (PANSS-6) (19), the Calgary Depression Scale for Schizophrenia (CDSS) (20) and the Depression Anxiety and Stress Scale (DASS-21) (21).

Neuropsychological Function was assessed using a battery of neuropsychological measures to assess aspects of attention, concentration, vigilance, verbal learning, executive functioning, planning and premorbid intelligence including The two-subtest versions of the Wechsler Abbreviated Scale of Intelligence (WASI) was used to provide an estimate of IQ (22). The two subtests include Vocabulary and Matrix Reasoning. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) assesses five indexes of neurocognition such as immediate memory, delayed memory, attention, construction visuospatial and language (23). Information processing speed and attentional control were assessed with the Trail-Making Test Part A and B. Social cognition was assessed using the Hinting Task (24) as a measure of Theory of Mind (ToM), the Penn Emotion Recognition Test (ER40) (25) as a test of emotion recognition; and the Ambiguous Intentions Hostility Questionnaire (AIHQ-A) as a test of attributional style (26).

Community functioning was assessed using the Social and Occupational Functioning Assessment Scale (SOFAS), which is an interviewer rated scale based on the evaluation of the participants' social and occupational functioning (27) and via the Activity and Participation Questionnaire (APQ) (28). The Assessment of Quality of Life (AQoL-8D) was used to measure subjective satisfaction and well-being (29).

Statistical Analysis

Participants were assessed on the battery of neurocognitive and functional measures at baseline, post-treatment, and follow-up at 3 months after the treatment. Repeated measures analysis of variance (ANOVA) was used to assess any potential interactions across time and between treatment groups. A chi-squared analysis was conducted to compare the demographics between the treatment and control groups inclusive of the diagnosed SMI and medication. Statistical analyses were conducted using SPSS Statistical Packaging for the Social Sciences (30).

RESULTS

A total of 39 participants were randomised between the two arms of the study (see **Figure 1**). The study group had an average age of 21.7 yrs (sd 3.0 yrs) and a duration of illness of 3.1 yrs (sd 2.5 yrs). Sixty five percentage of the group were male. There were no significant differences between treatment and control groups based on gender, diagnosis of SMI, medication, education, previous employment, and relationship status (see **Table 1**). It should be noted that percentages for medication does not add up to 100% due to some participants taking multiple medications, which is clinically common. Drop out through the trial was high with only 49% of participants completing the 3-month follow-up. There was no difference in participant attrition between the arms.

TABLE 1 | Demographic variables.

	Control *N* (%)	Treatment *N* (%)	*p*
Gender			0.109
Female	4 (10.8)	9 (24.3)	
Male	14 (37.8)	10 (27.0)	
Diagnosis			0.299
Schizophrenia	5 (13.5)	8 (21.6)	
First episode psychosis	6 (16.2)	7 (18.9)	
Schizoaffective disorder	2 (5.4)	0 (0)	
Bipolar affective disorder	3 (8.1)	4 (10.8)	
Major depressive disorder	2 (5.4)	0 (0)	
Other	0 (0)	0 (0)	
Medication*			
No medication	–	–	
Antipsychotic	14 (37.8)	16 (43.2)	0.618
Antidepressant	6 (16.2)	8 (21.6)	0.582
Mood stabiliser	4 (10.8)	5 (13.5)	0.772
Other	1 (2.7)	2 (5.4)	0.580
Chlorpromazine equivalent (M, sd)	377.77 (295.40)	227.92 (177.04)	0.187
Education			
Year 10 equivalent	18 (48.6)	19 (51.4)	–
HSC equivalent	16 (43.2)	12 (32.4)	0.068
University training	6 (16.7)	6 (16.7)	0.638
Tertiary training	8 (22.2)	6 (16.7)	0.342
Previous employment	13 (35.1)	12 (32.4)	0.556
Relationship			0.079
Single	18 (48.6)	16 (43.2)	
Dating	0 (0)	3 (8.1)	

**Percentages don't add to 100% due to participants taking multiple medications.*

The neurocognitive and functional outcomes at baseline, post-treatment and follow-up for the treatment and control groups are summarised in **Table 2**. Repeated measures ANOVA indicated that there was a significant main effect of time from baseline to post-treatment on the hinting task ($F = 8.880$, $df = 2$, $p < 0.001$). Pairwise comparisons adjusted for multiple comparisons revealed that this effect was only significant from baseline to follow-up ($p = 0.005$), and was not significant when measuring from baseline to post-treatment ($p = 0.073$), or post-treatment to follow-up ($p = 0.160$). There was no significant difference between groups and no interaction effect. Similarly, there was a significant main effect of time for the SOFAS measure from

TABLE 2 | Results: Neurocognitive and social functioning scales means and standard errors at baseline, post-treatment and follow-up for the control and treatment arms.

		Control			**Treatment**			**Group**		**Time**		**Interaction**	
Measure	***n***	**Baseline**	**Post-treatment**	**Follow-up**	**Baseline**	**Post-treatment**	**Follow-up**	**F**	***p***	**F**	***p***	**F**	***p***
Cognitive													
RBANS	19	76.8 (5.11)	80.1 (5.48)	77.3 (6.23)	75.67 (3.72)	76.44 (4.60)	81.33 (3.44)	0.002	0.967	0.457	0.637	0.714	0.497
Hostility Bias	18	10.22 (0.72)	10.78 (1.37)	10.44 (0.94)	12.56 (1.81)	11.44 (1.75)	10.89 (1.60)	0.372	0.550	0.629	0.540	1.262	0.297
Intentionality Bias	19	16.7 (1.42)	16.6 (1.94)	16.6 (1.80)	17.33 (2.01)	16.78 (1.61)	15.89 (1.94)	0.000	0.989	0.362	0.699	0.282	0.756
Anger Score	19	11.6 (1.44)	12.7 (1.78)	13.4 (1.56)	11.78 (1.22)	12.56 (1.36)	10.44 (1.68)	0.251	0.623	0.699	0.504	2.171	0.130
Blame Score	19	11.4 (1.13)	12.8 (1.45)	12.7 (1.33)	12.56 (1.71)	13.44 (1.17)	10.78 (0.94)	0.001	0.979	1.321	0.280	1.643	0.208
Aggression Bias	18	8.11 (0.59)	8.44 (0.47)	9 (0.5)	7.89 (0.54)	9.33 (0.88)	9.33 (0.5)	0.382	0.545	2.346	0.112	0.487	0.619
ER40 Correct Responses	19	30.8 (1.14)	31.5 (1.39)	31.6 (1.28)	31.89 (1.27)	33 (1.15)	33.22 (1.23)	0.812	0.380	1.245	0.301	0.074	0.929
ER40 Response Time (ms)	19	2479.45 (226.33)	2353.2 (332.05)	2589.5 (192.98)	2318.56 (190.05)	2058.22 (303.81)	2523.78 (267.70)	0.375	0.549	1.555	0.226	0.167	0.847
Hinting Score	19	13.8 (1.60)	14.9 (1.42)	15.6 (0.89)	13.33 (0.80)	15.22 (1.06)	17.11 (0.63)	0.101	0.754	8.880	<0.001	1.130	0.335
Clinical													
DASS	12	19 (7.7)	18.67 (6.32)	20 (6.95)	29.33 (3.57)	24.5 (5.62)	22.17 (6.36)	0.588	0.461	0.522	0.601	0.798	0.464
PANSS-6	19	14.5 (1.69)	14.4 (1.57)	14.4 (1.77)	14.78 (2.13)	13.78 (1.93)	12.22 (1.74)	0.124	0.730	1.477	0.243	1.281	0.291
CDSS	19	6.3 (1.65)	5.9 (1.7)	6 (1.84)	7.56 (2.37)	6.78 (2.09)	4.89 (1.55)	0.021	0.887	1.013	0.374	0.734	0.487
Functional													
AQoL	19	89.1 (8.09)	87.6 (8.03)	85.1 (7.63)	91.33 (5.69)	91.11 (6.03)	86.11 (6.96)	0.055	0.818	1.334	0.277	0.087	0.917
APQ hours	18	17.11 (3.61)	16.33 (2.52)	15.67 (4.19)	18.13 (3.61)	14.77 (3.20)	11.67 (1.67)	0.114	0.740	0.474	0.627	0.191	0.827
SOFAS	19	57 (3.06)	57.8 (3.81)	60.1 (4.42)	53.22 (3.22)	59.44 (4.92)	63.22 (3.37)	0.004	0.948	5.500	0.009	1.689	0.200

Between (group), within (time) and interaction effects are reported from a repeated measures analysis of variance. RBANS, Repeatable Battery for the Assessment of Neuropsychological Status; ER40, Penn Emotion Recognition Test; DASS, Depression Anxiety and Stress Scale; PANSS-6, Positive and Negative Syndrome Scale-6; CDSS, Calgary Depression Scale for Schizophrenia; AQoL, Assessment of Quality of Life-8D; APQ, Activity and Participation Questionnaire; SOFAS, Social and Occupational Functioning Assessment Scale.

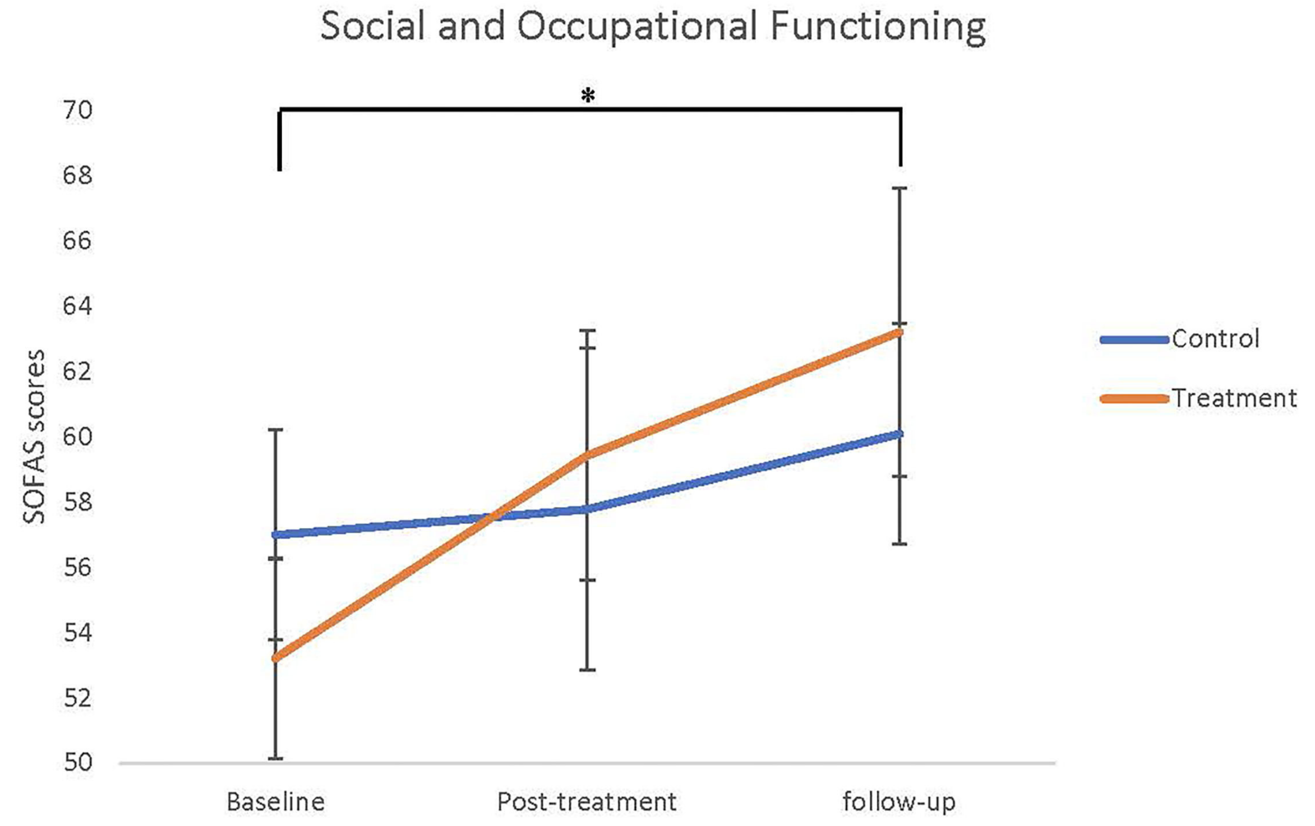

FIGURE 2 | Social and Occupational Functioning Assessment Scale (SOFAS) scores means (SEMs) as baseline, post-treatment, and follow-up. Asterisk indicated significant main effect of time from baseline to follow-up, but there were no differences between groups and interaction.

baseline to post-treatment ($F = 5.500$, $df = 2$, $p = 0.009$), as can be seen from **Figure 2**. Again, pairwise comparisons showed that this effect was only significant when comparing baseline to follow-up ($p = 0.010$), and was not significant when comparing baseline to post-treatment ($p = 0.480$) or post-treatment to follow-up ($p = 0.183$), and there was no significance between groups and no interaction effect. There were no significant differences between groups or over time for any other neurocognitive, clinical, or functional measures (all $p > 0.05$).

DISCUSSION

This study observed a positive effect on functioning in young people whether they received NEAR alone or NEAR and SCIT together. There was a weak trend suggesting that the combination of NEAR and SCIT improved functioning at 3 months follow-up. This finding is consistent with previous studies that found an improvement in functioning with exposure to both CRT and SCRT (16, 31, 32), with the suggestion that a broader based approach to remediation is more likely to lead to improvements in community functioning (9). The young people who persisted in therapy in the Advantage treatment group had a change of 10 SOFAS points as against 3 points for active control group over the nearly 9 months. This is a clinically significant improvement (33). Other studies have had mixed results with some finding a greater propensity to change in younger participants, such as ours compared to older, more chronically unwell people (34) or noting little (35) or no change in community functioning (36).

In contrast to our expectations, there were no significant differences in neurocognition or social cognition between groups or across time in either treatment arm. A possible explanation is that the RBANS was not sensitive to change in this group of young people that were less chronically unwell and relatively better educated. However, the group scores indicated a moderate level of neurocognitive impairment and ceiling effects are not a reason for the lack of change (37). The lack of change in social cognitive scores was also surprising. The lack of significant improvement in cognition accompanying an improvement in function was noted by Revell in her meta-analysis of cognitive remediation in early schizophrenia which found that higher quality blinded studies did not observe as much change as non-blinded studies (38). In our study the rater was blind to assignment. Another possibility is that young people may be less able to benefit from intensive training on computer assisted cognitive remediation compared to older and more chronically ill participants as they have more recently been exposed to teaching and training. Our sample was young and comparatively well-educated. We also note that the diagnostic heterogeneity of our sample with several subjects with affective disorders may have lessened the effect size of the cognitive improvement.

Participant attrition was high. Our participants were involved in two sequential treatment programs of 10 weeks duration followed by a further 3-month follow-up, totalling a commitment of nearly 9 months with the breaks required for testing. The biggest dropout rate was during the second phase of the study, when participants received either SCIT or TAU and after during follow-up. This was consistent across sites and suggests treatment fatigue among the young people coming for treatment. We note that high rates of participant attrition is not uncommon amongst long-term interventional studies. For example, Fisher and colleagues' (16) attrition loss of 45% of their participants over 33 weeks training was despite compensation for their attendance. In a randomised controlled trial of cognitive enhancement therapy in young people, Wojtalik et al. lost 52% of their sample over 18 months of treatment (35). This is in accordance with our own experience and that of the literature, that treatment programs limited to 12–16 weeks have a lower attrition rate. For example, Vidarsdottir et al. (36) combined NEAR, SCIT and additional compensatory cognitive training into a more intense 12 week program that in content was similar to our program and in a very similar group of young people. Their participant attrition rate was only 12%.

Although our study was not conclusive, it does support the importance of addressing social cognitive deficits as well as neurocognitive deficits in people with severe mental illness to improve community outcomes. Recovery in people with severe mental illness like schizophrenia has not improved despite the availability of new medications and psychotherapies (39). Recent large studies have underlined the contribution that social and neurocognition make to community function and the complex interaction at play with psychopathology—both negative symptoms and positive symptoms (40–42). The use of targeted cognitive remediation strategies early in the course of illness may help improve the long-term outcome of people with severe mental illness. Further work is required to explore the dynamics of how this is achieved.

Our study has several limitations. It was curtailed by the start of the global Covid-19 pandemic bringing recruitment to an end and is underpowered. The control arm consisted of a treatment-as-usual intervention that was specific to each site, as such there is variability across the sites for those in the control group. A standardised active control condition would have controlled for any potential confounding factors due to site-specific treatment-as-usual therapies. Although all therapists were trained using the standard manuals for the treatments, and continued supervision provided, therapy sessions were not recorded and monitored for treatment fidelity. Our study identified changes in function using the SOFAS which is a crude measure of function in the community. Further work would benefit from the use of a more reliable and valid measure such as the UCSD Performance-based Skills Assessment which has been noted to have a better correlation with cognitive performance (43). Nonetheless, the study had strengths in that it was a multi-site investigation, run in standard youth mental health teams, supporting the clinical utility of the interventions. All assessments were blinded to treatment allocation. Participants represented a group of subjects under-represented in the literature, which has concentrated on older, more chronically unwell subjects. In addition, participants were followed up enabling us to observe if changes were maintained after the end of treatment.

In conclusion, this study suggests that there are advantages for community functioning in combining neurocognitive with social cognitive remediation therapy. The provision of treatment would be assisted by a more concentrated and intense treatment program that delivered the therapy over a shorter period. The availability of computer assisted cognitive remediation is now being enhanced by the development of similar programs targeting social cognition. We look forward to combining these programs and investigating the role of additional psychosocial interventions that are known to synergise the effects of CRT (8) to improve the outcomes for young people with SMI.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Western Sydney Local Health District Human Research Ethics Committee. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AH, CD, JW, and MK designed the proposal, recruited the participants, and contributed to the interpretation and writing of the paper. CM contributed to the analysis, interpretation, and writing of the paper. All authors contributed to the article and approved the submitted version.

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Implementing psychosocial interventions within low and middle-income countries to improve community-based care for people with psychosis—A situation analysis

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Background: Globally, a treatment gap exists for individuals with severe mental illness, with 75% of people with psychosis failing to receive appropriate care. This is most pronounced in low and middle-income countries, where there are neither the financial nor human resources to provide high-quality community-based care. Low-cost, evidence-based interventions are urgently needed to address this treatment gap.

Aim: To conduct a situation analysis to (i) describe the provision of psychosocial interventions within the context of existing care in two LMICs-India and Pakistan, and (ii) understand the barriers and facilitators of delivering a new psychosocial intervention.

Method: A situation analysis including a quantitative survey and individual interviews with clinicians, patients and caregivers was conducted. Quantitative survey data was collected from staff members at 11 sites (private and government run hospitals) to assess organizational readiness to implement a new psychosocial intervention. To obtain in-depth information, 24 stakeholders including clinicians and service managers were interviewed about the typical care they provide and/or receive, and their experience of either accessing or delivering psychosocial interventions. This was triangulated by six interviews with carer and patient representatives.

Results and discussion: The results highlight the positive views toward psychosocial interventions within routine care and the enthusiasm for multidisciplinary working. However, barriers to implementation such as clinician time, individual attitudes toward psychosocial interventions and organizational concerns including the lack of space within the facility were highlighted. Such barriers need to be taken into consideration when designing how best to implement and sustain new psychosocial interventions for the community treatment of psychosis within LMICs.

KEYWORDS

severe mental illness, psychosis, psychological interventions, India, Pakistan, low and middle-income countries, situation analysis

Introduction

It is estimated that 5–8% of the world's population suffer from severe mental illness (SMI) (1). Despite its prevalence, the majority of individuals with SMI, do not have access to appropriate and effective community-based care (2, 3). Within low and middle-income countries (LMICs), an estimated 69–89% of people with SMI experience a treatment gap. This is most pronounced for psychosis, where 75% of all individuals fail to receive adequate care (4), despite a high financial burden and poor quality of life (5).

Approximately 20% of the world's population live in India and Pakistan, making it one of the most densely populated regions on the planet. The Global Burden of Disease study in 2017 estimated that 3.5 million people or 0.3% of the population in India have schizophrenia, with a further 7.6 million people (0.6% of the population) having bipolar disorder (6). Although estimating the percentage of people with psychosis in Pakistan is challenging due to the quality of data and a lack of electronic medical records in some regions, estimates suggest that approximately 1.5% of the population (3.3 million people) suffer from schizophrenia or related disorders (7).

Community-based psychosocial interventions are recommended in the treatment and management of psychosis across different high-income countries (8), as they have been shown to be effective in reducing symptoms, relapse and hospital admission rates, and improving functioning (9). A systematic review and meta-analysis that specifically focused on community-based psychosocial interventions within LMICs, mirrored these findings. However, only two of the included studies were conducted in India and none were included from Pakistan (7). Since the review, there has been further evidence of the positive impact of psychosocial interventions on outcomes for people with psychosis (10) including in India (11, 12) and Pakistan (13, 14) whilst small-scale studies have indicated that community-based family intervention can be feasible and beneficial for patients with depression and anxiety (15). Despite, these positive outcomes, treatment for people with psychosis within India and Pakistan predominantly consists of antipsychotic medication and tends to center on inpatient and hospital-based services (7).

Within LMICs such as India and Pakistan, there are limited financial and human resources to deliver psychosocial interventions, especially those specialist interventions that require certain professionals and/or competencies. Low-intensity interventions developed in high-income countries have not been routinely implemented or thoroughly tested within different LMIC contexts. Approaches that can be used by a range of staff within routine settings, without the need for expensive new services, have been identified as a feasible and sustainable way of reducing the treatment gap (16).

PIECEs is a National Institute of Health Research (NIHR-funded) Research and Innovation for Global Health Transformation (RIGHT) programme (NIHR200824) that aims to improve community based care for people with psychosis in India and Pakistan. The programme is working with key stakeholders including patients with psychosis, family and caregivers and clinicians to adapt an existing low-cost, generic and evidence-based intervention called DIALOG+ (17–20) so it can be feasibly applied within Pakistan and India to improve the quality of life for individuals with chronic psychosis.

DIALOG+ is a psychosocial intervention, which aims to make the routine meetings between clinicians and patients with mental illness, therapeutically effective. The intervention is delivered via an App on a tablet computer or smartphone and is based on the principles of quality of life, patient-centered consultations and solution focused therapy. DIALOG+ consists of a patient-centered assessment whereby patients rate their satisfaction with eight different life domains and three treatment aspects on a tablet computer. This is followed by a four-step solution-focused approach to identify their resources and develop solutions to deal with the concerns. The intervention has been shown to be effective in improving quality of life and reducing symptoms in a range of RCTs conducted in both high income countries (HICs) and LMICs, including the UK, Austria, Uganda, Colombia, and within five South-Eastern European countries (14, 21–23). With only minimal training (around 90 min), different staff members who have clinical contact with individuals with mental illness can be trained to deliver the intervention. Therefore, it is generic and requires neither specialist professionals, nor new services and referrals to bring about therapeutic change. Instead, it works by empowering patients to undertake actions to address their own concerns (24).

To adapt any psychosocial intervention, such as DIALOG+, it is vital to first understand existing services, assess stakeholder readiness, and determine any contextual barriers and facilitators of implementation. Consequently, the aim of this study was to conduct a situation analysis of the provision of existing psychosocial interventions for individuals with psychosis practiced in a range of settings within two urban areas of India and Pakistan. The investigation explored organizational and individual patient, caregiver and clinician-level barriers and facilitators of implementing a new psychosocial approach.

Methodology

Design

We conducted a situation analysis across two urban sites in India and Pakistan, utilizing both a quantitative survey (called the structured site visit form) and qualitative interviews with mental health providers, which were validated by people with psychosis and their caregivers.

Setting

This situation analysis took place in Chennai, India and Karachi, Pakistan. Government and non-government-run hospitals were included in each site, with a purposive sampling method used to identify services to be interviewed between March and April 2021. The Department of Psychiatry and Behavioral Sciences at the Jinnah Postgraduate Medical Centre (a public tertiary mental health facility) and Karwan-e-Hayat, a welfare-run mental health facility were included in data collection in Pakistan. In Chennai, the situation analysis was expanded to gather data on existing mental health services across the city. This included government run tertiary care hospital, single practitioner private psychiatric clinics, group psychiatric practices, general hospital psychiatry units, private psychiatric hospital, and non-government organizations.

Participants

Participants for the two sections of the situation analysis varied. For the quantitative survey, the lead clinician and/or service manager was approached to complete the information. For inclusion in the quantitative survey, participants were required to have (i) worked for a service providing care to people with psychosis and (ii) have an overview of the services provided within their organization. Lead clinicians and service managers were then asked to identify other clinicians in their service for the qualitative interviews with key informants. Additionally, clinicians from the different services were approached to take part in individual interviews. To validate the service provider interviews, the Lived Experience Advisory Panel (LEAPs) set up at for each site as part of the PIECES research project were used to identify eligible patient and caregiver representatives.

To be eligible, patients were required to (i) have current or previous lived experience of psychosis, (ii) have used mental health services within one of the included organizations, (iii) be aged 18 years and older, (iv) have capacity to provide informed consent and (v) be willing and able to discuss their experience of care with a researcher.

Materials

For the quantitative survey, the pre-designed structured site readiness tool was used. The tool has been previously used in global health studies evaluating the use of psychosocial interventions in routine care across different LMICs (25–27). The questionnaire is designed to assess the readiness of an organization to implement a new psychosocial intervention. It includes items on the following: (1) organizational structure of local services, (2) type and number of patients seen, (3) type and number of employed clinicians, (4) care components typically delivered, and (5) practical structural information regarding the physical environment and financial mechanisms underpinning the services. A full copy of the form is shown in Supplementary material 1.

The site readiness tool was complemented by semi-structured interviews with clinicians and service managers to capture in-depth, rich descriptions of the care provided and types of psychosocial interventions delivered within routine services. The topic guides for the clinician interviews with clinicians explored the following topics: (i) service structure and function, (ii) typical care provided to patients, (iii) experience of delivering existing psychosocial interventions, and (iv) barriers and facilitators including organizational readiness to adopt new psychosocial approaches. The topic guide was developed through consensus discussions within the research team, which includes individuals from India, Pakistan and the UK. The topic guide was adapted for use with patients and carer as part of the validation interviews, and to ensure appropriate language was used within each site.

Procedure

Included services were identified by the principal investigators at each site, based on previous experience with health facilities within the area and their professional networks. Following identification of a service, the lead clinician and/or service manager in charge of the services was approached to complete the structured questionnaire. All participants completed the pre-designed tool after signing the informed consent document. Each participant was also asked to respond qualitatively to the items in the structured tool.

Key clinicians within each healthcare facility, were identified through in-person snowballing techniques. Initially, the lead clinicians were asked to identify potentially eligible staff. Following the initial clinician interviews, staff, and members of the LEAPs in each site helped identify patients and caregivers to act as representatives for the validation interviews. Following completion of the informed consent form, researchers completed an in-depth interview. The interviews were conducted in English and Tamil by SJ, PR and LV in the Chennai site and in Urdu by AJ, AS and OQ in the Karachi sites. All interview facilitators received prior training for qualitative methods and data collection techniques. Researchers came from a range of backgrounds including health services research, psychiatry, psychology, and social work. The interviews were conducted in a quiet private space, were audio-taped, transcribed verbatim and translated into English as required.

In accordance with national COVID-19 guidelines, interviews were conducted through online conferencing software such as Zoom, Skype and WhatsApp and lasted between 40 and 60mins. Data saturation was defined when no new information was added to the codebook.

Data analysis

Basic descriptive statistics for participant characteristics (including gender and staff designation) and facility details (such as number of presenting patients each year, number of facility staff, availability of clinical supervision and opportunities for CPD) were collected through the structured site visit form, supplemented by interviews, and collated through Microsoft Excel. Additionally, basic demographic information was collected as part of the semi-structured interviews. In all cases, descriptive statistics including means and ranges were used to summarize the data.

For the qualitative data analysis, individual interviews were transcribed, translated and anonymized by each site before sharing. As the interviews were primarily interested in the experience of delivering and/or receiving psychosocial interventions rather than in-depth accounts of mental distress, the topic guide was used as an initial guide to develop the themes. After data immersion, two interviews were coded to inform a codebook developed by PR and shared with five members of the research team for review and iterations (PR, OQ, SD, LV, VB). The initial codebook was used for coding an additional four interviews by two members of the research team (OQ and SJ). Following a process of coding comparison and discussion to address areas of divergence, a final version of the coding framework was developed and used to code the remaining interviews on QSR NVivo.

Ethics

Ethical approval for this study was sought under the PIECEs programme. Ethical approval for the overall project was granted by Queen Mary University of London's Research Ethics Committee (QM28_10_20) and local ethics approval granted by IRD International Review Board in Karachi, Pakistan (IRD_IRB_2021_01_005) and the Schizophrenia Research Foundation's Ethics Committee in Chennai, India (SRF-CR/14/OCT-2020).

Results

Sample characteristics

A sample of 11 facilities (nine in Chennai, two in Karachi), which varied from large government run hospitals through to single private psychiatric practices, completed the quantitative structured questionnaire. Twenty-four individual interviews were conducted with a range of clinicians from 11 different mental health care facilities. The interviews explored existing practices for mental health treatment within healthcare systems across Chennai, India and Karachi, Pakistan. The data from the structured questionnaire has been integrated alongside the themes from the individual interviews, which explored the areas included in the questionnaire in more depth. The characteristics of individuals who took part in the interviews are shown in Table 1. Additionally, the themes from the clinician interviews were triangulated by interviews with three caregivers and three people with psychosis, who took part as patient representatives. Demographics of the patient and carer representatives are shown in Table 2.

Data from the structured questionnaires and themes from the individual interviews were organized using a thematic approach into the following overarching framework: (i) existing practice (ii) barriers and facilitators of implementing a new psychosocial intervention and (iii) organizational readiness to adopt a new approach. A full coding framework is shown in Supplementary material 2.

Existing practices

Contact with the mental health services

There was significant variance in the number of patients reported across facilities with large-scale hospitals or charity-run organizations seeing higher patient volumes compared to private practices (Table 3). The average duration of contacts varied depending on whether the contact was for a new or returning patient, with patient follow-up appointments shorter than the initial assessments. Duration of contact also varied by facility and was dependent on patient load, specific needs of the

TABLE 1 Socio-demographic profile of staff members interviewed at the selected facilities.

	India	Pakistan
Mean age (yrs)	47.7	49.5
Sex		
Male	5	5
Female	11	3
Mean duration of experience (yrs)	17.7	15.9
Types of participants	1. Psychiatrists 2. Psychologists 3. Social Workers 4. Management staff	1. Psychiatrist 2. Psychologist 3. Management staff
Type of organization	1. NGO 2. Pvt. Psychiatrist 3. Pvt. Psychiatric hospital 4. Pvt. GHPU 5. Pvt. Psychiatrist Group Practice 6. Govt. tertiary care hospital	1. NGO 2. Govt. tertiary care hospital

TABLE 2 Socio-demographic profile of patient and caregiver participants.

	India	Pakistan
Participant type		
Persons with mental illness	2	1
Carer	2 (father, brother)	1 (mother)
Sex		
Male	4	0
Female	0	2
Mean age of participants (yrs)	57	59.5
Mean duration of illness (yrs)	13.75	28.5

patient and caregivers and the setting e.g., whether in-patient admission, an OPD walk-in or planned appointment.

Across both settings, a range of psychosocial interventions were implemented, although patients varied as to whether they had access. The different types of services offered are outlined in Table 4.

Multidisciplinary working

In both countries, the majority of patients were seen by multiple mental health professionals, with an emphasis on providing an integrated multidisciplinary team. Within government /NGO services, the care pathway appeared to follow a flow from the reception (first point of contact) through to the case manager/trainee/nurse and then to the consultant psychiatrist. In contrast, in private clinics, the psychiatrist or the psychologist directly handled the contact from the off.

> *"We have Social workers, general doctors, clinical psychologists, rehab practitioners, occupational therapists, community nurses, community mobilisers, community psychologists and community psychiatrist, child psychologists, psychiatric nurses - all of these people work collaboratively to make up the core mental health team". [Head of medical services, NGO, Karachi, Pakistan]*

Across the sites, facility staff worked together as a team in a collaborative, integrated fashion to address the needs of patients and caregivers holistically. For example, the nurse manages their physical assessment, case-manager and psychologist their psychosocial assessment, and psychiatrist focuses on medication management.

> *"Ward psychologists, OPD psychologists, day care and rehab psychologists discuss patient treatment plans as a team and communicate with the psychiatrist whenever required. So in an integrated manner we are providing all the services to the patients" (Head of Medical Services in NGO, Karachi, Pakistan).*

Despite a lower number of allied health professionals, clinicians reported that a wide range of services were offered to individuals with psychosis (as shown in Table 4). These included medical consultations, psychosocial interventions, and psychological therapies. In addition, support services in the form of free medications, in-patient care when required, day care programmes and employment services were available in some services. This was corroborated in the individual interviews with patients also reporting a wide variety of services including non-pharmacological interventions, psychological therapies and structured psychosocial interventions. However, pharmacological interventions were still the most common form of treatment available to most patients, especially those in government run facilities, who were able to provide subsidized medicines to patients.

New cases

In both locations, the procedure for registering new cases involved a range of staff including case managers, social workers and consultants who work together to take the patient's physical and mental history and evaluate their treatment needs. Special care is given to the needs identified by the patient, or their caregivers and psychoeducation is provided at this stage with the aim of increasing awareness and treatment compliance.

The duration of sessions for new cases depends on symptom severity and can take anywhere between 10 and 90 min (with

TABLE 3 Description of patient volumes, average duration of contact, frequency of contact, decision making by type of facilities.

	NGOs (3)	Private psychiatric facility (6)	Government hospitals (2)
Number of patients seen in a week	281	64	2250
Average duration of each contact	10 mins—1 h	10 mins—30 mins	10–30 mins
Frequency of contact	1 week—6 months	1 week—6 months	1 week—1 month
Individuals initiating treatment decisions	Clinicians	Clinicians and caregivers	Clinicians

TABLE 4 Summary of types of services offered to people with severe mental illnesses by type of mental health facility in the study sample.

NGOs (3)	Private psychiatric facility (6)	Government hospitals (2)
Psychological Services e.g., CBT, family interventions, art therapy, psychoeducation, pharmacological therapy with psychiatric management, ECT, Vocational therapy, rehabilitation services, in-patient admission, long term care, community outreach, psychiatric management, out-patient services	Psychological services e.g., psychoeducation, pharmacological therapy with psychiatric management, ECT, vocational therapy, rehabilitation wards, in-patient admission, long term care, referrals to other specialists for comorbid conditions or halfway homes, tele counseling, job placements, government welfare schemes, specialist mental health treatments e.g. transcranial stimulation and ketamine transfusion	Psychological services e.g., CBT, social skills training, pharmacological therapy with psychiatric management, ECT, vocational therapy, rehabilitation services, in-patient admission

the average estimated at 30 min). Many clinicians report that decisions around treatment options are generally clinician-led. Clinicians are aware of this responsibility, noting that caregivers and patients depend heavily on them for directing priorities and managing care. Some clinicians also see this as an opportunity to build rapport with family members to support the patient's on-going management at home.

> *"Patients and families they sort of surrender all responsibilities of what needs to be done" (Psychiatrist, NGO, Chennai, India).*

> *"We spend a lot of time with relatives, especially primary caretakers. So we cashed into the Indian social, system where the parents and or, or the family plays a very, very vital role supporting the patient. And that family support is pretty strong. So we try to cash in on it as much as possible. So a lot of emphasis from our side is to work with the family" (Psychiatrist, Private practice, Chennai, India).*

Follow-up

Patients are often called back to the facility for review on a fortnightly basis. Frequency of contact between patients and clinicians varied from 1 week to 6 months in India and 1 week to 1 month in Pakistan. In many facilities, the clinicians who initiated assessment and treatment for the patient remain consistent for their review, to enable the relationship to form and to maintain continuity of care – essential in the delivery of many psychosocial interventions. Another approach taken by some facilities, seen most commonly in Pakistan where medication is heavily subsided or free, is to link the quantity of medication prescribed so that it finishes by the next follow-up. This helps to encourage patients to come back to check in with their clinicians. Clinicians tend to increase the time (from 1 week to 6 months) between review sessions, and some offer other contact methods if the patient is managing their condition well-or lives far away.

> *"I see the patient today, probably after a week, then afterwards, I will see them after about a week and a half, then probably a month, then may be it is quite stable month and a half, 40 days" (Psychiatrist, Private practice, Chennai, India).*

The proportion of patients presenting with psychosis or psychosis-related conditions varied in the facilities from 30 to 45%. However, respondents in larger facilities reported that the majority of their cases (80%) present with severe or chronic mental health conditions and are typically admitted for inpatient care. Some of these patients belong to a lower socio-economic status and cannot afford mental health care. Clinicians within these facilities noted that included among those admitted were people who may be homeless, those with a long duration of untreated psychosis and individuals who have already experienced multiple types of medical and non-medical interventions.

> *"I can give you an example of a lady who kept a tub in her room and passed stool in that, because she was very scared of going to the washroom, because she had hallucinations. Her husband thought that it was the doing of some supernatural being [possessed] or somebody had done magic on her. So up until 2 years ago she was just being treated for magic and from faith healers. So the patients [. . .], estimated they come to us after 10 years. [. . .]. So by the time they come here, they have had such cognitive deterioration, and the symptoms are so great that that person takes more time, longer time to recover" (Clinical Psychologist and Rehab In-charge in NGO, Karachi, Pakistan).*

Involvement in care and treatment decisions

Some clinicians identified a disagreement between their own treatment goals and those presented by patients and caregivers. Whilst there was a general perception of the benefits of caregiver and patient involvement in treatment planning, clinicians find it necessary and sometimes challenging to counsel their clients to re-prioritize their treatment goals. They reported that most of the concerns identified by patients and their caregivers related to physical, social or lifestyle challenges i.e., sleep issues, weight gain, sexual dysfunction or reproductive health, rather than mental health symptomatology.

> *"Come in with acute relapse [. . .] and that is the time when they suddenly come and ask we are planning for pregnancy can we go ahead with it? [. . .] In the middle of the acute psychotic episode, those are the time we will have to put our foot down and say like your priorities are definitely not right" [Senior Psychiatrist, NGO, Chennai, India].*

One clinician also identified a struggle to encourage the caregivers to support patients to try non-pharmaceutical interventions, including psychosocial interventions. A general focus on the medical model was identified as a barrier in changing attitudes toward integrating psychosocial approaches in treatment.

In the majority of cases, it is the clinician or other healthcare worker who initiates the discussion and advises treatment options. While there are accounts of clinicians involving both caregivers and patients in these sessions, generally, more importance was given to caregiver accounts of the patient's condition as clinicians identified issues around capacity and a reduction in cognitive functioning of patients. Only a handful of clinicians assigned significant value toward facilitating more independence by patients in directing their treatment plans, as it was perceived as developing motivation for self-care and management.

> *"So then we sit down and then make a list of okay now you're presenting these things, how do you think we can help you and what are the things you want to work on first. [...] Typically, ensuring that the client presents, just so that the motivation levels are more than us trying to tell them, I think it's better to start working on this". - [Psychologist, Private practice, NGO, Chennai, India]*

This was triangulated by two of the caregivers interviewed, who felt they were actively involved to either verify the information relayed by the patient or to keep a check on them. However, involving caregivers in the long-run may not always be possible as often family members were only consulted once, right at the start of the treatment.

> *"Initially in 2013 when we came to meet her they called me separately and asked few things and then my son separately and asked few things then they would make us sit together and ask few other things, but after that nothing of that sort has happened till date."* [Caregiver in LEAP, Chennai, India]

Home visits

There were mixed responses to the system of home visits. In Chennai, while the NGO had a system in place for home visits, the private clinicians did not do any home calls and home visits were often limited to picking up patients for admission when family members made requests.

> *"No we don't do home visits. Personally I don't do home visits, but patients and families do request for home visits. But nowadays what we have started is, we have... we will send the ambulance to bring a patient who is not willing for treatment and is violent, we'll send the staff nurse. If the male nurse is going to fetch the patient and if the patient is willing to talk to the male nurse, immediately a video call will be done and I will try to talk to the patient.." (Private Psychiatrist in Private Practice, Chennai, India).*

Barriers and facilitators of implementing a new psychosocial intervention

The second overarching theme related specifically to the barriers and facilitators that different stakeholders anticipated when delivering a new psychosocial intervention. These barriers and facilitators were reported in the individual interviews with clinicians and further verified by the patient and caregiver representatives. Barriers and facilitators existed and operated at different levels, from the individual patient level, through to organizational difficulties.

Accessing appropriate care

Although not reported directly by clinicians, during the triangulation interviews, caregiver and patient representatives frequently discussed issues accessing appropriate care. This included logistical difficulties such as the distance and cost of services, to the beliefs of patients and relatives.

> "*Difficulties like costs of transportation, rent sometimes is a lot...she would insist on going in the rickshaw. So in the start I would take her in the rickshaw but then when coming back I would bring her in the bus...as its costing a lot of money like in rickshaws they used to ask us for a lot like 300..so yeah difficulties have come a lot in going to and fro (from the facility)*" [Caregiver in LEAP, Karachi, Pakistan].

> "*My family they thought it was black magic, so they didn't allow me to take my sister out to hospital...my family had history of mental illness; they were also not getting treatment...so that was the first barrier for me my own family members won't allow me to take her out*" [Caregiver in LEAP, Chennai, India].

One patient revealed being 'locked up' for 18 years due to a lack of awareness of mental health problems on the family's part. Another patient talked about their attendant making them discontinue medication.

Barriers that were specific to the patient's symptoms were a common theme. A caregiver in Karachi, discussed how their relatives were resistant to treatment follow-ups as it involved them waking up early to attend appointment which were mostly in the mornings. Another caregiver shared how their relative's cognitive issues, which can be compounded by facility wait times, meant patients could become difficult to manage.

> "*I have to get her ready in half an hour by the time I reach [Facility] she becomes more dull...it takes at least 30 min to 1 h to see the doctor...it takes 30 min, that is in a free time, if there are lot of people coming in then it will take more than 30 min and she tends to get very fidgety to sit somewhere other than home she doesn't find comfortable.*" [Caregiver in LEAP, Chennai, India]

Use of technology

The increased use of technology, especially in service delivery at both sites, could overcome and address barriers faced when accessing care. In particular, technology facilitated maintaining contact with patients, following up on clinical status, including early identification of relapse, increased medication compliance, and has helped to deliver some interventions.

> *"We use technology to maintain contact with the patient. To make sure that they take their medication in a timely manner, through their caregivers. How is the patient feeling, whether or not they are facing any relapse etc." (Service Director and Management, CEO of NGO, Karachi, Pakistan).*

Follow-up methods often increasingly made use of technology, for example, a respondent from India reported facilitating follow up via "*email communication*" (Lead Psychiatrist in Private Psychiatry Group Practice, Chennai, India).

Finally, within this theme, electronic medical record systems were identified as helpful in keeping track of review cases, with the exception of a government facility in Pakistan that depended entirely on paper-based records.

Funding availability

The availability of funding was reported to be a challenge in both sites. Whether an NGO in Chennai or the government run facility in Pakistan, limited availability of financial resources was seen to limit the scope of services provided, including the provision of psychosocial interventions. In a lot of cases, a nominal charge is paid by the family to access care, with families reporting that the cost of care was further compounded by the costs associated with travel.

> *"As we operate on zakat and donation, the welfare department ascertains whether a patient can pay a certain part of their fees and then charges the patient according to affordability." (Head of Medical Services of NGO, Karachi, Pakistan)*

COVID-19 pandemic

Clinicians across Pakistan and India reported a drastic drop in outpatient volume as well as admissions due to the COVID-19 pandemic. They attested to multiple challenges for patients seeking psychiatric help, ranging from a lack of public transport to reach facilities to the unavailability of psychiatric medication due to pharmaceutical companies shutting down or prioritizing the supply of other medicines. Clinicians also reported being cognisant of the fact that the pandemic had affected income for a large section of the population making it even more difficult to afford mental health services.

Numerous changes were introduced to the routine services including clinical contact with patients and caregivers and training opportunities for healthcare workers. Social distancing and the COVID measures put in place within services made it difficult to deliver many psychosocial interventions, which rely on extended face-to-face contacts.

> *"We received instructions from Admin because a huge number of patients are there in the psychiatric OPD in our 2 OPD days. We were told that you have to see only 50 patients in a major OPD day. So it was difficult to see which 50 patients should be seen, should it be initial patients who came first or do we see patient's with needs like if they are aggressive or violent or unmanageable at home." [Psychiatrist in Government hospital, Karachi, Pakistan]*

Alongside strict COVID-19 procedures including the use of masks, sanitiser, social distancing and screens between doctors and patients, clinicians reported shifting to prescribing cheaper and more readily available medicines, providing online and telephonic consultations, and ensuring that their patients are able to reach them via WhatsApp or email. However, these measures further hampered the delivery of psychosocial interventions, which were emphasized less compared to pharmacological approaches.

Organizational readiness to adopt a new intervention

The final part of the framework relates to organizational readiness to adopt new psychosocial interventions and approaches within services. Data for this section of the framework was initially collected via free-text items on the structured site visit form and supplemented with interviews with clinicians to elaborate on the emergent themes. Table 5 provides a summary of the themes reported across both countries.

Buy in or acceptance of the interventions

Clinician attitudes could either be a barrier or a facilitator to successful implementation. A senior psychiatrist from Chennai felt that older psychiatrists might be reluctant to adopt a new intervention due to their existing experiences.

> *"The first I think, its more a human barrier first I think if you ask me. In the sense people must be convinced that this is worth trying ....they could be sceptical about it right at the beginning you know. So it's a lot of attitude and as you said human barrier rather than managerial barrier or any other barrier so if you are able to get at least 50 to 60 % of the mental health professionals feel convinced about this and say 'it okay let's see if it works or not'," (Psychiatrist in NGO, Chennai, India)*

This was reiterated by others, who stated that many clinicians are resistant to change and there is a need to be committed and flexible to implement a new program. In addition, there was a strong need to create awareness specifically about non-pharmacological approaches within services. This also extended to the patients and their families, and was corroborated by family members as being an important influence on their attitudes toward psychosocial interventions.

> *"Awareness of non-pharmacological intervention is very very less like under their protection; my child or my daughter should come out of the symptoms, only the medicines will be sure is what they... Yeah front line of treatment is the medicines but alongside non-pharmacological intervention is also available is what we need to reintegrate, emphasize and repeatedly talk to them then only it will get registered" (Manager, NGO).*

Case load and time constraints

High caseloads in all study sites were noted as a main barrier to the implementation of psychosocial interventions. In all public mental health facilities, it appeared that caseloads were high.

> *"In an outpatient clinic to bring in a specialized intervention it is always going to be difficult because the number of patients who require services stays very high" (Psychiatrist in NGO, Chennai, India).*

Linked to high caseloads, the time required to implement psychosocial interventions and the lack of time during routine consultations was reported by the majority of clinicians as a major barrier to changing practice. Particular issues were encountered where psychiatrists provided private consultations, it was felt that psychosocial interventions, could potentially eat into the paid consultations in their practice.

> *"I think it is also a question of the amount of time that is being spent. So, again what will happen is if we are going to do this for a sub group of patients on any regular day, it may not be always possible to do it as part of the regular OPD, we will have to do on appointment on a separate day where there is no pressure of time or pressure of other patient...." (Management Staff in NGO, Chennai, India).*

The time spent delivering interventions was felt to affect the running of a busy service. Instead, many felt that psychosocial interventions should be offered as a specialized intervention for a select population only. In acute presentations or in busy OPDs it was felt that a structured psychosocial intervention would be too difficult to deliver due to time and resource constraints, particularly in terms of sustained implementation.

> *"But I always say this, I keep saying that at [Facility] there is extreme enthusiasm initially for everything, then after 3–4 months we wouldn't know what happens." (Psychiatrist in NGO, Chennai, India).*

TABLE 5 Key findings from healthcare workers on barriers and facilitators to the adoption of a new intervention at mental health facilities in India and Pakistan.

Themes	Key findings across sites
Acceptance of adopting new interventions	- Lack of suitability to local context (PK**), personal willingness (IN***+PK) were among the factors contributing toward reluctance among individual clinicians to adopting new interventions + Belief in enhanced quality of consultation structure (IN), and flexibility to adapt and utilize new approaches (PK+IN) were among the factors facilitating willingness among individual clinicians to adopting new interventions
Time and resource constraints	- Facilities experience a constant under-staffing of human resources (IN) causing high caseloads and pressure on existing workforce (IN+PK) makes the buy-in of a new intervention challenging - With limited consultation time and a crowded facility setting, clinicians identified the lack of time as a major barrier to the utilization of a new intervention (IN+PK)
Structural factors	- Long waiting times and lack of appropriate space in facility for ensuring privacy or storage (IN+PK) - Limited funding from public-sector (IN) for human resources and equipment (computers and software) needed for adopting new interventions (IN+PK) + New interventions should be adapted to align within routine care, scheduled appointments (IN+PK) and among specific providers at facilities (IN)
Managerial support	+ Facility management's support is paramount for willingness of clinicians to adopt new interventions (IN+PK) - Need to change multiple areas and practices to accommodate a new intervention (IN+PK)
Use of technology	- Younger clinicians more likely perceived to adopt technology-mediated interventions and resistance expected from more senior consultants (IN) + Facility staff open to use of new technology-based approaches for mental health delivery (IN+PK) + Existing practices as COVID-19 prompted the use of technology in mental health delivery e.g. virtual consultation and online M&E systems for data security and privacy (IN)
Training in using new interventions	- Facilities do not have a separate training department or structured training process for new recruits to learn how to utilize interventions (IN) + Existing systems of support and supervision (e.g. by peer clinicians and senior consultants) at mental health facilities facilitates the adoption of new interventions (IN+PK)

**PK Findings from Pakistani participants.
***IN Findings from Indian participants.

Scheduling appointments ahead of time was seen as one way of overcoming issues of clinician availability.

> *"Well, our schedule is very very tight and is difficult for us, but if there is training then we schedule our requirements and appointments beforehand to manage the time slot if we find out 2–4 days in advance. We schedule ourselves accordingly to manage." (Clinical Psychologist in NGO, Karachi, Pakistan).*

Within the triangulation interviews, caregivers overwhelmingly responded positively to accessing a new treatment method especially if it was recommended by their clinician or discussed with the care provider. Furthermore, one caregiver accepted a new intervention or treatment method even if it required more time since it can be an additional activity for the patients who otherwise are mostly homebound with limited activities.

> *"I usually defer it to [doctor's name] if she says you should take it, i usually take it. I won't say no to her." (Caregiver in LEAP, Chennai, India).*

Structural factors at the facilities

Linked to the above, hospitals and OPDs appeared to be crowded, with a high number of patients accessing the facilities on an average day. Within this context, privacy was noted to be a challenge, and one that occurred across all facilities.

> *"we are seeing a huge number of patients and it is very crowded. We have to examine patients in front of everyone, and there are usually two to three patients in the same room. We don't really have a choice in the matter as our existing set-up cannot accommodate the large volumes of patients [...]Our current building is not sound-proof and does not account for any form of privacy for the patient." (Psychiatrist, Government Hospital, Karachi, Pakistan).*

Although patients and clinicians in some facilities stated that there was always space for private consultations, in many services more than one clinician shared the space, which raised issues concerning patient confidentiality. Often space within OPDs were not large enough for the delivery of separate psychosocial interventions.

> *"we also simultaneously see two patients in one room – but those who need individual attention, psychosexual or private conversation, then they see a psychologist or transformation and within that set up we adjust them – we don't see every patient individually" (Psychiatrist and Dean, Dept of Psychiatry in NGO, Karachi Pakistan).*

Even where private rooms were available for consultations, there were still issues surrounding privacy.

> *"Yes, so we have separate rooms. They're not soundproof, but of course their voice cannot go outside the premises. We have two cubicles, but we have a library, and my office, basically in my office I take family intervention sessions. So that doesn't have an issue of confidentiality, but of course, in your case we have space." (Clinical Psychologist and Rehab In-charge, NGO, Karachi, Pakistan).*

Managerial support

Many respondents reported that management was supportive of implementing new approaches. However, a need for increasing clinician numbers, and managing the caseloads effectively was felt to be critical for successful implementation.

> *"I don't think anything needs to be changed in the organization, each individual will have to plan out his/her work and it must work on with appointments, it may not work as part of regular OP service" (Psychiatrist in NGO, Chennai, India).*

Many respondents felt that structural and functional changes were needed to accommodate new psychosocial interventions, like the DIALOG+ intervention within PIECEs. Clinicians suggested several areas where changes needed to be made to allow the seamless introduction and implementation of the intervention. One key suggestion was to only include patients who already have a good rapport with the clinician, stating these patients could initially be engaged in a novel intervention.

> *"I feel like with a few, when they do get to know me better, I think it depends a lot on the client & the psychiatrist engagement- So once the engagement & the- what do you call that- rapport is there then using this might be helpful with clients." (Psychiatrist in Private practice, Chennai, India).*

Use technology and technology-related issues

The psychosocial intervention within the PIECEs project, DIALOG+, is delivered on a tablet computer. There were mixed responses to the use of a tablet for delivering a psychosocial intervention. While one senior psychiatrist felt it was a matter of getting used to using the device, several others pointed out challenges in the use of devices for delivering interventions. These included the need for training and supervision, software related issues, difficulty in documenting on a device, internet connectivity and cost of devices.

> *"I think it is more to do with the internet bandwidth available, and some of the software that we are using can be little difficult to use and so making… no keeping records on that particular format in the software is a little bit stressful, actually it's not little bit stressful its quite stressful" (Psychiatrist in NGO, Chennai, India)*

Another respondent implied the difficulty in using a device when the caseload was high. Furthermore, many clinicians reported still preferring paper and pen format over a device, especially older clinicians.

Training in using new psychosocial interventions

The majority of interviews with clinicians and service managers in the NGO and Governmental organizations across both countries identified that facilities typically had structures in place for the continued professional development of their workers. These structures could be utilized in the event of capacity-building required for the delivery of a new intervention. This included residency programs for teaching hospitals, skills training for nurses, sessions for psychologists and social workers on counseling and communication, workshops on specific psychiatric topics or research methodologies. Training was either delivered in house or externally at conferences. Due to COVID-19, some of the facilities reported a reduction in the frequency of these trainings but there was general consensus on the benefit of structured capacity-building for a variety of medical staff at the facilities as well as being trained in the use of a particular psychosocial approach (Clinical Psychologist, NGO, Karachi, Pakistan) (Management Staff in NGO, Chennai, India).

> *"So that is amazing, the whole of the clinical team will be available for this training. Because to some extent every clinician is interacting with patients so there is a definite need for constant training. Why not from a versatile trainer too. We can make it possible, you arrange it and we will definitely ensure that all our clinicians attend" (Head of Medical Services, NGO, Karachi, Pakistan).*

Supervisory mechanisms for the evaluation and quality control of mental health service provision was available at all facilities interviewed with the exception of two NGOs and one private practice group in India.

> *"I am not very sure if the consultants themselves are getting supervised I don't think we have any regular audits or anything about how a particular patient or how a particular*

> *consultant is managing, because I think it is more an individual consultant or his or her own way of managing clients." (Psychiatrist in NGO, Chennai, India).*

In addition to organizational supervision being provided e.g., as part of a residency program or clinical practice, a handful of clinicians identified that peer supervision to troubleshoot issues related to complicated treatment protocols amongst the mental health workers in a facility was an enabler in supporting organizational readiness.

> *"Well like, like you have your peers in your department, you might not have them in one department but we still we still have a tightly knit circle of, you know, psychiatrist you know we who commonly, you know, share our challenges and the problems that we face" – [Psychiatrist, Private practice, Chennai, India).*

Discussion

The situational analysis aimed to understand the provision of psychosocial interventions within the context of existing services in the two study sites in India and Pakistan, and explore the readiness to integrate a new technology-based psychosocial intervention.

A diverse range of mental health care facilities were included in the study. There was an overall consensus on the benefits of taking a collaborative and integrated approach when delivering mental health care to patients with psychosis. This approach has been recognized as vital to the long-term successful and holistic management of the treatment needs of people with severe mental health conditions in a variety of contexts (28). Within the services included in the study, psychiatrists typically referred individuals in need of psychosocial therapies to psychologists, occupational and rehabilitation therapists, where available, as these staff members could spend more time with patients and their caregivers to resolve social concerns and provide psychoeducation for on-going self-care and management.

Although staff, patients and caregivers were positive about psychosocial interventions, there were a number of practical and organizational barriers to their routine delivery. In particular, the time taken to deliver a psychosocial intervention and the impact this would have on the rest of the caseload was a primary concern. This was especially the case for large government run hospitals and outpatient departments (OPDs) where staff were expected to see large volumes of patients per day, and typically could only spend 10 min per patient. In such services, pharmacological approaches tended to dominate.

The use of technology both to support and deliver new psychosocial interventions was seen as a barrier and facilitator, with some clinicians raising concerns about technical issues, whilst others stated that technology, including electronic medical records, could support an integrated approach to mental health care.

Strengths and limitations

The study had a number of strengths. Firstly, it recruited a range of different services, which varied in their size and funding mechanisms from single psychiatrists in private practices to large government run hospitals. Secondly, a mixed methods approach was used, with findings from the quantitative survey corroborated and expanded upon by in-depth individual interviews. The interviews with clinicians were further triangulated with data from patient and caregiver representatives. Thirdly, a wide range of clinician participants were included such as service managers, psychiatrists, social workers and nurses. This enabled us to understand the current provision of psychosocial interventions from multiple perspectives.

Despite these strengths, there were three main limitations. The selected services included in the study were from two cities, Chennai and Karachi, and were a self-selected sample. Services across India and Pakistan may vary in terms of their approach to the care of people with psychosis. However, in this case, the decision was taken to focus on services in the regions where the intervention within the PIECEs programme will be initially implemented in order to understand the local context for service delivery and help us develop tailored implementation plans. Finally, although used as a method for triangulation and validation, only six patient and caregiver participants were included in the project. The included individuals were patient representatives identified via the project's existing lived experience advisory panels. A decision to use only patient and caregiver representatives was taken, in part, due to the difficulties in accessing groups of individuals during the COVID-19 pandemic. Despite the low numbers, the interviews produced rich descriptions that corroborated and expanded upon many of the themes identified by the clinicians. Future studies could include a larger sample of patient and caregiver participants.

Clinical and research implications

In both India and Pakistan there is a dearth of specialized mental health professionals, with a range of 0.25–0.75 psychiatrists for every 100,000 individuals in the population (29, 30). Psychiatrists within the study viewed their workload as a barrier to addressing the psychosocial concerns raised by their patients and caregivers. If a holistic approach that integrates both psychosocial and pharmacological management is to be integrated into this workforce, system strengthening, capacity-building, and managerial changes to build human resources is required. This includes the introduction of collaborative approaches with primary health care facilities to reduce the institutional burden attributed to mental health problems within low resource settings (31, 32).

A few clinicians in the included facilities acknowledged the importance of utilizing a patient-centered model and actively engaged their patients to contribute toward their treatment priorities and goals. However, it was often felt that patient concerns differed from the clinical symptom management goals set by the clinicians. Furthermore, the majority of clinicians demonstrated resistance in relying on the account of patients with psychosis as they did not consider them to have enough insight and capacity to be independently involved. In recent years, normative guidelines, including those published by the Lancet Global Health Commission on High-Quality Health Systems (33), and the World Health Organization underscore the importance of patient-centered approaches in health systems in recognition that 'people have the right to receive dignified and respectful care that is responsive to their needs' (34). While this approach is still in formative stages in LMICs, there is strong evidence to suggest that mental health services that are patient-centered and responsive to individual needs are linked to improved contact rates with mental health services, better treatment compliance and a high level of patient satisfaction. Given that many people with psychosis in LMICs struggle with continuity of care, social disempowerment and access barriers (35), integrating a holistic and patient-centered psychosocial response to psychiatric management within facilities in India and Pakistan has the potential to strengthen mental health response and make mental health more equitable and responsive to patient needs.

Clinicians highlighted a need for increased community awareness of mental health, arguing that awareness raising does not stop at providing patients with proper mental health care and support, but should cover the importance of continuity of care. A lack of awareness at the community and family level can lead to worsening treatment prospects and outlook. Since the majority of the clinicians report involving caregivers, psychosocial interventions that include a component that actively engages support systems from caregivers and other people around the patient's family can be well-received. A previous study has shown that family psychoeducation that aims to improve the caregiver's insight into the illness, enabled both the family and the patient to cope in a more effective way and resulted in a significant improvement in overall quality of life scores (36). More recent studies related to employment of persons with psychosis also point to the need of involving families in the provision of vocational rehabilitation services (37, 38). As seen in the interviews by caregivers, buy-in for existing or new interventions is heavily dependent on the clinicians who manage their relative's condition. Based on this evidence, it is worth ensuring that facility-based psychosocial interventions, in South Asian contexts, should involve a multi-collaborative stakeholder approach and target clinicians, caregivers and patients together to improve acceptability and access to support. In addition, interventions should also factor in the caregiver's needs due to the additional burden of care on them and consider integrating access that limits the cost of transport to facilities.

Contrary to popular belief, patients with psychosis in both Pakistan and India attested to a variety of mental health services being accessible for them, although this varied across institutions. Additionally, most patients, if not all, confirmed that they were easily able to get in touch with their clinicians via email or text for advice on medicines or management of symptoms – a service that has undoubtedly helped many during the COVID-19 pandemic. However, it must be noted that individuals included within the study, were already in contact with services. Further work may be required to include the perspectives of individuals with mental distress who are not in contact with mental health services.

Although there was a clear want and need for psychosocial interventions, expressed by clinicians and then validated by patients and caregivers, a range of structural organization and personnel related barriers to their sustained implementation were highlighted in both the quantitative survey and the interviews. The range of barriers suggests that merely focusing on the cultural competence and sensitivity of a new psychosocial intervention to be implemented will not be sufficient. Instead, projects aiming to implement new approaches need to consider the local context, and especially any context specific barriers, when designing both the intervention and implementation plans.

Conclusion

Across the different services and settings for the interviews, there was consistent support for the use of psychosocial interventions to treat patients with psychosis in a multidisciplinary and integrated approach. However, there is a need to address organizational level barriers, mainly surrounding the lack of human resources across mental health services in India and Pakistan. Any new psychosocial will need to develop implementation and awareness strategies in a multi-level approach, targeting patients, caregivers, clinicians and the organization as a whole. Additionally, there is a need for local mental health services that incorporate the expectations of caregivers of people with mental health conditions to foster better coordination between stakeholders, and enhance support for reintegration into the community, and ultimately recovery for individuals.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Queen Mary University of London and the Ethics Committees of Schizophrenia Research Foundation and Interactive Research and Development. The patients/participants provided their written informed consent to participate in this study.

Author contributions

VB and PR were responsible for obtaining the original funding for the project. All authors contributed to the design, conduct, analysis, and write up of the manuscript.

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Conflict of interest

Authors AJ, OQ, and AS were employed by Interactive Research and Development.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2022.807259/full#supplementary-material

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