

## CHAPTER 4

### RESULTS

#### 4.1 Baseline demographic and clinical characteristic data

This study was carried out between February and August, 2010. Of 64 participants, 32 each were randomly allocated to intervention and control groups. All participants completed the study, and, therefore, the data of all 64 patients were included in the analyses. Most baseline demographic and clinical characteristics were similar between groups. However, the intervention group was significantly older ( $p=0.03$ ), tended to be less severely ill (CGI-S,  $p=0.05$ ), had larger waist circumferences ( $p=0.05$ ) (see Table 1). Approximately 43.8% of the participants were taking clozapine or olanzapine.

**Table 1.** Baseline demographic and clinical characteristics of obese/overweight schizophrenic patients participating in WIMET program and controls<sup>a</sup>

| Item  | Intervention<br>(n=32) | Control<br>(n=32) | Significant<br>difference <sup>b</sup> |
|---|------------------------|-------------------|--|
| Sex (male, %)                                     | 23 (71.9%)             | 18 (56.3%)        | $\chi^2=1.70$ , $p=0.30$               |
| Age (years)                                       | 43.16 (9.27)           | 37.59 (10.83)     | $t=-2.21$ , $p=0.03$                   |
| Education (years)                                 | 12.94 (5.95)           | 12.06 (4.90)      | $t=-0.64$ , $p=0.52$                   |
| Age at onset (years)                              | 28.47 (10.34)          | 26.12 (9.76)      | $t=-0.93$ , $p=0.36$                   |
| No. of hospitalizations (times)                   | 4.44 (4.76)            | 6.72 (7.28)       | $t=1.48$ , $p=0.14$                    |
| No. of patients receiving<br>clozapine/olanzapine | 14 (43.8%)             | 14 (43.8%)        | $\chi^2=0.00$ , $p=1.00$               |
| Clinical global impression,<br>severity (CGI-S)   | 1.25 (0.44)            | 1.56 (0.67)       | $Z=-1.98$ ; $p=0.05^*$                 |
| MMSE  | 26.69 (4.53)           | 27.84 (1.73)      | $Z=-1.06$ ; $p=0.29$                   |
| Bodyweight (kg.)                                  | 76.27 (10.81)          | 73.70 (12.31)     | $t=-0.89$ , $p=0.38$                   |
| Body mass index (kg/m <sup>2</sup> )              | 28.40 (3.14)           | 28.18 (4.43)      | $t=-0.23$ , $p=0.82$                   |
| Waist circumference (cm.)                         | 94.96 (7.98)           | 90.58 (9.32)      | $t=-2.02$ , $p=0.05^*$                 |
| Waist to hip ratio                                | 0.93 (0.09)            | 0.90 (0.06)       | $t=1.56$ , $p=0.02^*$                  |
| <b>WHOQOL-BREF</b>                                |                        |                   |  |
| Physical health score                             | 23.59 (3.83)           | 24.09 (4.67)      | $Z=-0.31$ ; $p=0.76$                   |
| Mental health score                               | 20.56 (4.01)           | 20.31 (3.79)      | $Z=-0.55$ ; $p=0.59$                   |
| Social relationships score                        | 11.00 (2.23)           | 11.69 (2.53)      | $Z=-1.11$ ; $p=0.27$                   |
| Environment score                                 | 27.72 (5.14)           | 28.53 (6.26)      | $Z=-0.61$ ; $p=0.54$                   |
| Total score                                       | 82.88 (12.35)          | 84.62 (14.79)     | $Z=-0.33$ ; $p=0.74$                   |
| Physical self-efficacy                            | 11.13 (4.01)           | 11.59 (4.83)      | $Z=0.36$ ; $p=0.72$                    |

<sup>a</sup>Except sex and no. of patients receiveing clozapine/olanzapine, data presented as mean and standard deviation

<sup>b</sup> $\chi^2$  = Chi-square test,  $t$  = Student-t test, and  $Z$  = Mann-Whitney U test

\*  $p \leq 0.05$

#### 4.2 Decreased body weight of the intervention and control groups

In comparison to the control group, the of the intervention group decreased bodyweight significantly more at week 12 ( $p=0.03$ ) with the mean difference of the decreased bodyweight of 2.21 kg. (95% confidence interval of 4.12 to 0.29) (see Table 2).

**Table 2.** Decreased body weight between obese/overweight schizophrenic patients participating in WIMET program and controls<sup>a</sup>

| item                       | Intervention<br>(n=32) | Control<br>(n=32) | Significant<br>difference <sup>b</sup> |
|----------------------------|------------------------|-------------------|--|
| Decreased body weight (kg) |                        |                   |  |
| Week 4                     | 0.27 (3.95)            | -0.83 (3.06)      | $t=-1.24, p=0.22$                      |
| Week 8                     | 0.82 (3.04)            | -0.69 (3.78)      | $t=-1.76, p=0.08$                      |
| Week 12                    | 0.80 (3.58)            | -1.41 (4.08)      | $t=-2.30, p=0.03^*$                    |

<sup>a</sup> All data presented as mean and standard deviation

<sup>b</sup>  $t$  = Student-t test

\*  $p \leq 0.05$

#### **4.3 Changed body mass index, waist circumference, and waist-hip ratio of the intervention and control groups**

The body mass index the intervention group decreased more than that of the control group at week 4, week 8, and week 12 (see Table 3). However, only the means of decreased body mass index at week 12 were significantly different between groups ( $p=0.03$ ). At this week, the body mass index of the intervention group decreased significantly more with the mean of  $0.78 \text{ kg./m}^2$  (95% CI of 1.49 to 0.60). The decrease of waist circumference was also significantly more in the intervention group for all three time points of assessment ( $p \leq 0.01$ ).

**Table 3.** Changed body mass index, waist circumference, and waist-hip ratio of obese/overweight schizophrenic patients participating in WIMET program and controls<sup>a</sup>

| Item  | Intervention<br>(n=32) | Control<br>(n=32) | Significant<br>difference <sup>b</sup> |
|---|------------------------|-------------------|--|
| Decreased body mass index<br>(kg/m <sup>2</sup> ) |                        |                   |  |
| Week 4  | 0.12 (1.36)            | -0.26 (1.11)      | t=-1.22, p=0.23                        |
| Week 8  | 0.32 (1.15)            | -0.20 (1.38)      | t=-1.67, p=0.10                        |
| Week 12   | 0.32 (1.30)            | -0.45 (1.55)      | t=-2.17, p=0.03*                       |
| Decreased waist circumference<br>(cm)             |                        |                   |  |
| Week 4  | 2.63 (6.67)            | -1.56 (5.26)      | t=-2.79, p=0.01*                       |
| Week 8  | 3.41 (3.71)            | -1.51 (6.22)      | t=-3.84, p=0.01*                       |
| Week 12   | 3.38 (4.39)            | -0.86 (5.18)      | t=-3.53, p=0.01*                       |
| Decreased waist hip ratio                         |                        |                   |  |
| Week 4  | 0.20 (0.06)            | 0.00 (0.50)       | t=-1.59, p=0.86                        |
| Week 8  | 0.03 (0.03)            | 0.00 (0.07)       | t=-2.23, p=0.00*                       |
| Week 12   | 0.91(0.06)             | 0.06 (0.01)       | t=-1.28, p=0.65                        |

<sup>a</sup> All data presented as mean and standard deviation

<sup>b</sup> t = Student-t test

\* p≤0.05

#### 4.4 Changed quality of life and physical exercise self-efficacy scale of the intervention and control groups

The quality-of-life and physical exercise self-efficacy scores of both groups were not significantly different on any dimension (see Table4).

**Table 4.** Quality of life and physical exercise self-efficacy scale at week 12 of obese/overweight schizophrenic patients participating in WIMET program and controls<sup>a</sup>

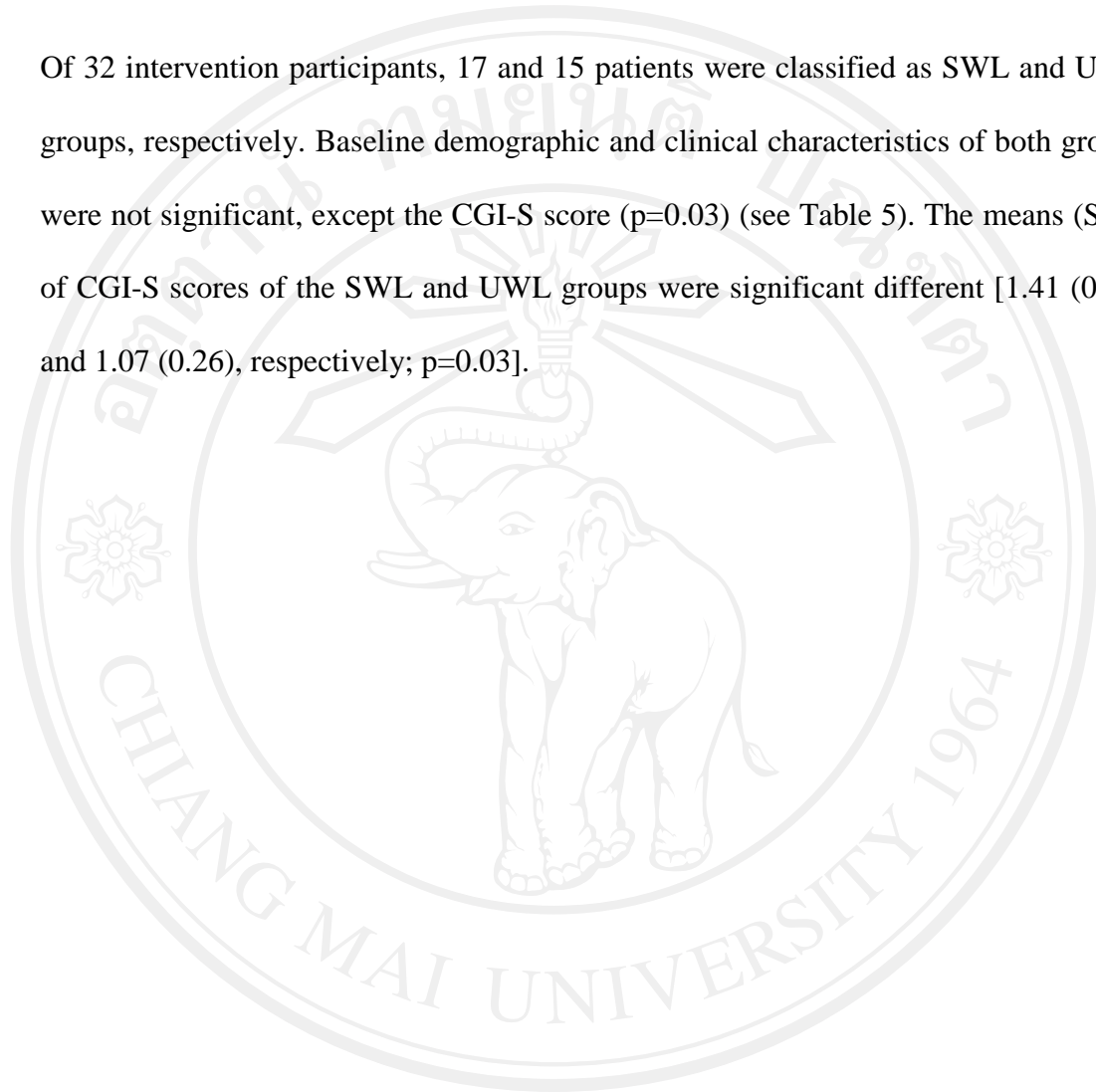
| item                       | Intervention<br>(n=32) | Control<br>(n=32) | Significant<br>difference <sup>b</sup> |
|----------------------------|------------------------|-------------------|--|
| WHOQOL-BREF                | 24.72 (3.76)           | 26.16 (9.99)      | Z=-0.33, p=0.74                        |
| Physical health score      |                        |                   |  |
| Mental health score        | 20.69 (3.19)           | 20.91 (3.33)      | Z=-0.05, p=0.96                        |
| Social relationships score | 11.03 (2.01)           | 11.34 (2.28)      | Z=-0.35, p=0.73                        |
| Environment score          | 28.53 (4.26)           | 29.75 (4.73)      | Z=-0.84, p=0.40                        |
| Total score                | 84.97 (10.62)          | 88.16 (16.73)     | Z=-0.32, p=0.75                        |
| Physical self-efficacy     | 0.56 (5.26)            | 0.0 (5.82)        | Z=-0.34, p=0.73                        |

<sup>a</sup> All data presented as mean and standard deviation

<sup>b</sup> Z = Mann-Whitney U test

#### **4.5 Comparison of intervention participants with successful and unsuccessful weight reduction**

Of 32 intervention participants, 17 and 15 patients were classified as SWL and UWL groups, respectively. Baseline demographic and clinical characteristics of both groups were not significant, except the CGI-S score ( $p=0.03$ ) (see Table 5). The means (SDs) of CGI-S scores of the SWL and UWL groups were significant different [1.41 (0.51) and 1.07 (0.26), respectively;  $p=0.03$ ].



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**Table 5.** Differences of baseline demographic and clinical characteristics of obese/overweight schizophrenic patients responding and not responding to the in WIMETprogram <sup>a</sup>

| Item   | Successful weight loss group (n=17) | Unsuccessful weight loss group (n=15) | Significant difference <sup>b</sup> |
|--|-------------------------------------|---------------------------------------|-------------------------------------|
| Sex (male, %)                                  | 13 (76.47%)                         | 10 (66.67%)                           | $\chi^2=0.38, p=0.70$               |
| Age (years)                                    | 42.47 (7.76)                        | 43.93 (10.96)                         | $t=0.44, p=0.66$                    |
| Education (years)                              | 12.35 (4.42)                        | 13.60 (7.42)                          | $t=0.58, p=0.56$                    |
| Age at onset (years)                           | 26.06 (10.00)                       | 31.12 (10.36)                         | $t=1.43, p=0.16$                    |
| No. of hospitalizations (times)                | 4.65 (4.86)                         | 4.20 (4.80)                           | $t=-0.26, p=0.80$                   |
| No. of patients receiving clozapine/olanzapine | 9 (52.94%)                          | 5 (33.33%)                            | $\chi^2=1.25, p=0.31$               |
| Clinical global impression, severity (CGI-S)   | 1.41 (0.51)                         | 1.07 (0.26)                           | $Z=-2.21; p=0.03^*$                 |
| MMSE - Thai                                    | 25.88 (5.98)                        | 27.60 (1.72)                          | $Z=-0.65; p=0.52$                   |
| Bodyweight (kg)                                | 76.27 (10.81)                       | 73.70 (12.31)                         | $t=1.22, p=0.23$                    |
| Body mass index (kg/m <sup>2</sup> )           | 28.40 (3.14)                        | 28.18 (4.43)                          | $t=1.39, p=0.18$                    |
| Waist circumference (cm)                       | 94.96 (7.98)                        | 90.58 (9.32)                          | $t=1.22, p=0.23$                    |
| Waist to hip ratio                             | 0.93 (0.41)                         | 0.93 (0.07)                           | $t=-.27, p=0.79$                    |
| WHOQOL-BREF                                    |                                     |                                       |                                     |
| Physical health score                          | 22.70 (4.15)                        | 24.60 (3.29)                          | $Z=-1.27; p=0.20$                   |
| Mental health score                            | 20.06 (4.24)                        | 21.31 (3.82)                          | $Z=-0.80; p=0.43$                   |
| Social relationships score                     | 10.41 (2.15)                        | 11.67 (2.19)                          | $Z=-1.24; p=0.21$                   |
| Environment score                              | 26.94 (4.28)                        | 28.60 (6.01)                          | $Z=-1.06; p=0.29$                   |
| Total score                                    | 80.12 (11.95)                       | 86.00 (12.44)                         | $Z=-1.36; p=0.18$                   |
| Physical exercise self-efficacy                | 10.59 (3.86)                        | 11.73 (4.22)                          | $Z=-1.03; p=.031$                   |

MMSE – Thai = Mini-Mental State Examination - Thai version

<sup>a</sup>Except sex and no. of patients receiving clozapine/olanzapine, data presented as mean and standard deviation

<sup>b</sup> $\chi^2$  = Chi-square test,  $t$  = Student-t test, and  $Z$  = Mann-Whitney U test

\*  $p \leq 0.05$