Psychiatry Research 241 (2016) 55–60

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

Evaluations of treatment efficacy of depression from perspective of both patients' symptoms and general sense of mental health and wellbeing: A large scale, multi-centered, longitudinal study in China

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ARTICLE INFO

Article history:
Received 10 June 2015
Received in revised form
2 March 2016
Accepted 29 April 2016
Available online 30 April 2016

Keywords:
Symptom
Mental health
Wellbeing
Hamilton Rating Scale for Depression (HRSD-17)
Observational design, Remission Evaluation and Mood Inventory Tool (REMIT)

ABSTRACT

Relying on the absence, presence of level of symptomatology may not provide an adequate indication of the effects of treatment for depression, nor sufficient information for the development of treatment plans that meet patients' needs. Using a prospective, multi-centered, and observational design, the present study surveyed a large sample of outpatients with depression in China (n=9855). The 17-item Hamilton Rating Scale for Depression (HRSD-17) and the Remission Evaluation and Mood Inventory Tool (REMIT) were administered at baseline, two weeks later and 4 weeks, to assess patients' self-reported symptoms and general sense of mental health and wellbeing. Of 9855 outpatients, 91.3% were diagnosed as experiencing moderate to severe depression. The patients reported significant improvement over time on both depressive symptoms and general sense after 4-week treatment. The effect sizes of change in general sense were lower than those in symptoms at both two week and four week follow-up. Treatment effects on both general sense and depressive symptomatology were associated with demographic and clinical factors. The findings indicate that a focus on both general sense of mental health and wellbeing in addition to depressive symptomatology will provide clinicians, researchers and patients themselves with a broader perspective of the status of patients.

1. Introduction

The World Health Organization (WHO, 2012) reported that depression is one of the most prevalent mental disorders. Characterized by chronicity it is one of four main diseases contributing the global burden of disease, accounting for 4.4% of total disability-adjusted life years (Ferrari et al., 2013). Although the prevalence of depression is lower in Chinese communities when compared to other countries or regions (Lee et al., 2009; Phillips et al., 2009), the disease burden remains significant (Hu et al., 2007), and has become a major public health issue.

Effective outcome measures are essential for clinicians to monitor the patient response to treatment and inform treatment decisions for depression. Quantitative measures, based on patient self report, are commonly employed for this purpose. The current assessment criteria of the treatment effect for depression are mainly based on the symptom index. For example, declaration of remission is frequently based on the criterion of a total score equal to or less than seven using the Hamilton Depression Rating Scale for Depression (Hamilton, 1967), or a total score less than five using the Patient Health Questionnaire (Kroenke et al., 2001). However, remission may be more complex than the absence of depressive symptoms as assessed by such measures because the diagnostic criteria upon which they are based might not completely summarise the patient's experience of depression. For example, Zimmerman et al. (2012a, 2012b) found that some patients who are in remission according to scores on the Hamilton Depression Rating Scale do not consider themselves to be in remission, while some others who are not in remission according to the rating scale nonetheless consider themselves to be in remission. This is despite both being self-report. In support of this findings, Nease et al. (2011) found that although highly associated with each other, patients' self assessment of general sense of mental health

Abbreviations: HRSD, Hamilton Rating Scale for Depression; REMIT, Observational design, Remission Evaluation and Mood Inventory Tool

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http://dx.doi.org/10.1016/j.psychres.2016.04.111
0165-1781/

and wellbeing are not perfectly related to their depressive symptoms. Despite the above, in evaluating treatment effects, the vast majority of researchers and clinicians focus on depressive symptoms only, without paying attention to patients' self-reported mental health status and wellbeing. This was well demonstrated by Cuijpers' analysis (2011) which found that only 387 (0.6%) of 67,605 studies of depression focused on patients' perspectives of their mental health and wellbeing. On the basis of the argument that remission from depression based exclusively on the presence or absence of symptoms, may be uninformative. Riedel et al. (2010) emphasised the integration of symptoms and other dimensions into the evaluation of treatment effect. In fact, the Remission Evaluation and Mood Inventory Tool (REMIT) was developed for that purpose (Nease et al., 2011).

By regularly measuring both depressive symptoms and patients' general sense of mental health and wellbeing, the present study aimed to provide a comprehensive understanding of the outcome of treatment among outpatients with depression in China, by examining the relationships between depressive symptoms and other important latent domains. Understanding the changes in these factors and the relationship between them will provide enhanced evidence for clinicians to improve treatment plans.

The primary aims of this study were:

i. to evaluate the treatment effect longitudinally among outpatients with depression based both on self-reported depressive symptoms and sense of mental health and wellbeing,
ii. to examine the relationships between the two assessment approaches.

A secondary aim was to identify the factors related to treatment effects as assessed by each assessment approach.

2. Methods

2.1. Study design and sampling

A large-scale, prospective, multi-centered, and observational design was utilized in the current study. The recruiting sites were spread across 18 provinces/municipalities and 24 cities, scattered in seven administrative regions in East, North, South, Central, Northeast, Southwest, and Northwest China. Participants were aged 18 years and above, and had visited one of 40 hospitals (16 psychiatric hospitals and psychiatric/psychological outpatient departments in 24 general hospitals) in the study sites. Participants were excluded from this study if they had been diagnosed with either psychotic disorders or physical conditions that may have interfered with their capacity to engage in the study, or had communication difficulties due to physical disability or language barrier.

All participants met the diagnosis criteria for depression outlined in the 3rd version of Chinese Classification of Mental Disorders (CCMD-3) which is based on the International Classification of Diseases 10 (ICD-10, WHO, 1992). Although there are some differences among CCMD-3, ICD-10 and DSM-IV (American Psychiatric Association, 1994) in terms of symptoms included in and the level of severity of depressive episodes, there are no major differences in terms of illness duration, severity definition, and exclusion criteria. A previous study found that even with different utilized diagnostic systems, the diagnosis of depression was highly consistent (inter-rater reliability=0.997, Cohen's kappa=0.946) (Wang et al., 2008).

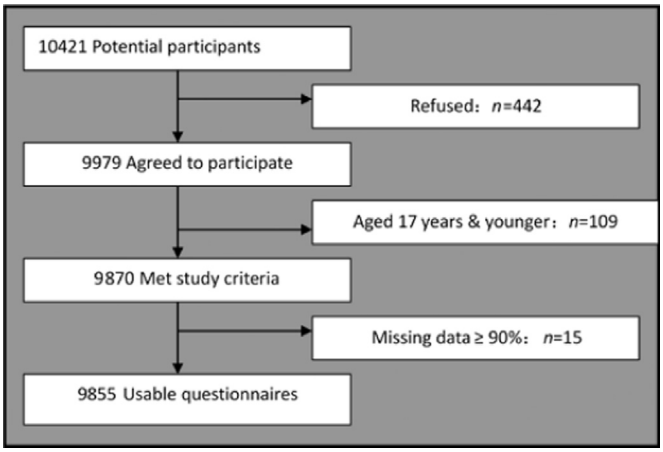

Fig. 1. Study recruitment flow chart.

2.2. Procedure

Ethics approval was provided by the Ethics Committee, Shanghai Mental Health Center. All participants provided signed informed consent. The study was conducted between 1 January 2012 and 31 December 2012. The follow-up assessments were carried out at Week 2 and Week 4 after baseline. All the information collected was either reported by the participants or recorded by the clinicians depending on the requirements of the different assessment tools.

Fig. 1 shows the flowchart of the recruitment process in the study. Of the 10,421 depressive patients recruited into the study, 442 patients refused to continue, and 109 patients were excluded as they aged less than 18 years. The remaining 9870 patients agreed to participate and provided written consent. After 15 were excluded due to over 90% of missing data, the final initial study sample was 9855. Of these, 9672 (98.1%), 9000 (91.3%), 8948 (90.8%) subjects completed Week 2, Week 4, and all scheduled follow-up visits, respectively.

2.3. Instruments

2.3.1. Demographic and clinical background

Demographical variables included age, gender, occupation, and education. Clinical background information, including hospital name, visit status, and antidepressant use prior to admission into the study were also collected at baseline, recorded by clinicians based on patients' reports.

2.3.2. Severity of depressive symptoms, treatment efficacy, and remission

The Hamilton Rating Scale for Depression (HRSD) version 17 (Hamilton, 1967) was used to assess the severity of clinical symptoms of depression over the previous two weeks. This instrument was administered by clinicians at baseline and follow-up visits. Most items of the HRSD use a 5-point Likert scale response format, ranging from 0 to 4 (0=*none*, 1=*mild*, 2=*moderate*, 3=*severe*, and 4=*extremely severe*). A few items use a three-category ordinal scale, ranging from 0 to 2 (0=*none*, 1=*mild to moderate*, and 2=*severe*). The total score of the HRSD reflects severity of depression. Scores of 7 or less represent no depression, scores between 8 and 17 indicate mild depression, scores between 18 and 24 suggest moderate depression, and scores over 24 correspond to severe depression (Frank et al., 1991). A total score of 7 or less for an individual who had been previously diagnosed with depression would suggest remission (Leucht et al., 2013). The present study used these thresholds to assess clinical severity,