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Original Article

Independent and Social Living Skills Training for People with Schizophrenia in Iran: a Randomized Controlled Trial

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Objectives: Schizophrenia is responsible for a significant proportion of burden of mental diseases in Iran. Lack of a follow-up system has resulted in the repeated hospitalizations. In this study it is hypothesized that standardized living skills training delivered to participants with schizophrenia in outpatient and inpatient centers can be effective compared to a control group (with occupational therapy) in reducing psychopathology severity and increasing quality of life.

Methods: This is a multi-centered parallel group randomized controlled trial in Iran and it is single-blinded. Eligible participants are randomly allocated into two groups in a 1:1 ratio. Participants are assigned by stratified balanced block randomization method. The trial is conducted in the cities of Tehran and Mashhad. Its aim is to recruit 160 clients with schizophrenia. The intervention for the experimental group is social living skills training. The intervention for the control group is occupational therapy. The intervention for both groups is conducted in 90 to 120-minute group sessions. The primary outcome of the study would be a decrease in psychopathology severity, an improvement in participants' quality of life, and reduction in family burden will be followed for 6 months.

Discussion: This paper presents a protocol for a randomized controlled trial of independent and social living skills training intervention delivered to participants with schizophrenia. If this intervention is effective, it could be scaled up to be developing for policymaking and improving outcomes for schizophrenic participants and their families in Iran.

Keywords: social living skill training, schizophrenia, inpatients, outpatients, occupational therapy

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Introduction

Schizophrenia is a severe mental disorder that usually onsets in early adulthood and is often associated with persistent or relapsing symptoms and a range of adverse outcomes (1,2). Impairments in social functioning are among the most debilitating and treatment refractory aspects of schizophrenia (3). A survey in Iran showed that the lifetime prevalence of psychotic disorders in Iran is 1% (4). It is estimated that there are at least 400,000 participants suffering from schizophrenia in Iran (5). In low-income countries the availability of

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community services is the exception not a norm (6). Thus, for the majority of clients with schizophrenia and their families there is little access to any psychological care (7). In the past five decades, mental health services have seen major strategic changes (8,9). Mental health services in developing countries have improved but they are not efficient, not well designed and public-private centers are inadequate and insufficient (10). In Iran services are limited to psychiatric hospitals and private offices. Revolving door phenomenon generally is occurring (11).Providing psychosocial services can have a significant impact on decreasing relapse and improving participants' clinical condition (12). It can also reduce burden of psychiatric disorders and increase the efficacy of interventions (13). During 1960s and 1970s the effectiveness of social skills training has been studied and emphasized (14).In several studies, participants' families have reported their major needs to be gaining knowledge and learning necessary skills to cope with this mental issue of their family members (15,16). Many studies have shown that family intervention with the aim of connecting with participants' family and educating and supporting them are effective in decreasing the rate of relapse, hospital stay period and family burden (17). Family intervention can also improve participants' functioning (18). Various clinical guidelines have suggested family intervention as the main part of treatment for serious mental disorders (19).

Social skills training along with group therapy can improve patient's functioning and quality of interpersonal interactions (20). Study of the effects of social skills training has showed an increased ability in performing daily life activities and improving the negative signs of schizophrenia (21). Thus scaling up an accessible, acceptable and effective structured and feasible services for clients with schizophrenia is an urgent mental healthcare system (22). Promising results need to be rigorously tested through a randomized controlled trial. The objectives of the trial are to see whether clinical skill training will be effective in improving a range of outcomes in participants with schizophrenia and their families in a 6 months follow-up and to determine if the skill training intervention is applicable in Iran. The primary objectives of the trial are to determine whether the social and independent and social living skills training (SISLST)[1] will be effective in participants with schizophrenia, i.e. reducing psychopathology severity, and improving global functioning. The secondary objectives are to determine whether SISLST will be effective in improving adherence to antipsychotic treatment and service satisfaction. The objectives for schizophrenic participants' families are to determine whether SISLST will be effective in improving quality of life and reducing family burden.

Methods

This is a randomized controlled trial with equal allocation of participants between parallel groups. The study (allocation ratio is 1:1) will compare two groups of people with schizophrenia allocated to receive either (I) SISLST or (II) occupational therapy with 6 months follow up. The participants are schizophrenic participants in the age range of 18 to 55 years old, literate, are in the active phase of illness and have a diagnosis of schizophrenia as per diagnosed schizophrenia diagnostic and statistical manual of mental disorders, 4th Edition, Text Revision criteria (DSM-IV-TR) (23). They have been hospitalized at least once before and have an overall moderate severity of the illness based on the global assessment of functioning (GAF) (40-70) scale (24). All participants are living with a family member. Also, the participants do not suffer from clinically significant physical or neurological disorders/mental retardation and drug dependence or abuse. If there is risk that a participant might harm himself/herself and others, s/he will be excluded from the study. Participants are recruitment from within the existing cases at each center.

The trial will be conducted in two centers in Iran: a university-affiliated hospital in Tehran and in social welfare-affiliated center (aka BEHZISTY) in Mashhad. Both centers have been chosen to reflect a diversity of health system contexts. Interventions will be conducted 3 times per week at outpatient centers and 5 times per week at inpatient centers for a period of 90 to 120 minutes per session. Each session is conducted in a group with 4 to 6 participants. In the maintenance phase during months 6, the therapists will monitor the progress and discuss strategies to deal with the emerging issues. Almost all clients with schizophrenia in the studied centers should have psychotropic medication. The SISLST includes the following components: medication and symptom management, leisure management and basic conversational skills. Each module teaches from 4 to 9 skills and each skill is taught with "learning activities". All

1. Designed by Dr. Robert Paul Liberman

information has been systematically translated into the Farsi for the use of participants and families. The intervention has been systematically piloted at inpatient and outpatient centers. Based on the results of the field-testing (content analysis), the final version has been adapted.

Also family members of the intervention group will participate, as generalization agents, in separate sessions (one weekly two-hour 4 family group sessions) where they will be provided structured educational information concerning learned skills as well as problem solving and home assignment. The occupational therapy (control) group will receive psychosocial occupational therapy services including group therapy (group discussion), leisure activities, arts and structured activities. This group will receive the same assessments as the intervention group. They will receive traditional occupational therapy. The prescribed occupations are health-related activities (personal health, medication monitoring, daily activity monitoring, living skills training, physical activities, art groups, recreation activities, social groups). In the inpatient setting (Iran psychiatric hospital in Tehran) a psychologist will screen participants after the active phase in wards one time a week for eligibility criteria. In outpatient setting, two psychologists will choose the participants. The screeners will provide a brief overview of the trial through a group meeting and ask the person and the caregiver(s) whether they want to participate in the trial or not. All clients with schizophrenia will be assigned a unique ID. For those who have refused, the screener has the option of motivating their participation during the course of the recruitment period. Trial consent procedures have been designed in a non-technical language to reduce the cognitive problems (25). Participants will be informed with verbal and written information regarding the study in a (individual and group) meeting. If they refuse to participate, the screener will record their reasons. The participants will be supervised and reported in compliance with the recent CONSORT recommendations (26). Eligible participants are then assigned randomly to intervention or control groups by stratified balanced block randomization method with allocation concealment (allocation ratio 1:1). The allocation list has been generated independently by a statistician and diffused to the researcher before the beginning of the recruitment for the trial. The researcher will be responsible for assigning the unique trial ID for each participant in the trial and will notify the center coordinator. The nature of such services prevents adequate blinding of participants and the raters in follow-up evaluations process. To maintain blinding of these assessments, researchers are independent of the assessors.

Outcome measurements- We will use the assessments, at baseline, after the end of intervention, and 6 months follow up. For the symptoms of schizophrenia the primary outcome assessments will be recorded with the positive and negative symptoms scale (PANSS) (27). Also, world health organization quality of life (WHOQOL)-BREF will be used for measuring quality of life (28). For measuring the secondary outcomes for clients with schizophrenia, we will measure participants' satisfaction with the services by the client satisfaction questionnaire (CSQ)-8 (29). For measuring global functioning, we will use the GAF. The family burden will be assessed by the Experience of Caregiving Inventory (ECI) (30).

Data collection- Data are collected from all participants at time of index admission, discharge and at 6-month follow-up. Raters are clinical psychologists who are trained in a 2-day workshop on how to use data collection tools before the initiation of the study. Inter-rater reliability of ratings is also examined. Raters are not chosen from care providers to minimize bias. Studies show that the rate of "loss to follow up" for ratings in these setting is high (31).

Quality assurance and fidelity management- The same supervision procedure and protocol is employed for the whole process of case recruitment and data collection. To ensure fidelity, the intervention process indicators will be checked for significant divergence from pre-protocol norms related to the delivery of the intervention. In addition, randomly some of the sessions at each center will be assessed by a key researcher. To ensure quality assurance, all assessors have equal 3-sessions trainings with a single team and single training module and guidelines in both centers to ensure adequate inter-rater reliability.

Statistical analysis- SPSS version 19 will be used for data analysis. The findings will be displayed as frequencies, percentages, means and standard deviations, using tables and plots. Chi-squared analysis will be used to explore associations in the data. We will use the logistic regression analysis for the dichotomous outcome, and linear regression analyses for all other outcomes. The study data will be examined using t-tests, analysis of covariance,

and repeated measures of analysis of variance (ANOVA). An "intention to treat" approach will be employed based on the data from the earlier non-randomized study (32). Sample size calculation is based on the PANSS as the primary outcome measure. The following formula is used for the calculation: $N=2[z(1-\alpha/2)+z(1-\beta)]2x(SD2)/d2$.
Sample size is estimated 4O per group; assuming about 30% losses to follow-up (total: 160).
Ethical considerations- Before the conduct of the study, participants and their family members are thoroughly informed regarding the services. Written informed consent (non-technical language) is then obtained from the participants in compliance with the good clinical practice (GCP) guidelines (33). There is no penalty for not participating in the program. Participants will have the right to quit from the trial at any time. Participants' data will be strictly confidential. Questionnaires are filled out anonymously and are specified by an ID number. All the expenses are provided from the study budget. The study is approved at ethics committee of University of Social Welfare and Rehabilitation Sciences and is fully compliant with the Helsinki declaration 2011 (34).

Discussion

Providing skill training for people with schizophrenia in Iran is an urgent mental healthcare priority. The SISLST randomized controlled trial builds on previous observational evidence of the feasibility, acceptability and effectiveness of skill training programs. This trial is designed to provide evidence about the clinical effectiveness of the social and independent and social living skills training. Based on the participants and the diversity of the centers, we believe that the results of the study can be generalized beyond the study population. If the results confirm the hypotheses, this can have a significant impact on mental health policy and function of practitioners related to the scaling up psychosocial services for people with schizophrenia in Iran. This paper presents a protocol for an RCT of living skills training delivered to participants with schizophrenic participants in hospital or at outpatient centers. Also, the trial tries to understand participants' satisfaction of receiving this type of intervention. This study will be conducted according to the good clinical practice guidelines recommended for conducting multi center RCT.

Competing interests- The authors have no competing interest.

References

1. Thara R. Twenty-year course of schizophrenia: the Madras Longitudinal Study. Canadian Journal of Psychiatry. 2004;49:564-9.
2. Kurihara T, Kato M, Reverger R, Tirta I. Eleven-year clinical outcome of schizophrenia in Bali. Acta Psychiatrica Scandinavica. 2005;112(6):456-62.
3. Bellack AS, Green MF, Cook JA, Fenton W, Harvey PD, Heaton RK, et al. Assessment of community functioning in people with schizophrenia and other severe mental illnesses: a white paper based on an NIMH-sponsored workshop. Schizophrenia bulletin. 2007;33(3):805-22.
4. Rahimi-Movaghar A, Amin-Esmaeili M, Sharifi V, Hajebi A, Radgoodarzi R, Hefazi M, et al. Iranian Mental Health Survey: Design and Field Procedures. Iranian Journal of Psychiatry. 2014;9(2):96-109.
5. Education MoHM. Situational analysis of psychiatric services for severe mental participants. In Ministry of Health and Medical Education. Tehran2008.
6. Thornicroft G, Tansella M. Components of a modern mental health service: a pragmatic balance of community and hospital care Overview of systematic evidence. The British Journal of Psychiatry. 2004;185(4):283-90.
7. Jacob K, Sharan P, Mirza I, Garrido-Cumbrera M, Seedat S, Mari JJ, et al. Mental health systems in countries: where are we now? The Lancet. 2007;370(9592):1061-77.
8. Organization WH. The World health report: 2001: Mental health: new understanding, new hope. 2001.
9. Srinivasa Murthy R, Burns B. Community Mental Health–Proceedings of Indo–US Symposium. National Institute of Mental Health and Neurosciences, Bangalore. 1992.
10. Organization WH, Colleges WOoN, Academies, Physicians AAoGPF. Integrating mental health into primary care: a global perspective: World Health Organization; 2008.
11. Sharifi V. Urban mental health in Iran: challenges and future directions. Iranian Journal of Psychiatry and Behavioral Sciences. 2009;3(1):9-14.
12. Coldwell C, Bender W. The effectiveness of assertive community treatment for homeless populations with severe mental illness: a meta-analysis. American Journal of Psychiatry. 2007;164(3):393-9.
13. Malakouti K, Norouzi M. Mental health follow-up in chronic mental participants. Andeesheh va Raftar. 1995;4(15):5-13.
14. Dilk MN, Bond GR. Meta-analytic evaluation of skills training research for individuals with severe mental illness. Journal of Consulting and Clinical Psychology. 1996;64(6):1337.
15. Group IEPAW. International clinical practice guidelines for early psychosis. The British Journal of Psychiatry. 2005;187(48):s120-s4.
16. Peyman N, BAHRAMI MANIZHEH SY, VAHEDIAN M. Assessing the family problems and the rate of their tendency to admitting and keeping mentally–Ill patients at home after discharging from Mashhad Hospitals (1380-1382). The Quarterly Journal of Fundamentals of Mental Health. 2005.

17. Pharoah F, Mari J, Rathbone J, Wong W. Family intervention for schizophrenia. Cochrane Database Syst Rev. 2010;12.
18. Penn DL, Waldheter EJ, Perkins DO, Mueser KT, Lieberman JA. Psychosocial treatment for first-episode psychosis: a research update. American Journal of Psychiatry. 2005;162(12):2220-.
19. Dixon L. Providing services to families of persons with schizophrenia: present and future. The journal of mental health policy and economics. 1999;2(1):3-8.
20. Daniels L. A group cognitive-behavioral and process-oriented approach to treating the social impairment and negative symptoms associated with chronic mental illness. The Journal of psychotherapy practice and research. 1998;7(2):167.
21. Patterson TL, McKibbin C, Taylor M, Goldman S, Davila-Fraga W, Bucardo J, et al. Functional adaptation skills training (FAST): a pilot psychosocial intervention study in middle-aged and older patients with chronic psychotic disorders. The American journal of geriatric psychiatry. 2003;11(1):17-23.
22. Wang PS, Aguilar-Gaxiola S, Alonso J, Angermeyer MC, Borges G, Bromet EJ, et al. Use of mental health services for anxiety, mood, and substance disorders in 17 countries in the WHO world mental health surveys. The Lancet. 2007;370(9590):841-50.
23. Association AP. Diagnostic and statistical manual of mental disorders, text revision. American Psychiatric Association, Washington, DC. 2000.
24. Association AP. Global assessment of functioning scale. Diagnostic and statistical manual of mental disorders, 4th edition, text revision Washington, DC: American Psychiatric Association. 2000;34.
25. Carpenter WT, Gold JM, Lahti AC, Queern CA, Conley RR, Bartko JJ, et al. Decisional capacity for informed consent in schizophrenia research. Archives of general Psychiatry. 2000;57(6):533-8.
26. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010;8(1):18.
27. Kay SR, Flszbein A, Opfer LA. The positive and negative syndrome scale (PANSS) for schizophrenia. Schizophrenia bulletin. 1987;13(2):261.
28. Group W. Development of the World Health Organization WHOQOL-BREF quality of life assessment. Psychological medicine. 1998;28(03):551-8.
29. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation and program planning. 1982;5(3):233-7.
30. Motaghipour Y, Shams J, Salesian N, Sharifi V, Alaghband Rad J. Cultural Adaptation, Validity and Reliability of Persian Version of Experience of Caregiving Inventory in Families of Patients with Severe Mental Disorders. Iranian Journal of Psychiatry and Clinical Psychology. 2011;17(3):226-31.
31. Killaspy H, Banerjee S, King M, Lloyd M. Prospective controlled study of psychiatric out-patient non-attendance characteristics and outcome. The British Journal of Psychiatry. 2000;176(2):160-5.
32. Yildiz M, Veznedaroglu B, Eryavuz A, Kayahan B. Psychosocial skills training on social functioning and quality of life in the treatment of schizophrenia: A controlled study in Turkey. International journal of psychiatry in clinical practice. 2004;8(4):219-25.
33. Organization WH. Handbook for good clinical research practice (GCP): guidance for implementation. 2005.
34. Association WM. Declaration of Helsinki. Ethical principles for medical research involving human subjects. 2009.