Statistical Analysis Plan

A Randomized Controlled Trial of a psychoeducational program "BalancingMySwing" for patients with bipolar disorder

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The psychoeducation BalancingMySwing (BMS) program has been developed manually and its feasibility has been tested in our previous study. This 3-year research project aimed to further examine the immediate and lasted effects of BMS program for BD, and to assess its knowledge dissemination and the transferability of its evidence-based practice across multiple sites.

During the first 2 years, a randomized controlled trial was conducted. One-hundred and twenty patients diagnosed with BD were recruited and 104 patients were randomly assigned to treatment as usual (TAU) or to 8 BMS sessions. A battery of three outcome indicators—social rhythm, illness perception, and symptom severity—were used to examine the effects of the two groups at baseline, after intervention, and every 3 months until half year. Mean age of all participants was 35.93, mean illness years were 12.15, and hospitalized times were 5.77. The majority was female, unmarried, college-graduated, and unemployed. Except marital status, there were no differences on illness perception, sleep quality, and symptom severity between two groups. At first post-intervention assessment, the BMS group demonstrated significantly superior on symptom identity, personal control of illness perception, and risk factors of illness causes than TAU ($p=0.031-0.044$), and depressive symptoms showed marginal effect ($p=0.057$). At 3-month assessments, the BMS group demonstrated significantly superior on personal control of illness perception and depressive symptoms than TAU($p=0.007, 0.002$). There was no significant difference between two groups at 6-month assessments. Through GEE analysis for group effects at different assessments, BMS group demonstrated superior effects on personal control of illness perception and depressive symptom than TAU. Time effects on timeline cyclic, personal control, illness coherence, sleep quality, symptoms severity were also significant. After controlling age and marital status, and the improvement of depressive symptoms was significant superior on BMS group than TAU. The effects on illness identity and personal control of illness perception were marginal significant($p=0.09，0.08$), and time effects on timeline cyclic, personal control, illness coherence, sleep quality, and symptoms severity were also significant. These findings supported that patients who received the BMS performed better improvements on illness perception and depressive symptoms than the TAU, and the effects of illness perception was lasted at 3-months assessments. Future studies are needed to support the effects

of sleep quality and manic symptoms, and the lasting effects of other outcome variables.

In the third year, a pre- and post-test quasi-experimental study combined with qualitative design was used to assess the translational feasibility of BMS and to explore related barriers and facilitators of implementing BMS in clinical settings. Nine nurses from 4 Hospitals received the BMS training, and 20 patients with BD received the BMS translated in practice. By using non-parametric Wilcoxon sign-rank test, all patients improved their illness perceptions on timeline cyclic, personal control, risk factors of illness causes, and sleep quality, but the differences were not significant. Patients' treatment satisfaction was 4.67±0.49, indicated they were high satisfied for the BMS program. Nurses' treatment adherence was above 80%, and they expressed positive experiences, even with some challenges, indicated that the BMS has been adequately implemented and translated in clinical practice.

In summary, the BMS could benefit patients with BD in their depressive symptom and illness perceptions on personal control. The triangulation research also supported its clinical utility for BD care in different settings. Our findings may establish the empirical knowledge on evidence-based psychosocial intervention for BD in Taiwan, and translate evidences into practice of multi-contextual clinical settings in order to disseminate empirical knowledge and modify the original theoretical understanding.