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The effect of timing of lifestyle factors in addition to a regular lifestyle intervention

Submission date
06/11/2023

Recruitment status
No longer recruiting

Registration date
07/12/2023

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

A combination of physical activity and a healthy diet, with added education and behavioural change techniques, has been shown to be effective in treating people with obesity, preventing type 2 diabetes, decreasing BMI and glucose concentrations and improving quality of life. Therefore, different combined lifestyle interventions (CLIs) are introduced in the basic health insurance in The Netherlands. In addition, the timing of lifestyle factors has been of increasing interest. For example, exercising in the afternoon or evening seems to be better for improving glucose compared to the morning, social jetlag (the result of the difference between an individual's circadian rhythms and imposed social schedules) is negatively associated with metabolic health and night-time snacking should be avoided. Therefore, it is expected that adding advice about the timing of these behavioural factors may be an essential addition to the currently available CLIs. However, this has not been tested before. Therefore, this three-armed intervention study will investigate the effect of intervening on the timing of a combination of lifestyle factors in addition to an existing online CLI on BMI and fasting glucose in adults with a CLI indication, compared to only the CLI or an observational arm of regular care by the general practitioner. This study will use the MiGuide-CooL online CLI. A secondary aim will also look into the effects of health-related quality of life, HbA1c (average blood sugar levels) and waist circumference.

Who can participate?

Participants are adults aged over 18 years old who have a CLI indication as described in the MiGuide-CooL CLI for regular care of either obesity or overweight with at least one comorbidity of sleep apnea, vascular diseases, type 2 diabetes, arthrosis, and increased waist circumference (men >102cm; women >88cm).

What does the study involve?

The study involves a two-year online MiGuide-CooL CLI, which is a program that includes both individual and group sessions. Furthermore, participants can use the MiGuide app to help adhere to the intervention. Part of the participants will be randomly assigned to the Timed CLI, in which they get the same MiGuide-CooL CLI but with added advice about the timing of healthy lifestyle behaviours, namely exercise, meal intake and sleep. During the intervention, all participants will be asked to fill in some questionnaires and perform a finger prick at home at baseline and after

three and nine months, which will take approximately 30 minutes extra per time point. These results will be compared with an observational arm, which will be extracted from the general care database.

What are the possible benefits and risks of participating?
The study participants are already planning on doing the CLI, therefore the CLI itself is not an additional benefit or risk. The questionnaires and at-home finger prick specific to the research will take 30 minutes extra per time point at three timepoints. Furthermore, at baseline and nine months, the MiGuide-CooL evaluation is already standard in the CLI. An extra evaluation (20 min) is added at three months which is specifically for the trial.

Where is the study run from?
Amsterdam UMC, although participants will be recruited via 'Huisartsenorganisatie West-Friesland', and 'Diabetes Care System' in Hoorn, 'Extramural LUMC Academic Network' in Leiden and via the MiGuide-CooL website.

When is the study starting and how long is it expected to run for?
April 2023 to July 2027

Who is funding the study?
1. The Netherlands Organization for Health Research and Development (ZonMw) [459001021]
2. Dutch Diabetes Research Foundation (Diabetes Fonds) [2019.11.101]
3. The Canadian Institutes of Health Research (CIHR) [TNC-174963]
4. Health-Holland [LSHM20107].
This collaborative project is co-financed with a PPP allowance made available by Health-Holland, Topsector Life Sciences & Health, to stimulate public-private partnerships.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of timing of lifestyle factors in addition to a regular care combined lifestyle intervention (CLI) on health outcomes in adults with a CLI indication

Acronym
TIMED

Study objectives
Adding advice about the timing of lifestyle factors, will improve BMI and fasting glucose to a greater extent than the regular combined lifestyle intervention alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/01/2024, non-WMO Committee of the Medical Ethics Review Committee of Amsterdam University Medical Centers (Medische Faculteit, A325, Amsterdam, 1081BT, Netherlands; +31 (0)20-4445585; metc@amsterdamumc.nl), ref: 2023.0836

Study design
Three-armed pragmatic intervention randomized study with a regular combined lifestyle intervention of 2 years

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Either 1) obesity (BMI>30 kg/m2); or 2) overweight (BMI >25 and <30 kg/m2) with at least one comorbidity of sleep apnea, vascular diseases, type 2 diabetes, arthrosis, or increased waist circumference (men >102cm; women >88 cm)

Interventions
Current interventions as of 27/01/2025:

Participants will be randomly assigned in a 1:1 ratio to one of the two intervention arms using a variable block randomization algorithm (blocks of 2, 4 or 6) in Castor EDC. The intervention is

performed in small groups with one lifestyle coach. To prevent knowledge spill-over, i.e. to prevent coaches of the timed group from using their knowledge in the original CLI group, coaches will either facilitate all original groups or all timed groups.

Study arm 1: CLI
Combined Lifestyle Intervention named MiGuide-CooL, which is an online program of 2 years including individual and group sessions.
Participants will receive the existing Combined Lifestyle Intervention CooL-MiGuide, which is an online program of 2 years, with 4 individual sessions and 8 group sessions in the basic program (6-8 months) and 4 individual sessions (60 min.) and 8 group sessions (90 min.) in the maintenance phase (16-18 months). All sessions are online and group sessions take place in a group of 8-15 participants. A registered lifestyle coach will lead the group sessions as well as the individual sessions. Participants can use the MiGuide app, which is an online platform originally developed for patients with T2D and their healthcare providers. The connection with CooL makes the app relevant to a broader audience and helps participants of CooL-MiGuide adhere to the intervention. The app can be tailored to the goals and needs of the participant. Furthermore, the app can be connected to the participant's medical records. At baseline, after three and nine months, participants receive online questionnaires from the MiGuide as well as from the research centre. At 24 months the participants only receive questionnaires from MiGuide.

Study arm 2: Timed CLI
Same Combined Lifestyle intervention as study arm 1, but with added advice on the timing of lifestyle factors, specifically on the timing of exercise, meal intake and sleep.

Observational arm: general care database
Participants will be extracted from the general care database.

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Previous interventions:

Participants will be randomly assigned in a 1:1 ratio to one of the two intervention arms using a variable block randomization algorithm (blocks of 2, 4 or 6) in Castor EDC. The intervention is performed in small groups with one lifestyle coach. To prevent knowledge spill-over, i.e. to prevent coaches of the timed group from using their knowledge in the original CLI group, coaches will either facilitate all original groups or all timed groups.

Study arm 1: CLI
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Study arm 2: Timed CLI
Same Combined Lifestyle intervention as study arm 1, but with added advice on the timing of lifestyle factors, specifically on the timing of exercise, meal intake and sleep.

Observational arm: general care database
Participants will be extracted from the general care database STIZON.

Intervention Type
Behavioural

Primary outcome(s)
The following primary outcome measures are assessed at baseline and after 3 and 9 months:
1. Fasting glucose measured at home using the Contour Plus Blue glucose monitor; 1 drop of blood is deposited from a finger prick on the stick, which is then inserted in the device and a photo will be taken of the measurement. The photo is then sent by email or phone to the researcher.
2. BMI calculated using the self-reported height and weight measured with standard methods

Key secondary outcome(s))
1. Health-Related Quality of Life measured using the Dutch PROMIS scale V1.2 - Global Health
2. HbA1c measured using the Contour Plus Blue glucose monitor and HPLC assay
3. Waist circumference self-reported

Completion date
31/07/2027

Eligibility

Key inclusion criteria
1. Have a CLI indication as described in the MiGuide-CooL CLI for regular care. These inclusion criteria are either obesity (BMI>30 kg/m2) or overweight (BMI >25 and <30 kg/m2) with at least one comorbidity:
1.1. Sleep apnea
1.2. Vascular diseases
1.3. T2D
1.4. Arthrosis
1.5. Increased waist circumference (men >102cm; women >88cm)
2. Aged 18 years or older
3. Motivated to change lifestyle behaviour
4. Digitally skilled and in the possession of a smartphone
5. Being able to speak and understand the Dutch language

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
105

Key exclusion criteria
1. Unable to give written informed consent
2. Serious mental impairment i.e. preventing understanding of the study protocol/aim
3. Pregnant women
4. Working in night shifts or irregular phase shifts
5. Taken sulphonylurea (SU)

Date of first enrolment
01/07/2024

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC
Meibergdreef 9
Amsterdam
Netherlands
1105AZ

Sponsor information

Organisation
Amsterdam UMC Location VUmc

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Diabetes Fonds

Funder Name
Canadian Institutes of Health Research

Funder Name
Health Holland

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request from the Hoorn Steering Committee (hoornstudy@amsterdamumc.nl). All participants provided consent. Data can only be shared within the consent restrictions. Only pseudo-anonymized data can be shared when the application is approved.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes