

# Bouncing Metformin Intervention (BMI) Study: a long term randomized controlled trial to invert early type 2 diabetes.

Published: 16-12-2021

Last updated: 06-05-2024

To study the potential of the daily use of a mini-trampoline or metformin added to the NHG - guided lifestyle to cure early type 2 diabetes in overweight and obese patients. PICO research question. What is the effect of the mini-trampoline or...

|                              |                                                       |
|------------------------------|-------------------------------------------------------|
| <b>Ethical review</b>        | Approved WMO                                          |
| <b>Status</b>                | Pending                                               |
| <b>Health condition type</b> | Glucose metabolism disorders (incl diabetes mellitus) |
| <b>Study type</b>            | Interventional                                        |

## Summary

### ID

NL-OMON51497

### Source

ToetsingOnline

### Brief title

BMI study

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

### Synonym

Diabetes mellitus, Type 2 diabetes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Bethesda Diabetes Research Center

**Source(s) of monetary or material Support:** Bellicon AG, Provincie Drenthe; Stichting C.W.

## Intervention

**Keyword:** early type 2 diabetes, lifestyle, metformin, minitrampoline

## Outcome measures

### Primary outcome

Primary outcomes of the BMI study:

Remission of diabetes after 1, 2, 3 and / or 4 years.

Remission of diabetes is defined as an HbA1c level  $< 48$  mmol/mol (6.5%) and an FPG  $\leq 6.9$  mmol/l in the absence of any diabetes medication (but metformin) or bariatric surgery.

Reduction of HbA1c.

### Secondary outcome

Secondary outcomes of the BMI study are blood pressure, heart rate, need for additional pharmacotherapy, insulin resistance (with fasting insulin, C-peptide, FPG) , body weight, body mass index, waist-hip ratio, body composition, muscle strenght development of co-morbidity, development of infections, metabolic and biomarkers in blood and urine (predefined list, like Advanced Glycation Endproducts, AGE\*s) , treatment satisfaction, quality of life (EQ5D-5L) and physical activity as well as cost utility & effectiveness analyses by a HTA expert (HTA = health technology assessment).

# Study description

## Background summary

Type 2 diabetes has a huge impact on morbidity, mortality and costs for the community worldwide. Early treatment may help to reverse type 2 diabetes. Smart approaches to improve lifestyle, body composition and insulin sensitivity may be successful, especially if started early. Therefore, we designed the Bouncing Metformin Intervention (BMI) Study.

## Study objective

To study the potential of the daily use of a mini-trampoline or metformin added to the NHG -guided lifestyle to cure early type 2 diabetes in overweight and obese patients.

PICO research question. What is the effect of the mini-trampoline or metformin, added to routine care compared to routine care only, on the presence and development of early type 2 diabetes in overweight and obese patients?

## Study design

This study is an open label RCT to study the effects of the daily use of a mini-trampoline (Bellicon R - also suitable for fragile persons) or metformin versus control group on predefined outcomes. After randomization (stratified for age and BMI), patients will be 1:1:1 allocated to group C (Controls), group B (Bouncing) or group M (Metformin), and subsequently be treated during an intervention period of 2 years, followed by an observation period of 2 years. All patients (N=300, n=100 per group) will receive lifestyle consultation according to the NHG standard - embedded in regular practice.

## Intervention

Routine Care. All patients are treated according protocol and good clinical practice with counselling for a healthy lifestyle. All participants in all groups will note in an diary, once weekly, the duration, frequency, type and intensity of their physical activities/ exercises. Additionally, every year questionnaires will be used.

Intervention with the mini-trampoline. Participants in group B are trained to stimulate the adherence to the daily use of the mini-trampoline (15 minutes per day - possible more). This intervention will be specifically monitored by sensors.

Intervention with metformin for insulin sensitization. Participants in group M receive metformin, 850 mg up to 3 times daily, if tolerated, unless

contraindicated. The daily dose of metformin is minimized at 850 mg and maximized at 2550mg. In the BMI study, metformin is primarily used as a prevention drug.

## Study burden and risks

The burden and risks of this study are minimal. In all study groups, we intend to improve the quality of life to reduce overweight / obesity and to invert early type 2 diabetes.

Mild burdens can be expressed as:

1. protocol visits (14 )
2. venous punctures (8 x 40 ml in 4 years)
3. mild side effects of metformin use
4. muscle transient pain due to exercise

## Contacts

### Public

Bethesda Diabetes Research Center

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Hoogeveen 7909 AA  
NL

### Scientific

Bethesda Diabetes Research Center

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NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Early type 2 diabetes diagnosed within 4 years before inclusion:

- FPG > 6.9 mmol/l and/or
- PPG > 11.0 mmol/l and/or
- HbA1c 48 - 64 mmol/mol

FPG = fasting plasma glucose; PPG = postprandial plasma glucose

Willing and able to use the Bellicon on a daily basis

BMI 25 - 40 kg/m<sup>2</sup>

Age 30 - 80 years

## Exclusion criteria

HbA1c >64 mmol/mol

Use of antidiabetic agents during the last 2 months before inclusion

Compelling need for antidiabetic agent (e.g. SGLT2 inhibition)

Contra-indication or intolerance for metformin use

Bariatric surgery

Type 1 diabetes

Expected bad compliance

Serious psychiatric illness

Malignancy, except nonmelanoma skin cancer

Pregnancy or willing to become pregnant within 2 years

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |
| Primary purpose:    | Prevention                  |

### Recruitment

NL

|                           |             |
|---------------------------|-------------|
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-03-2022  |
| Enrollment:               | 300         |
| Type:                     | Anticipated |

## Medical products/devices used

|               |                           |
|---------------|---------------------------|
| Product type: | Medicine                  |
| Brand name:   | Metformin HCL TEVA 850 mg |
| Generic name: | Metformin                 |
| Registration: | Yes - NL intended use     |

## Ethics review

|                    |                                                         |
|--------------------|---------------------------------------------------------|
| Approved WMO       |                                                         |
| Date:              | 16-12-2021                                              |
| Application type:  | First submission                                        |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO       |                                                         |
| Date:              | 05-04-2022                                              |
| Application type:  | First submission                                        |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO       |                                                         |
| Date:              | 24-04-2024                                              |
| Application type:  | Amendment                                               |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

**Other (possibly less up-to-date) registrations in this register**

No registrations found.

**In other registers**

| <b>Register</b> | <b>ID</b>              |
|-----------------|------------------------|
| EudraCT         | EUCTR2021-005568-23-NL |
| CCMO            | NL79388.042.21         |