CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study design: overview

3.1.1 Ethical approval and consent

Effect of walking plus individual motivational enhancement therapy (WIMET) program for schizophrenic patients with overweight or obesity; the study was approved by Ethics Committee for Research in Human Subjects, Faculty of Associated Medical Sciences, Chiang Mai University and the Ethical Review Committee for Research on Human Subjects, Suanprung Psychiatric Hospital, Chiang Mai (see Appendix A).

3.1.2 Study setting

After the ethics approval of the Ethics Committee for Research in Human Subjects, Faculty of Associated Medical Sciences, Chiang Mai University and the Ethical Review Committee for Research on Human Subjects, Suanprung Psychiatric Hospital, Chiang Mai, the study was carried out at Suanprung Psychiatric Hospital, Chiang Mai

Stratified randomization was applied for allocating participants into intervention and controlled groups. Participants were divided into those taking antipsychotics with high propensity to induce weight gain (i.e., clozapine, olanzapine) and without high propensity to induce weight gain (all other antipsychotics). Participants in controlled group will be given a leaflet of “What s a healthy lifestyle”. Only the subjects randomized into intervention group received walking plus individual motivational enhancement therapy (WIMET) program. The one-week, WIMET program consists of

five one-hour sessions of individual motivational interviewing, group education, goal setting, and practicing of pedometer walking. The pedometers were given to the intervention group only. Weight, height, body mass index, waist circumference, and quality of life were assessed at baseline, week 4, week 8, and week 12. The primary outcome of this trial was changed bodyweight at week 4, week 8, and week 12. In addition, physical exercise self-efficacy and WHOQOL-BREF were measured and used to predict the achievement of weight

3.1.3 Ethical considerations

Written inform consent (see Appendix A) to participate in this study was given by schizophrenic patients only. Because this study was carried out in schizophrenic patients who were waiting for discharge, most of them should be fully or almost fully recovery. In addition, only the patients with a CGI-S score of 3 or less (mild severity or less) were invited to participate in this study (see Inclusion criteria).

Participants provided their written inform consent before participate in this program. The participants were given a study number. They were not be identified personally on any study documentation; the study number appeared on all study documents Inform consent were kept separately from other study documents in a locked filing cabinet. The participants could withdraw from the program any time.

3.1.3.1 Risk and discomforts associated with study procedures

At present, most psychiatric hospitals, including Suanprung Psychiatric Hospital, had no formal weight-reduction program for schizophrenic patients. Giving a leaflet of

education (on nutrition/exercise) to control groups (see Appendix C), therefore, did not cause any disadvantage for the subjects.

Most public health guidelines recommend that adults participate in 30 minutes of moderate intensity physical activity as walking on most days of the week. Establishing new ways to achieve these targets and then weight loss in sedentary populations needed to be explored. No study had confirmed the efficacy of walking with pedometer on weight reduction in schizophrenic patients with obesity. The advantage and disadvantage in participating in either intervention group (received leaflet of education and WIMET program) or control group (received leaflet of education only) should not be much different.

The intervention in this study would be associated with minimal risks because:

1. Patients with unstable medical conditions or medical conditions contraindicated for exercise were excluded (see Exclusion criteria).

2. Education, practice, supervision, and feedback were be given by an investigator, a qualified occupational therapist (Waritnun Methapatara).

3.2 Study participants

3.2.1 Sample size

Population participating in study: Obese schizophrenic patients at Suanprung Psychiatric Hospital who were waiting for discharges were assessed. Those who were consistent with inclusion/exclusion criteria were given the full details of the study and requested for giving written informed consent.

The study carried out by Melamed and colleagues (2008) is similar to the present one. That study examined the effect of behavior intervention, nutrition information and physical exercise on the body mass index and weight people who were hospitalized with persistent schizophrenia and schizoaffective disorders. Fifty nine in-patients with a body mass index greater than 25 participated, (28 intervention group and 31 control group). Significant reduction in body mass index and weight were observed in the intervention group after 3 months. Means of the changed body mass index (SDs) of the intervention and control groups were 2.8 (4.5) and 0.2 (3.3), respectively. By setting the alpha level of 5% and the beta level of 50%, the sample size of this study should be 29 patients per group. To compensate for 10% loss to follow-up, the target sample size of this study was 32 patients per group. The sample size of the project was calculated online by using the program of researcher's toolkit (Researcher's toolkit. 2009).

3.2.2 Inclusion criteria

1. Aged 18-65 years old
2. Genders both
3. DSM-IV diagnosis of schizophrenia
4. Body mass index $\geq$23.0 kg/m^2
5. Stable on the same antipsychotic medication for at least 1 month prior to study entry
6. Mild degree of the severity (or less) of mental disorders as indicated by a Clinical Global Impression – Severity (CGI-S) (Guy, 1979) score of 3 or less (mild

severity or less), which has been found to be comparable to the PANSS (Positive and Negative Syndromes in Schizophrenia) score of 62 or lower (Levine, 2008).

7. No plan for pregnancy in the next 6 months

3.2.3 Exclusion criteria

1. An unstable medical condition
2. Medical condition contraindicated for weight reduction/exercise
3. Mental retardation
4. Mini-mental state examination: Thai version (Wongchaisuwan et al., 2005) ≤ 22 (see Appendix D)
5. Participating in a drug trial
6. Participating in a weight management program
7. Use of weight reduction medication
8. Pregnancy or breastfeeding

3.2.4 Discontinuation criteria

1. Meeting the exclusion criteria
2. Loss to follow-up for more than 4 weeks
3. Consent withdrawal
4. Hospitalization by any cause for 2 days or more

3.3 Intervention: walking plus individual motivational interviewing (WIMET) program

Motivation for increasing walking: Motivation is important to successful weight loss, and motivational counseling techniques can help patients need to walk off weight. To help determine patient motivation the author assessed the following factors:

1. What s a healthy lifestyle?
2. Patient's understanding of the causes of obesity and the contribution of obesity to disease
3. Reasons for weight loss
4. Availability for weight loss intervention

- Setting individual SMART goal:
  1. How to set SMART goal
  2. How to create and design SMART goal
  3. How to achieve success SMART goal
  4. How to write SMART goal
- Seeking personal step count limits by shifting boundaries:
  1. Common roadblock prevent people from exercise
  2. Benefits of walking with pedometer
  3. How to walk off weight with pedometer
- Setting a personal goal:
  1. How much of you are fat?
  2. Monitoring your heart rate
  3. Goal setting is important

For evaluation and the pedometer walking, the counselor gives information about self regulation principles to cope with laps and relapse.

- Keep up motivation

1. Fitting walk off weight into daily routine

For manual of Manual of WIMET program please see Appendix B.

One week after the discharge, the investigators called patients in the intervention group to ask about difficulties in compliance with the program.

3.4 Assessment and outcomes

3.4.1 Bodyweight, body mass index, waist circumference, and waist-hip ratio

Weight, height, body mass index, waist circumference, and quality of life were assessed at baseline, week 4, week 8, and week 12. Body weight was measured digitally with the subject wearing light cloth and no shoes. Waist circumference was measured in a horizontal plane, midpoint between the inferior margin of the ribs and the superior border of the iliac crest.

3.4.2 WHOQOL-BREF

The quality of life was evaluated by using WHOQOL-BREF (see Appendix F), a 26-items assessing four dimensions of quality of life, namely, physical health, mental health, social relationships, and environment. The WHOQOL-BREF is a shorter version of the original instrument that may be more convenient for use in large research studies or clinical trials (World Health Organization, 2004). The WHOQOL-BREF provides a valid and reliable alternative to the assessment of domain profiles

using the WHOQOL-100. It is envisaged that the WHOQOL-BREF will be most useful in studies that require a brief assessment of quality of life, for example, in large epidemiological studies and clinical trials where quality of life is of interest. In addition, the WHOQOL-BREF may be of use to health professionals in the assessment and evaluation of treatment efficacy (Yao, 2002). It was assessed at baseline, week 4, week 8, and week 12.

3.4.3 Physical exercise self-efficacy

Physical exercise self-efficacy scale (see Appendix E), a 5-item, 4-point scale (1-4, very uncertain to very certain) was used to measure the patient's physical exercise self-efficacy for exercise. It was developed by Schwarzer and Rrenner (2008). The measures to assess perceived self-efficacy for physical exercise was tested in the German versions. Adaptations to other languages have not yet been evaluated. It was translated into a Thai language back to the foreign language. It was assessed at baseline, week 4, week 8, and week 12.

3.5 Data analysis

3.5.1Primary and secondary outcomes of efficacy study

Bodyweight change was the primary outcome of this study. Secondary outcomes included changes of waist circumference, and waist-to-hip ratio. All outcomes assessed at baseline, 4, 8, and 12 weeks after treatment. Then these outcomes were compared between each week and baseline. Physical exercise self-efficacy and WHOQOL-BREF were assessed baseline, 4, 8, and 12 weeks. Their scores at week 12 were compared between groups.

3.5.2 Characteristics of participants responding to the WIMET program

Intervention patients were then divided into those who could reduce their weight more than 1 kg (successful weight loss or SWL group) and those who could reduce their bodyweight for 1 kg or less (unsuccessful weight loss or UWL group). The characteristics of both groups were compared.

3.5.3 Statistic tests and software

The data were analyzed on an intention-to-treat basis. The data of patients assessed at least once (at week 4) were included in the analysis. Last observation carried forward analysis was applied for the bodyweight, body mass index, waist circumference, physical self-efficacy, and WHOQOL-BREF scores. Descriptive analysis was done on baseline demographic and clinical characteristic data. For dichotomous, ordinal, and scale data, the differences between groups were assessed by using Chi-square ($\chi 2$), Mann-Whitney U (Z), and Student-t (t) tests, respectively. A value of $p<0.05$ (two-tailed) was used to determine the statistical significance.

The characteristics of SWL group and UWL group were compared. For dichotomous, ordinal, and scale data, the differences between groups were assessed by using Chi-square ($\chi 2$), Mann-Whitney U (Z), and Student-t (t) tests, respectively. A value of $p<0.05$ (two-tailed) was used to determine the statistical significance. All analyses were performed using SPSS software, version 17 (SPSS Inc., Chicago, Ill).