論文の内容の要旨

論文題目　Effects of Cognitive Behavioral Therapy Led by Peer Counselor on Depressive Symptoms and ART Adherence among People Living with HIV in Yangon, Myanmar: a Cluster-Randomized Controlled Trial

(ミャンマーの HIV 感染者におけるピアカウンセラーによる認知行動療法の抑うつ症状および抗レトロウイルス薬服用遵守に与える影響：クラスターランダム化比較試験)

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Introduction: World Health Organization estimated that approximately 37.9 million people suffer from HIV across the world. With an increased access to highly active antiretroviral therapy (HAART), is no longer considered a terminal disease, but rather as a chronic disease. Diagnosed of HIV carries threats to personal's psychology such as social isolation, loss of self-esteem etc, and as a chronic disease condition, people suffered from long-term physical discomfort, illness and physical changes. The stage of chronic conditions and stress due to the personal's psychology consistently has been with depression. People living with HIV (PLHIV) are nearly two times more likely to have had a recent episode of major depressive disorder. In addition, the highest depression prevalence rate was found in South-East Asia region at 40%, PLHIV is a high risk group for developing clinical and non-clinical depression.

Higher depressive symptoms score corresponded to immunological suppression, and it leads to the faster progression to the stage of AIDS. Similarly, ART adherence above 95% is necessary to maximize the treatment outcome and maintain positive immunological outcomes. In addition, depression was associated with ART non-adherence; it leads to more progress to the AIDS stage.

Cognitive behavioral therapy (CBT) has been proven to be an effective treatment for depression in many chronic conditions including HIV. Evidences showed that group-based CBT has an effective for depression and ART adherence among PLHIV. However, most the trials conducted in high-income countries and the limited evidence was available for the low resources setting of low- and middle-income countries.

Peer involvement in HIV treatment is mixed effect in nature, and CBT led by peer counselors has not been studied, although, peers play as an essential role in the HIV prevention and treatment. Therefore, we set the following objectives for the study.

This study aimed to develop a new group-based cognitive behavioral therapy (CBT) led by peer counselors targeting depressive symptoms and antiretroviral therapy (ART) adherence and to investigate its effects on improving depression (primary outcome), ART adherence (primary outcome), and immunological outcome (CD4 count) (secondary outcome) among people living with HIV (PLHIV) in Yangon, Myanmar, using a cluster randomized controlled trial design.

Methods: This trial was conducted among PLHIV from six ART institutions (clusters) in Yangon Region were randomly assigned to the intervention and control groups, stratifying urban and peri-urban settings. PLHIV who have Myanmar version Beck depression Inventory II (mBDI-II) score greater than 10 at the baseline were invited either the intervention or control groups. Randomization was done based on the size of ART institution (3-15 staff, > 15 staff), and performed with a computer program. Three ART institutions were allocated to the intervention group and the rest three were designated to the control group. The intervention groups were offered a cognitive behavior therapy program for eight weeks and the control group was offered usual ART counseling. An intervention program was developed consisting of eight elements including ART adherence, behavior activation, problem identification, challenging negative thoughts, and self-care plan. The CBT program was provided by peer counselors who taking ART. Two group-based CBT were conducted and ten PLHIV included in each group. The outcomes were measured using a structured questionnaire at the baseline, 3-month and 6-month follow-ups: Myanmar version of the Beck Depression Inventory II (mBDI-II), Hopkins Symptom Checklist for Depression (HSCL-D), a four-item scale for ART adherence, CD4 cell counts. Outcomes were analyzed by linear mixed models with maximum likelihood to express the effect of intervention by using SPSS version 22.

Results: At the 6-month follow-up evaluation, 20 PLHIV (71.4%) in the intervention group and 31 PLHIV (79.5%) in the control group completed the survey. There were no statistically significant differences in the depressive symptoms comparing the CBT to TAU whether evaluating outcomes on the mBDI-II (21.1 ± 9.2 vs. 20.4 ± 7.7) or on the HSCL-D (16.1 ± 6.7 vs. 13.6 ±7.6) at the baseline. The mean depressive scores were improved over 6-month follow-up in both groups. The overall depressive level in the intervention group was significantly decreased compared with that in the control group in both depression scales (mBDI-II: b= -8.1, SE= 3.0, p= 0.007, HSCL-D: b= - 5.5, SE= 2.4, p= 0.03). The Cohen's *d*at 6 months was - 1.0 from mBDI-II and -0.8 for HSCL-D. The unstandardized

coefficient for ART adherence was not significant at 3-month or 6-month follow-ups (b= 9.0, SE= 6.1, p= 0.15, b= 8.8, SE=5.2, p= 0.1). The Cohen's *d*at 6 months was – 0.15. The coefficient for CD4 count at 6-month follow-up was not significant (b= 135.3, SE= 135.5, p= 0.32). The Cohen's *d*at the 6-month follow-up was 0.4.

Conclusion: This cluster randomized controlled trial showed that peer-led cognitive behavioral therapy is feasible, acceptable and displayed efficacy in improving depressive symptoms and CD4 count among PLHIV who currently are taking ART and have depressive symptoms. Generally the size of the treatment effects, across outcome, was large in magnitude. This study is the first cRCT to demonstrate a positive effect on the depressive symptoms and CD4 count among PLHIV. The intervention program is unique because it was developed within the local context of PLHIV listening to voices from peer counselors who served as CBT providers. The program developed in this study may be useful in improving depressive symptoms of PLHIV in low- and middle-income countries with low health care resources**.**