ISRCTN13046877 https://doi.org/10.1186/ISRCTN13046877

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

Submission date
12/04/2022

Recruitment status
No longer recruiting

Registration date
21/04/2022

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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/m² 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

Contact information

Type(s)
Public

Contact name
Dr Judith Jelsma

ORCID ID
https://orcid.org/0000-0001-7943-9160

Contact details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081BT
+31 (0)610146084
j.jelsma@amsterdamumc.nl

Type(s)
Scientific

Contact name
Dr Judith Jelsma

ORCID ID
https://orcid.org/0000-0001-7943-9160

Contact details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081BT
+31 (0)610146084
j.jelsma@amsterdamumc.nl

Type(s)
Principal investigator

Contact name
Prof Willem van Mechelen

ORCID ID
https://orcid.org/0000-0001-7136-6382

Contact details
Van der Boechorststraat 7
1081BT Amsterdam
Amsterdam
Netherlands
1081BT
+31 (0)655147374
w.vanmechelen@amsterdamumc.nl

Additional identifiers

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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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 ≥18 years
4. Body Mass Index (BMI) of ≥25 kg/m² and /or patients who smoke

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Netherlands
9679 BJ

Sponsor information

Organisation
Amsterdam UMC Location VUmc

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
Netherlands

Results and Publications

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?
Protocol article		17/02/2023	22/02/2023	Yes	No
Statistical Analysis Plan	version 2	24/06/2025	16/07/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes