PROTOCOL STUDY AND STATISTICAL ANALYSIS PLAN

Effect of foot-ankle exercise using an elastic band on diabetic foot ulcer incidence in patients with diabetic neuropathy

1 May 2025

Design

The study used a randomized controlled trial (RCT) with blinding.

Outcomes

Primary Outcome Measure:
Diabetic foot ulcer (DFU) incidence DFU, defined as a wound in the area below the ankle that reaches at least the epidermis and part of the dermis, as diagnosed by an internist. Time frame 1 year.

Secondary Outcome Measure:

1. Diabetic neuropathy examination score The accumulation score of the result measurement consists of eight items, two testing muscle strength, one a tendon reflex, and five testing sensation. The min-max score is 0-16. The higher the score indicates the more severe the neuropathy. The score was determined by doing a physical examination. Time Frame: 0, 12 weeks, and a year.
2. Control glycemic HbA1c levels, which are the level of blood sugar control over a period of time. 3 months, measured by analyzing blood serum in a laboratory using the National Glycohemoglobin Standardization Program (NGSP). Time Frame: 0, 12 weeks, and a year \
3. Brain-derived neurotrophic factor BDNF levels, which are defined as biomolecular markers that can indicate the severity of diabetic neuropathy, as measured by analyzing blood serum using the ELISA technique Time Frame: 0, 12 weeks, and a year
4. Walking speed Walking speed is the ratio between times measured while walking in second as fast as possible on a flat and straight trajectory at a certain distance. The track distance used in the study was 5 meter. The time of waking was measured using a stopwatch. Time Frame: 0, 12 weeks, and a year
5. Foot ankle range of motion ankle range of motion, which is the degree of joint movement in the feet during flexion, extension, inversion, and eversion, as measured using digital goniometry. Time Frame: 0, 12 weeks, and a year
6. Callus incidence: Callus is the thickness of the plantar skin area that can be determined by inspection. Time Frame: 0, 12 weeks, and a year
7. Neuropathy symptom score. The accumulation score of the result measurement consists of sixteen item about the symptoms of neuropathy. The min-max score is 0-16. The higher score indicates the more severe of neuropathy. The score was determined by interviewing the patient. Time Frame: 0, 12 weeks, and a year.

Population and Sample

The population in this study consisted of patients with diabetic neuropathy residing at the first health facility in Central Java, Indonesia. The sample consisted of approximately 80 participants, divided into an intervention group (n = 40) and a control group (n = 40). Randomization was conducted using block randomization.
The inclusion criteria were

- having type 2 diabetes
- can walk a minimum 10 meters
- having diabetic neuropathy

The exclusion criteria were

- having a stroke
- having an active ulcer
- having fractures on the foot
- Having a diabetic ulcer history

Instrument

We used an elastic band with 0.5 and 0.65 thickness to give the foot-ankle exercise. Diabetic neuropathy symptoms were measured using the neuropathy symptom score questionnaire. The diabetic neuropathy sign was measured using the diabetic neuropathy examination score questionnaire. We also used a turning fork at 128 Hz, a monofilament 10g, a hammer to measure the diabetic neuropathy examination score. Digital goniometry was used to measure the foot-ankle range of motion. A stopwatch was used to measure the walking speed.

Intervention

The intervention and control groups will receive usual care, which includes pharmacological treatment and self-care guidelines. The intervention group will receive ankle-foot exercises using elastic bands for one year. The ankle-foot exercises focus on the ankle, metatarsophalangeal, and interphalangeal joints. In accordance with exercise guidelines for preventing DFU, the exercises will be supervised by a trained healthcare professional for 12 weeks, and will be continued with the aid of a video protocol for ankle-foot exercises using elastic bands for 9 months. The exercise was done 3 times a week (15x/until they tired x 2 sets). The exercise used an elastic band with different thicknesses (0,5 mm in 12 weeks and 0,65 mm in nine months). Compliance with the foot exercises will be monitored by researchers through a logbook. Researchers will visit participants every three months to monitor the implementation of the exercises. Both the control and intervention groups will receive standard care for diabetes patients from the community health center.

Data Collection

Data will be collected at baseline, 12 weeks, and one year after the intervention by researchers not involved in the randomization process to ensure blinding.

Statistical analysis plan

Data will be analyzed using SPSS. Intention-to-treat analysis will be conducted in this study with blinded analysis (blinded data analyst). Baseline characteristics include individual characteristics such as age and gender, as well as factors related to diabetes that may be associated with DFU, such as duration of diabetes, duration of signs and symptoms related to neuropathy, HbA1c levels, BDNF levels, walking speed, range of motion (ROM), vibration sensitivity, ABI, degree of neuropathy, and hypertension. The baseline characteristics homogeneity of both groups will be assessed using chi-square, independent t-test, or Mann-Whitney U test. Repeated ANOVA or Friedman and post hoc will be used to analyze the difference in the outcomes before and after intervention in both groups. Significant difference will be considered with $\acute{\alpha}$=5%, but for he description of the effect of the intervention, the effect size (Cohen coefficient) and the difference between the means will be calculated with their respective 95% confidence intervals.