

## The Summary of the Trial Design

### Exploring the Effectiveness and the Feasibility of a Social Cognitive Theory-Based Physical Activity Intervention in Type 2 Diabetes Patients in Yogyakarta City Indonesia

#### 1. Study Participants

The effectiveness of a Social Cognitive Theory (SCT)-Based Walking Program in Type 2 Diabetes (T2D) Patients in Yogyakarta City Indonesia will be assessed in a pilot randomized control trial (RCT). The participants in this study will be recruited from the Local General Hospital of Yogyakarta Municipality. The inclusion criteria will be clinically confirmed T2D patients who have ability to walk, own a mobile phone, use text message and able to read and write.

#### 2. Study Design

Figure 1 depicts the pilot RCT design.

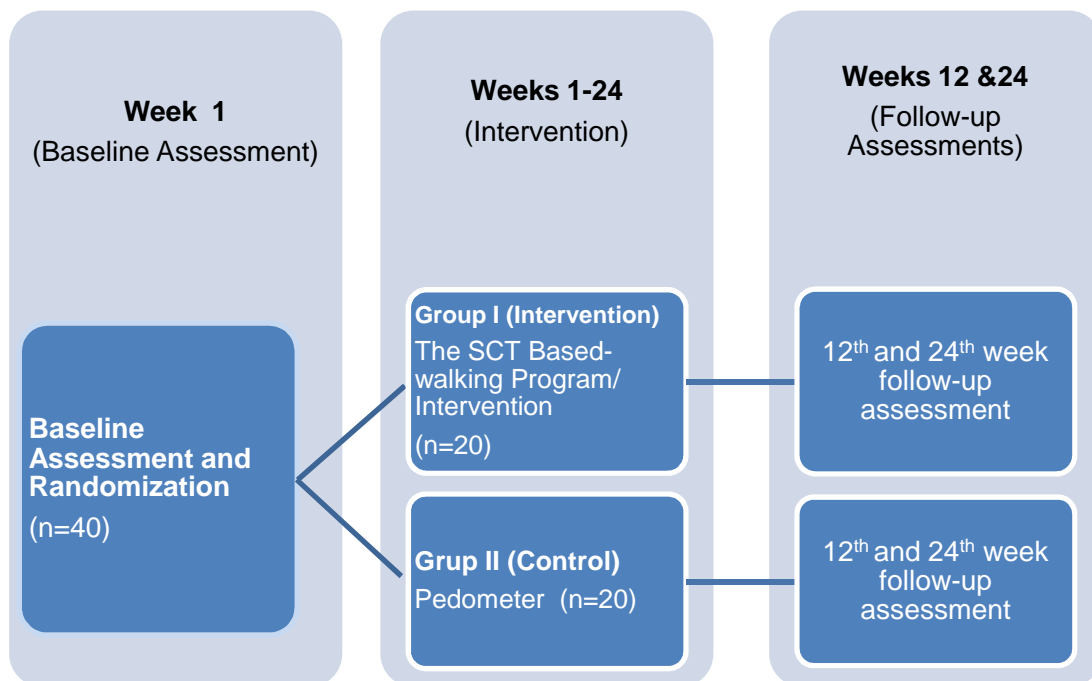


Figure 1. Pilot Randomized Control Trial Study Design

### **3. Intervention Description and Justification**

As illustrated in Figure 1, the key difference between the groups is that the intervention group will receive a SCT-based physical activity intervention which include the provision of pedometer, as well as SCT-based workbook and text message to improve their daily walking , while the control group will only receive pedometers.

Providing the pedometers to both groups is intended to avoid a disruption in the T2D patients' community who participate in this study, because the participants who do not receive pedometers might infer discrimination. This is particularly important as in this close community, the feeling of discrimination could be detrimental to the study as the participants may become less cooperative and therefore affect the dropout rate in the control group. This needs to be avoided because it potentially introduces bias and would be a threat to the internal validity of the research. Providing pedometers to both groups is also essential because the physical activity levels in this study will be measured objectively using pedometers. In this context, providing pedometers to both groups is intended to give them the same exposure to the pedometers so that both may experience the same chance of eliciting some degree of pedometer reactivity. This is essential because differential pedometer reactivity would also be a threat to the internal validity of the research. This approach is chosen because the focus of the research is not to estimate the benefit of pedometer use for improving physical activity levels, but to assess the effectiveness of the SCT-based physical activity intervention incorporating pedometers in increasing physical activity levels, compared to providing a pedometer alone.

### **4. Outcome Measures and Endpoints**

The intervention will be conducted for 24 weeks. The data collection will be conducted at baseline, 12 and 24 weeks. Variables to be assessed include physical activity levels which will be assessed using pedometer and 7 day Physical Activity Recall, SCT constructs (using the adapted self efficacy, outcome expectation, self regulation and social support questionnaires), glycaemic control (Hemoglobin A1c, fasting plasma glucose and 2-hour plasma glucose) and health-related quality of life (using the adapted Euro Qol 5 Dimensions 3 Levels). At baseline, demographic characteristics (i.e. gender, education level, employment status and marital

status), anthropometric measures (i.e. weight, height and waistline circumference) and information related to the participants' T2D conditions (i.e. T2D duration and medication status) will also be sought.

## **5. Statistical Analysis Plan**

The descriptive analysis and inferential interpretation of the data using the linear mixed-effects models technique will be carried out to describe and summarize the effectiveness of the intervention compared to the control group, both in 12 and 24 week follow-ups. The linear mixed-effects model is selected because it handles well correlated data resulting from repeated measurements and it takes into account the data covariance structures in the model building.