Joining forces to develop and evaluate a toolkit to promote sustained lifestyle change among overweight and obese multimorbid individuals with a combination of the chronic diseases type 2 diabetes mellitus, cardiovascular disease, and/or cancer: the Lifestyle medicine for individuals with multiple chronic diseases (LifeMeds) study

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

Summary

ID

NL-OMON56754

Source
ToetsingOnline

Brief title
LifeMeds

Condition

- Other condition

Synonym
comorbidity, multimorbidity, multiple chronic diseases

Health condition

multimorbiditeit (type 2 diabetes, hart- en vaatziekten 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: Co-creation, Lifestyle, Multimorbidity, Overweight

Outcome measures

Primary outcome

In-depth information on the most important perceived barriers and facilitators of sustained lifestyle (change) (obtained from the interviews and focus groups) and insight into the real-time interrelation and relative importance of observed barriers and facilitators of lifestyle (change) and how these are influenced by contextual factors (e.g. social and physical environment). Eventually, the study endpoint is a co-created toolkit and training program for the promotion of (sustained) lifestyle changes. These will undergo feasibility and pre-efficacy testing, ultimately resulting in a plan for its adoption, implementation, and evaluation.

Secondary outcome

Not applicable

Study description

Background summary

The aging population is accompanied by an increase in the prevalence of chronic diseases like Type 2 diabetes mellitus (T2DM), cardiovascular disease (CVD), and cancer. These chronic diseases share similar lifestyle-related risk factors such as overweight and obesity. The increasing coexistence of these diseases, referred to as multimorbidity, increases the burden on healthcare providers and healthcare costs. Sustained lifestyle changes may improve health outcomes in individuals with multimorbidity and eventually reduce the burden on healthcare (costs). However, a suitable approach to achieving sustained lifestyle changes in individuals with multimorbidity is lacking. Both in prior research and in clinical practice, the focus is typically on singular chronic diseases rather than on multimorbidity. Additionally, little is known on how to achieve sustained lifestyle among multimorbid individuals with a low socioeconomic status (SES), low health literacy and/or from ethnic minorities, as they face unique challenges. Given the complexity of the physical, and psychosocial challenges that individuals with multimorbidity are confronted with, a tailored approach to accomplish sustainable lifestyle changes and improve health outcomes is warranted.

Study objective

Objective 1. To conduct an extensive needs assessment on how to promote individually tailored (sustained) lifestyle changes in individuals with multimorbidity, including vulnerable groups and ethnic minorities.
Objective 1.1: To gain in-depth information on the most important perceived barriers and facilitators of sustained lifestyle (change).
Objective 1.2: To gain detailed insight into the real-time interrelation and relative importance of observed barriers and facilitators of lifestyle (change) and how they are influenced by contextual factors (e.g. social and physical environment).
Objective 2. To co-create a toolkit and training program for patients and healthcare providers for the promotion of individually tailored (sustained) lifestyle changes considering disease- and treatment-related, psychological, and socio-demographic determinants.
Objective 3. To assess feasibility, usability and user satisfaction of the LifeMeds toolkit.
Objective 4. To evaluate the pre-efficacy of the LifeMeds toolkit and create a plan for the adoption, implementation, sustainability and evaluation of this

toolkit in clinical practice.

Study design

The ORBIT model will be used to guide the development and evaluation of the toolkit. Within the first phase of the ORBIT model, to guide the development of the toolkit, intervention mapping (IM) will be used for mapping elements of behavioral interventions. As part of the needs assessment, a prospective observational mixed-methods study will be executed on individuals with overweight and multiple chronic diseases will be conducted. Approximately 16 participants will be invited to participate in in-depth interviews. Additionally, 4 focus groups will be formed to identify perceived barriers and facilitators of (sustained) lifestyle changes. Based on these qualitative results, a single case design, Ecological Momentary Assessment (EMA), and Longitudinal Real-Time Assessment (LRTA) will be used over fourteen consecutive days with six daily EMA assessments to examine insight into the observed barriers and facilitators of lifestyle changes at the individual level. A mixed-methods feasibility study will be conducted to assess the feasibility, acceptability, and usability of the LifeMeds toolkit using a single-arm quasi-experimental pre-post design before evaluation and implementation of the toolkit. Pre-efficacy will be evaluated with a single-case experimental design, using a multiple baseline approach.

Study burden and risks

The risks of participation are minimal. The burden associated with participation includes the time invested. It is important to note that participants will be invited to participate in some of the studies described. Participants will join either a focus group or will be interviewed. Additionally, some of these participants and new participants will be requested to participate in an EMA and LRTA study. During this EMA and LRTA study, participants will wear a smartwatch/accelerometer for 14 days, complete a 3-day food diary, and complete six daily EMA assessments using their smartphone. For the co-creation sessions, participants will be requested to participate in 4 co-creation sessions of the development of the toolkit. Similarly, the time investment is requested of some patients to participate in a study to assess the feasibility of the co-created toolkit, which requires a time investment of around 2 months to familiarize themselves with the toolkit and apply it as well as completion of some questionnaires and a semi-structured interview. Finally, some participants will be asked to provide a larger time investment by evaluating the pre-efficacy of the toolkit throughout 20 weeks.

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

- A combination of cancer (colorectal, breast), CVD (Stroke, IHD, Peripheral Artery Disease) and/or T2DM.
- A BMI of 25 or higher
- Aged 18 years or older

Exclusion criteria

- A life expectancy of less than 1 year
- Not fluent enough in spoken Dutch or English language at a sufficient level to be able to complete questionnaires.
- Refusal to IC.
- With significant cognitive impairment (e.g. major neurocognitive disorder)
- Diagnosed with a psychiatric disorder

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	17-05-2024
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	NL86582.028.24