Prevalence and characteristics of somatic symptom disorder in the elderly in a community-based population: a large-scale cross-sectional study in China

Assessment of Somatic Symptom in Chinese Community-Dwelling People

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STUDY PROTOCOL SYNOPSIS

Title	Prevalence and characteristics of somatic symptom disorder in the elderly in a community-based population: a large-scale cross-sectional study in China
Sponsor	Investigator-Initiated Trial (IIT)
Primary Objectives	1. to clarify the prevalence of somatic symptom disorder (SSD), depressive disorders, and anxiety disorders in the elderly in China; 2. to identify physical and psychological differences between the elderly and non-elderly; 3. to explore risk factors for SSD in the elderly.
Study Design	This prospective cross-sectional study (Assessment of Somatic Symptom in Chinese Community-Dwelling People, ClinicalTrials.gov identifier NCT04815863, registered on 06/12/2020) is a multicenter registry conducted in Shanghai, China, under the supervision of the Shanghai Association of Chinese Integrative Medicine. A multistage and stratified systematic sampling technique will be used to choose representative districts from sixteen districts in Shanghai, which are then divided into low, medium, and high economic levels according to the per capita gross domestic product of each district in 2018. Eleven districts will be selected proportionally and randomly and represented by 105 community health service institutions. The study was approved by institutional review committees at each center. The study is compliant with the 1975 Declaration of Helsinki guidelines. (1) assessment of somatic symptom disorder (SSD) The Somatic Symptom questionnaire is self-administered with an abbreviated 20-item measure. Briefly, it is composed of four dimensions: physical disorders, depressive disorders, anxiety disorders and depressive and anxiety disorders. Half of the items ask about physical complaints (one item per body system). SSS-CN scores ranging from 20 to 29, 30–39, 40–59 and ≥ 60 correspond to normal, mild, moderate and severe SSD, respectively. (2) assessment of depressive and anxiety disorders All participants will be assessed for depressive and anxiety disorders according to the PHQ-9 and GAD-7, which evaluate the frequencies at which certain symptoms had been experienced over the last two weeks, ranging from 0 (‘not at all’) to 3 (‘nearly every day’). The cutoff values are listed below. For PHQ-9, scores of 5–9 indicate mild depressive disorder, 10–14 indicate moderate depressive disorder, 15–19 indicate moderately severe depressive disorder and≥20 indicate severe depressive disorder. For GAD-7, scores range from 0 to 21, with scores of 5–9, 10–14, and ≥ 15

	representing mild, moderate, and severe anxiety symptom levels, respectively. (3) sociodemographic and clinical characteristics Sociodemographic data, including age, gender, level of education and marital status, will also be collected. A semi-structured questionnaire concerning clinical characteristics will be administered to survey participants' medical and medication histories.
Number of Subjects	Enrollment: 9110 [anticipate] Elderly group: 6874 [anticipate] Non-elderly group: 2236 [anticipate]
Enrollment Criteria	Inclusion criteria were: (1) voluntary participation and provision of written consent to participate in the study's evaluation and assessment; (2) completion of the SSS-CN questionnaire, Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD- 7) questionnaires. Exclusion criteria were : (1) patients lacking self-assessed abilities or who refused to participate; (2) patients who have been previously confirmed to have serious mental disorders, mental retardation, or dementia; (3) patients with cancer or central nervous system diseases; (4) patients with any missing data within questionnaire items or with more than one item missing from sociodemographic information; (5) patients with any medical conditions that in the opinion of the investigators will not be appropriate to participate in the study.
Safety Assessment	Adverse events were not required in this study protocol.
Endpoints	1. Number of Participants With Somatic Symptoms Disorder 2. Number of Participants With Somatic Symptoms Disorder Accompanied With Anxiety 3. Number of Participants With Somatic Symptoms Disorder Accompanied With Depression
Statistical Analysis	Descriptive statistics for each group, such as counts and percentages (%) for non-continuous variables, will be reported for all sociodemographic and clinical characteristics. The prevalences of SSD of various severities for different genders and for participants diagnosed with depressive and anxiety disorders will be calculated. In order to assess whether SSD, depressive and anxiety disorders are associated with aged groups and whether depressive and anxiety disorders are associated with the severity of SSD, binary logistic regressions will be performed, adjusting for gender, educational level (middle school and below, high school, college, master and above), marital status (never married, married, divorced, widowed), hypertension (yes/no), diabetes mellitus (yes/ no), CV disease

	(yes/no), endocrine and metabolic disease except DM (yes/no), other diseases (yes/no), surgery (yes/no) and antipsychotic intake (yes/no) in all models. Univariate analyses and binary logistic regression models will be used to assess the effects of sociodemographic factors and clinical characteristics on SSD in the non- elderly and elderly. Categorical sociodemographic and clinical variables will be analyzed by chi-square test. Binary logistic regressions will be performed using SSD (yes/no) as the dependent variable, adjusting for gender, educational level, marital status, and antipsychotic intake. Fisher's exact test was used instead of the chi-square test only when one or more expectations for each cell of the 2-by-2 tables was below 5. A significance level was set at a p-value < 0.05 (two-tailed). Missing data were imputed with a multiple imputation approach. All statistical analyses were performed with SPSS 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).