

# A hospital-based lifestyle front office to provide patients with guidance on lifestyle medicine-related issues

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| <b>Submission date</b><br>12/04/2022   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>21/04/2022 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>19/11/2024       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims:

A healthy lifestyle is important for the prevention and treatment of non-communicable diseases. However, lifestyle medicine is inhibited by time constraints and the competing priorities of treating physicians. A dedicated lifestyle front office (LFO) may provide a solution to optimizing patient-centered lifestyle care. The main aim of this study is to determine the (cost) effectiveness of a hospital-based dedicated LFO in comparison with usual care 12 months after participation.

### Who can participate?

Patients aged 18 years and over with an increased risk for (i.e. diabetes, high blood pressure, high cholesterol) or who suffer from (cardio)vascular disease or osteoarthritis with or without arthroplasty, who have either a body mass index (BMI) of 25 kg/m<sup>2</sup> or over and/or smoke

### What does the study involve?

Participants allocated to the lifestyle intervention have a face-to-face coaching session with a dedicated LifeStyle Broker (LSBs) who is trained in motivational interviewing. The LSB will build in dialogue with the patient's motivation for lifestyle change and refer patients to local community-based lifestyle change initiatives (neighborhood lifestyle coaches etc), while always maintaining a feedback loop with the treating healthcare professional. A network communication platform will be used to further communication between the lifestyle broker, the patient, the referred community-based lifestyle initiative and other relevant stakeholders (e.g. general practitioner). An LSB is specialized to target the following lifestyle behaviors: physical activity, sedentary behavior, diet, alcohol, smoking, stress and sleep. Patients in the control group will receive care as usual from their healthcare professional. Data is collected at the start of the study and at 3, 9, and 12 months follow-up for a composite health risk and lifestyle score consisting of resting blood pressure, objectively measured physical activity and sitting time, body mass index, fruit and vegetable consumption and smoking behavior.

### What are the possible benefits and risks of participating?

Although the researchers can't promise that taking part in the study will directly benefit the

patients, it is hoped that LOFIT will help patients to lead healthier lifestyles. It is very unlikely that patients will come to any harm from taking part in this study.

Where is the study run from?

Amsterdam UMC, location VUmc (Netherlands)

When is the study starting and how long is it expected to run for?

November 2020 to July 2025

Who is funding the study?

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Who is the main contact?

Dr Judith Jelsma

j.jelsma@amsterdamumc.nl

### **Study website**

<http://www.lofitleefstijlloket.nl>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr Judith Jelsma

### **ORCID ID**

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**Type(s)**

Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## Study information

**Scientific Title**

LOFIT: Lifestyle front Office for Integrating lifestyle medicine in the Treatment of patients. A novel care-model towards community-based options for lifestyle change

**Acronym**

LOFIT

**Study objectives**

The aim of this study is to evaluate the effectiveness and cost-effectiveness of a lifestyle front office in routine hospital care. It is hypothesized that this lifestyle front office care pathway will

increase the uptake of a healthy lifestyle, consequently reduce disease symptoms, medical complications, the amount of prescribed medication, prevent the development of (other) non-communicable diseases, and thus lower healthcare and societal costs.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 07/03/2022, Ethics Committee VUmc Amsterdam (Medisch Ethische Toetsingscommissie VUmc De Boelelaan 1109, room number 08A-08, 1081 HV Amsterdam, the Netherlands; +34 20 444 5585; metc@vumc.nl), ref: 2021.0712

### **Study design**

Multicenter pragmatic randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

(Cardio)vascular disease, osteoarthritis with or without total hip or knee arthroplasty

### **Interventions**

Randomization:

Randomization occurs separately for both trials and patients will be randomly allocated to receive the LOFIT intervention or usual care in a 1:1 ratio. A computerized random number generator (Sealed Envelop) draws up an allocation schedule pre-stratified for hospital centers using randomized permuted blocks of size 4 and 6. Sealed opaque envelopes will be prepared that contain the group to which a patient is allocated.

Intervention:

To overcome barriers such as lack of time, skills and knowledge of healthcare professionals to discuss lifestyle during consultation, a lifestyle front office (LFO) in secondary/tertiary care is hypothesized to enhance integration of lifestyle medicine for patients with non communicable diseases. In this dedicated LFO trained lifestyle brokers build motivation for lifestyle change in dialogue with the patient and refer patients to local community-based lifestyle change initiatives. After referral to a community-based lifestyle initiative the lifestyle broker will monitor progress and will maintain contact through an online network communication platform as long as the patient is under treatment in the hospital. This platform enables communication

between the patient, community-based lifestyle initiatives and other relevant stakeholders (e.g. general practitioner, informal caregiver). Frequency of contact between the involved parties is tailored to patients preferences and scheduled hospital appointments. The duration of the community-based lifestyle intervention depends on where the patient is referred to, for example a combined lifestyle intervention program usually lasts 2 years and a quit smoking trajectory usually 6 months.

Control:

Control group patients will receive care as usual from their healthcare professional(s).

## **Intervention Type**

Behavioural

## **Primary outcome measure**

The adapted-Fuster-BEWAT score is a composite health risk and lifestyle score which consists of six components measured at baseline and 12 months:

1. Resting blood pressure (mmHg) measured with blood pressure monitor
2. Objectively measured physical activity (steps/24h) using activPAL
3. Objectively measured sitting time (time/24 h) using activPAL
4. Body mass index (BMI) based on weight and height measure
5. Fruit and vegetable consumption (servings 24/h) measured with questionnaire
6. Smoking (units/24 h) measured with questionnaire

## **Secondary outcome measures**

1. Cardiometabolic markers: fasting plasma glucose, lipids (triglycerides, total cholesterol, high density lipoprotein cholesterol (HDL) and low density lipoprotein cholesterol (LDL)), insulin, Hemoglobin A1C (HbA1C), liver function (Gamma-Glutamyl Transferase (GGT), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST)), kidney function (creatinine). measured at baseline and 12 months
2. Anthropometric measurements (body height (stadiometer), body weight (scale), waist circumference (tape measure), neck circumference (tape measure), resting blood pressure [systolic, diastolic] (OMRON M6 bloodpressure monitor) at baseline and 12 months
3. Behaviour measured at baseline and 12 months:
  - 3.1. Sitting time, upright time, step count measured using activPAL
  - 3.2. Dietary quality measured with 18 items from the Dutch Food Frequency questionnaire
  - 3.3 alcohol intake measured using Alcohol Use Disorders Identification Test (AUDIT) questionnaire
  - 3.4. Sedentary behaviour measured using Marshall questionnaire
  - 3.5. Physical activity measured using International Physical Activity Questionnaire – Short Form (IPAQ-SF) questionnaire
  - 3.6. Fitness measured using FitMax questionnaire
  - 3.7. Sleep insomnia measured using Insomnia Severity Index (ISI) questionnaire
  - 3.8. Sleep quality measured using Brief Pittsburg Sleep Quality Index (B-PSQI) questionnaire
  - 3.9. Obstructive sleep apnea syndrome (OSAS) measured with the STOP BANG Sleep Apnea questionnaire
  - 3.10. Smoking status measured using Fagerström Test for Nicotine Dependence (FTND) questionnaire
4. Psychological outcomes measured at baseline and 12 months:
  - 4.1. Wellbeing measured using Cantril ladder questionnaire
  - 4.2. Health-related quality of life measured using EQ-5D-5L questionnaire
  - 4.3. Resilience is measured using Brief Resilience Scale (BRS) questionnaire

- 4.4. General self-efficacy is measured using the General self-efficacy scale (GSES) questionnaire
- 4.5. Stage of Change is measured in a questionnaire based on transtheoretical model.
5. Disease-specific patient-reported outcome measures: functional limitations measured using HOOS-PS; KOOS-PS questionnaires at baseline and 12 months
6. Cost-effectiveness: productivity and healthcare use (measured using the iMTA productivity Cost and Medical Consumption questionnaires (iPCQ and iMCQ)); consequences for employment; medication use; travel costs to hospital, measured at baseline, 3, 6, 9 and 12 months
7. Process evaluation: implementation, context and mechanism of impact following UK MRC Guidance on process evaluation of complex interventions measured with a questionnaire and qualitative interviews at baseline, 3 months, 12 months

**Overall study start date**

01/11/2020

**Completion date**

01/07/2025

## Eligibility

**Key inclusion criteria**

1. Patients with an increased risk for cardiovascular disorders (i.e. cardiovascular disease, hypertension, high cholesterol, diabetes mellitus I and II) or with musculoskeletal disorders (i.e. osteoarthritis, total knee or hip arthroplasty)
2. Visiting the participating outpatient clinics of Amsterdam UMC, UMC Groningen (UMCG) or Ommelander Ziekenhuis Groningen (OZG)
3. Aged  $\geq 18$  years
4. Body Mass Index (BMI) of  $\geq 25$  kg/m<sup>2</sup> and /or patients who smoke

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

552

**Total final enrolment**

325

**Key exclusion criteria**

1. Not able to walk at least 100 meters safely (e.g. wheelchair bound)
2. Pregnant

3. Cognitively unable to comply with a healthy lifestyle intervention referral or to complete study measurements
4. Not able to communicate in the Dutch or English language

**Date of first enrolment**

25/04/2022

**Date of final enrolment**

25/04/2024

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre****Amsterdam UMC, location VUmc**

Boelelaan 1118

1081 HZ Amsterdam

Amsterdam

Netherlands

1081HZ

**Study participating centre****Amsterdam UMC, location AMC**

Meibergdreef 9

1105 AZ Amsterdam

Amsterdam

Netherlands

1105 AZ

**Study participating centre****UMC Groningen**

Hanzeplein 1

9713 GZ Groningen

Groningen

Netherlands

9713 GZ

**Study participating centre****Ommelander ziekenhuis Groningen**

Pastorieweg 1

9679 BJ Scheemda

Scheemda  
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## Sponsor information

### Organisation

Amsterdam UMC Location VUmc

### Sponsor details

Boelelaan 1118  
Amsterdam  
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1081 HV  
+31 20 44 425 12  
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### Sponsor type

Hospital/treatment centre

### Website

<https://www.vumc.nl/>

### ROR

<https://ror.org/00q6h8f30>

## Funder(s)

### Funder type

Not defined

### 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



## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

01/08/2025

### Individual participant data (IPD) sharing plan

Available on request

The investigator/body who should be contacted for access to the datasets: d. judith jelsma – j. jelsma@amsterdamumc.nl

Type of data: quantitative data

Availability date of the data: approximately in year 2025

Length of availability: 12 years after completion of this research project

Access criteria: only for lifestyle medicine related research questions

Type of analyses: quantitative analysis

Mechanisms: to be decided

Consent from participants: yes, participant can optionally make their data available for use in future research

Data anonymization: data is pseudonymized

Ethical or legal restrictions: none

Any other comments: none

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                      | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |         | 17/02/2023   | 22/02/2023 | Yes            | No              |