

Modified *Ling-Gui-Zhu-Gan* decoction combined with short-term fasting improves therapeutic response in type 2 diabetic patients

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Abstract

Objective: To evaluate the effects of a Traditional Chinese Medicine herbal decoction (modified *Ling-Gui-Zhu-Gan* decoction) combined with short-term fasting/very-low-calorie-diet (VLCD) on the therapeutic response in type 2 diabetes mellitus (T2DM) patients.

Materials and methods: A randomized controlled pilot-study was conducted with 60 T2DM patients (age 52.1 ± 13.4 y, BMI 25.7 ± 3.7 kg/m²) with a lack of glycemic control. Patients were randomly allocated to the intervention group ($n=30$) or the control group ($n=30$). All patients received in-hospital treatment for one week followed by lifestyle recommendation. Patients in the intervention group participated in a 5-day modified fasting/VLCD combined with an intake of *Ling-Gui-Zhu-Gan* decoction. Patients in the control group received standard treatment only. Outcomes were assessed at baseline and at 3-months.

Results: Fasting plasma-glucose, 2-h plasma-glucose after oral glucose tolerance-test, HbA_{1c}, and the use of anti-diabetic medication decreased significantly in the intervention group compared to the control group after three months. Body weight also decreased significantly.

Conclusions: A combined integrative treatment approach including fasting/VLCD and a Traditional Chinese Medicine decoction might be superior to standard treatment in T2DM patients. This therapeutic concept should be further evaluated.

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Keywords: Very-low-calorie-diets; Fasting; Chinese medicine; Diabetes mellitus; Glycemic control; Herbal medicine

Introduction

Modified fasting and very-low-calorie-diets (VLCDs) had come to clinical researchers' attention since the 1990s due to their effects on weight loss and improvement of cardiovascular risk factors in patients with T2DM and metabolic syndrome (MS). In the management of obese patients with T2DM these dietary treatments are used to initiate lifestyle modification and to improve weight control. [1–8] On the other hand, we empirically found that Chinese T2DM patients, which numbers are growing rapidly, tend to be unable to distinguish mild tastes

and frequently exhibit a greasy and thick tongue coating as well as other pattern signs of so-called “turbid mucus distressing the spleen” according to the principles of Traditional Chinese Medicine (TCM). Hence, we developed a new treatment, combining short-term modified fasting/VLCD with a TCM herbal treatment, i.e. modified *Ling-Gui-Zhu-Gan* decoction, including the herbs of *Sclerotium Poriae Cocos* (*fu ling*), *Ramulus Cinnamoni Cassiae* (*gui zhi*), *Rhizoma Atractylodis Macrocephalae* (*bai zhu*), *Radix Glycyrrhizae Preparata* (*zhi gan cao*), *Radix Codonopsis Pilosulae* (*dang shen*), *Radix et Rhizoma Rhei* (*da huang*). According to TCM the application of these herbs is postulated to warm and resolve mucus (*wen-hua-tan-yin*) as well as to strengthen the spleen and to remove turbidity (*jian-pi-xie-zhuo*). In preliminary clinical observations we found that this treatment approach may promote the acceptance of caloric restriction and, moreover, may improve glycemic control. We designed and conducted the present pilot-study in order to investigate the effects of a combined dietary and TCM herbal treatment on patients with T2DM.

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Materials and methods

Subjects and study design

All patients were admitted consecutively to the hospital department of the *First affiliated Hospital of the Sun-Yat Sen University* for intensified in-patient treatment of T2DM. A total of 60 eligible patients (34 male and 26 female) participated in the trial. The diagnosis of T2DM was based on the WHO criteria of 1999. Patients were considered for the trial if they presented with a manifest and previously treated T2DM, however, with no sufficient glycemic control ($\text{HbA}_{1\text{C}} > 6.1\%$).

The study was designed as a clinical randomized pilot study, all patients were allocated randomly to either the intervention group or to the control group. Each group consisted of 30 patients. Treatment group allocation was performed by a non-stratified block-randomization with varying block lengths. Random numbers were generated by a computer program (see Fig. 1).

The study protocol was approved by the institutional review board. Written informed consent was obtained from all study subjects.

Interventions and treatment protocol

All patients had received the same amount of diabetes mellitus education classes before the trial. Patients in the intervention group were treated internally with a modified *Ling-Gui-Zhu-Gan* decoction combination with a 5-day modified fasting/very low calorie diet (VLCD). The modified *Ling-Gui-Zhu-Gan* decoction contained *Sclerotium Poriae Cocos* (*fu ling*) 20 g, *Ramulus Cinnamoni Cassiae* (*gui zhi*) 12 g, *Rhizoma Atractylodis Macrocephalae* (*bai zhu*) 15 g, *Radix Glycyrrhizae Preparata* (*zhi gan cao*) 9 g, *Radix Codonopsis Pilosulae* (*dang shen*) 30 g, and *Radix et Rhizoma Rhei* (*da huang*) 9 g. According to the principles of TCM the decoction aims to warm and resolve mucus (*wen-hua-tan-yin*), to strengthen the spleen and to remove turbidity (*jian-pi-xie-zhuo*). As previously described [9], the dietary fasting/VLCD treatment consists of three phases: (1) the pre-fasting phase, (2) the 5-day strict modified fasting/VLCD phase and (3) the food reintroduction phase. The pre-fasting phase consists of 1–2 dietary “relief” days with an intake of fruits and vegetables only. The pre-fasting phase aimed to prepare patients for the fasting phase, to adapt digestion and to stepwise control subjective perception of hunger. The fasting/VLCD phase

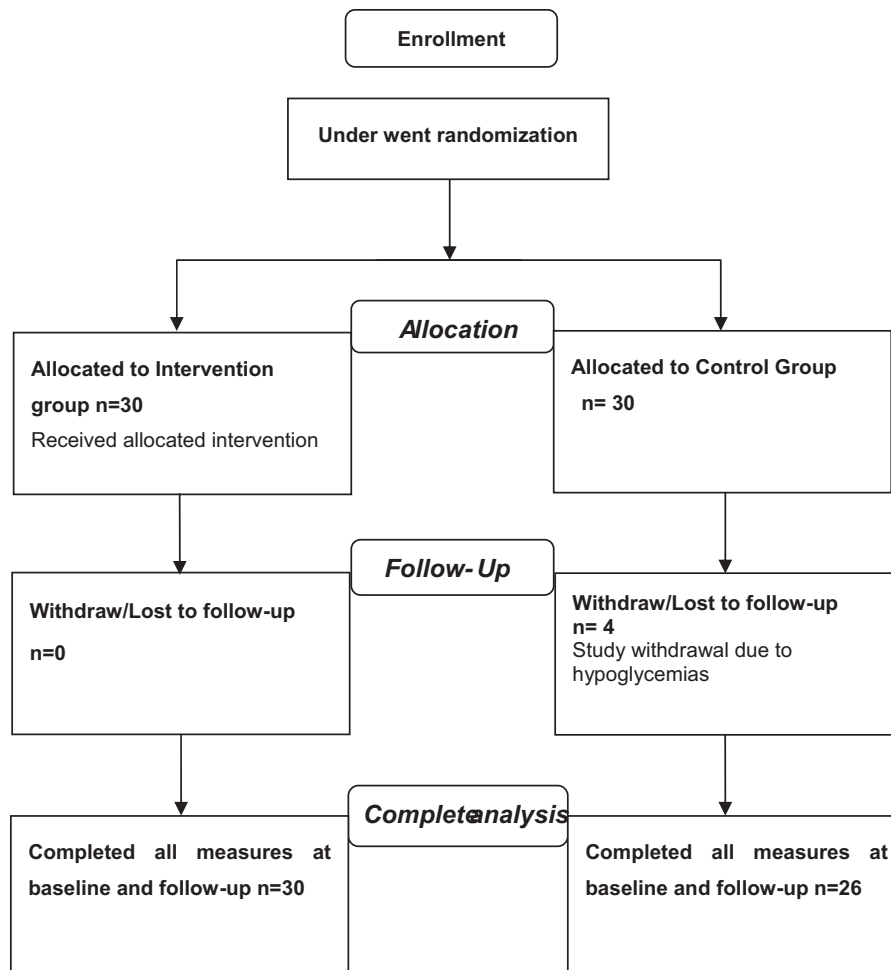


Fig. 1. Participant flow diagram.

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