Joining forces to assess (determinants of) lifestyle behavior, morbidity and mortality among multimorbid individuals with a combination of the chronic diseases type 2 diabetes mellitus, cardiovascular disease, chronic respiratory diseases and/or cancer: the LifeStyle Medicine for individuals with multiple chronic diseases (LifeMeds) cohort.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57412

Source
ToetsingOnline

Brief title
LifeMeds

Condition

- Other condition

Synonym
comorbidity, multimorbidity, multiple chronic diseases

Health condition

multimorbiditeit (type 2 diabetes, hart- en vaatziekten, chronische luchtwegaandoeningen en/of kanker)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lifestyle, Multimorbidity

Outcome measures

Primary outcome

Lifestyle variables include physical activity, dietary intake, alcohol

consumption, sleep, stress, medication adherence, smoking and weight control.

Determinants include sociodemographic, medical, social and psychological

factors.

Endpoints:

- Mortality: all-cause and cardiovascular

- Hospitalizations during the first year post- percutaneous coronary

intervention, includ-ing elective and acute hospitalizations.

- Major Adverse Cardiac Events (myocardial infarction, coronary artery bypass

graft, heart transplantation, revascularization)

Secondary outcome

Not applicable

Study description

Background summary

Although there is a growing number of individuals with multimorbidity, previous studies have predominantly focused on single diseases. It is known that unhealthy lifestyle behaviors are more prevalent among individuals with multimorbidity compared to those with a single morbidity. Consequently, the encouragement of healthy lifestyles is essential, yet challenging given the lack of knowledge regarding determinants of lifestyle behaviors and future morbidity and mortality in this population. Therefore, the LifeMeds cohort aims to longitudinally identify sociodemographic, medical, social, and psychological determinants of lifestyle, morbidity and mortality in individuals with multimorbidity. The findings will support the development of disease-overarching approaches, tailored to the needs and characteristics of the individual with multimorbidity, rather than focusing on disease-specific approaches.

Study objective

Objective 1: The LifeMeds cohort aims to longitudinally identify characteristics of individuals with multimorbidity (at least two of the following chronic diseases: CVD, CRDs,T2DM and/or cancer), including lifestyle behavior and its determinants.

1a. To longitudinally characterize lifestyle trajectories of individuals with multimorbidity and to identify potential similarities and differences in lifestyle
trajectories between individuals with different combinations of multimorbidity.
1b. To identify determinants of lifestyle behaviors in individuals with multimorbidity and monitor changes over time.
1c. To link different lifestyle-trajectories to future morbidity and mortality risk.

Objective 2:
To investigate the impact of multimorbidity on health outcomes, including

quality of life, mortality and other significant health events, and to identify the sociodemographic, medical, social and psychological determinants associated with these outcomes.

2a. To assess quality of life, morbidity and mortality risk among individuals with different combinations of multimorbidity.
2b. To identify the clinical, sociodemographic, medical, social and psychological determinants associated with morbidity and mortality incidence in individuals with different combinations of multimorbidity.

Study design

The LifeMeds cohort is an observational, prospective cohort study, employing 10 yearly repeated measures to investigate the progression and development of multimorbidity, and lifestyle behaviors and its determinants in individuals with multimorbidity. Incident patients with multimorbidity (individuals newly diagnosed with a second condition making them affected by multimorbidity) as well as prevalent patients with multimorbidity (individuals who are already living with multimorbidity) will be eligible for participation. The aim is to recruit a large, heterogeneous sample, with various combinations of diseases to ensure diverse representation

Study burden and risks

We expect no risk for patients participating in this study, as involvement requires completing 1 questionnaire each year for a duration of 10 years. Participation in this study is entirely voluntary, and participants have the autonomy to decline or not answer items in the questionnaires.

It should be noted that participation in the study will necessitate a certain time commitment from the participants, an estimated 10 hours required over a 10 year timespan. Additionally, some of the questions may be perceived as sensitive, including those pertaining to personal life events, and income. This may be confronting to some participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- The cohort will include participants who have been diagnosed with at least two of the following chronic diseases: T2DM, CVD, CRD, cancer. The study will specifically include most common subtypes of diseases with etiologies strongly linked to lifestyle-related risk factors:
1. Cancer: breast, colorectal, prostate, lung/ brochus.
2. T2DM
3. CVD: coronary artery heart disease, heart failure, peripheral artery disease, hypertension.
4. CRD: chronic obstructive pulmonary disease, asthma.

- Aged 18 years or older

Exclusion criteria

- Refusal to informed consent
- Have significant cognitive impairment (e.g. major neurocognitive disorder)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	3000
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-03-2025
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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

Register	ID
CCMO	NL88127.028.24