Lifestyle InterVEntion Study in General Practice: LIVES - GP

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Primary Objective:Our primary goal is to investigate the feasibility of a large pragmatic study of the effectiveness of a tailored MLI for patients with depression in general practice and to evaluate potential barriers and facilitators in a process...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON56076

Source
ToetsingOnline

Brief title
LIVES

Condition

- Coronary artery disorders
- Mood disorders and disturbances NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
depression; cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Provincie Drenthe

Intervention

Keyword: depression, general practice, lifestyle, overweight or obese

Outcome measures

Primary outcome

Our main study parameter is the feasibility of implementing and researching an MLI for depression in general practice using the following elements of the RE-AIM framework (Reach, Adoption and Implementation):

- Reach of our intervention as defined by the absolute number, proportion, and representativeness of individuals who are willing to participate in out of those invited. Reach is considered sufficient if it appears at least 20%. Representativeness will be assessed by comparing demographic variables (age and gender) between those who participate and who do not. GPs will be asked to document reasons for not inviting eligible patients. Reasons of patients to refrain from participation will be documented as well. GPs will be instructed to perform these documentations completely anonymous.

- Adoption is assessed as the representativeness and the participation rates (denominator those invited) of general practices, general practitioners, and life style coaches participating in this study. Sufficient adoption is defined as at least 20% participation of GPs. The former is assessed where applicable in terms of practice size, years of experience, and urban or rural location. Qualitative interviews among involved caregivers will be performed to obtain in depth information about barriers and facilitating factors in participating into

this study and adopting GLI-LEEF.

- Implementation is defined as both adherence and drop-out. Adherence to the lifestyle intervention GLI-LEEF is defined by the number of sessions attended by the participant out of the total of 18 sessions. Adherence to the assessment schedule is defined as the proportion of assessments completed, both at the measurement and the participant level; Drop-out from the GLI-LEEF intervention as defined by the proportion of participants who decide to prematurely stop taking part in the intervention. Sufficient adherence is defined as at least 50% of sessions attended, and at least 50% of assessments completed at the participant level. Unacceptable drop-out from the intervention is defined as higher than 50%. Potential barriers and facilitators of the GLI-LEEF implementation will be identified using a qualitative approach by interviewing approximately 10 participants who dropped out and 10 who completed GLI-LEEF, if opportune.

We consider our large scale study as feasible when in this study all criteria for reach, adoption and implementation as described above are met.

Secondary outcome

Our secondary research parameter concerns the variance of the outcome measures of mental health, lifestyle factors, functioning, recovery, well-being, sleep quality, self-esteem, quality of life, health care costs, anthropometry and blood pressure.

Study description

Background summary

Depression is a large problem, with a lifetime prevalence of 15-18% (WHO 2008) and a 42% relapse rate over 20 years (Hardeveld et al. 2013). The yearly economic burden of depression in het Netherlands is 1.6 billion euro for healthcare costs and 1.8 billion euro for loss of work productivity (Trimbos Instituut 2009). In the Netherlands, general practitioners (GP) treat 70-80% of the patients with depression (Verhaak et al. 2009).
Next to a decreased quality of life (Rapaport 2015), patients with depression also have a markedly heightened cardiovascular disease (CVD) risk and CVD mortality. Studies showed that patients with depression have 81% excess risk of developing CVD (Nicholson, Kuper, and Hemingway 2006), and a 1.4-1.8 times elevated risk of heart disease, hypertension, and stroke (Nicholson, Kuper, and Hemingway 2006; Meng et al. 2012). Furthermore, CVD is the most common cause of death in patients with mental disorders (Druss and Walker 2011), vastly exceeding the risk of suicide (Kisely et al. 2013). A small portion of this elevated risk of CVD and CVD mortality can be attributed to antidepressant use (Simoons et al. 2019) and underutilization of health care (Ten Have et al. 2013). However, the largest part of the elevated risk is attributed to an unhealthy lifestyle (De Hert et al. 2010). Interestingly, this unhealthy lifestyle feeds back to increased depressive symptoms and decreased quality of life, thus creating a hazardous vicious circle. Therefore, a lifestyle change might be twofold beneficial for patients with depression.
Multimodal lifestyle interventions (MLIs) are known to be effective in preventing CVD, and as treatment of obesity and diabetes (Doughty et al. 2017). There is also evidence that patients with mental health problems may benefit from MLIs, both in terms of physical and mental health, mostly from studies conducted in psychiatric outpatient settings. In patients with psychosis, a lifestyle intervention had a large effect on depressive symptoms and resulted in a moderate reduction in body weight after two to six months (Bruins et al. 2014). In patients with recurrent depression, a lifestyle intervention was efficacious in preventing depressive relapse (Goracci et al. 2016), and nutritional counseling was effective in reducing depressive symptoms (Jacka et al. 2017). The conclusion of a recent systematic review and meta-analysis, which included studies conducted in various settings, is that lifestyle interventions can result in a clinically significant improvement in both depressive symptoms and quality of life, albeit a modest one (Wong et al., 2021).
To our best knowledge, only one study has been performed on a MLI for patients with depression or anxiety in primary care (Forsyth, Deane, and Williams 2015). This randomized controlled trial (RCT) with 119 participants showed a significant effect on body mass index over a three-month period, but not on depression scores. So even though lifestyle interventions appear to be

effective in psychiatric outpatient settings, the evidence for their use in primary care patients is based on a single study only. This is unfortunate because the majority (65% to 80%) of patients with mild and moderate depression are treated in general practice (Verhaak et al., 2012). The most important difference between primary care and psychiatric outpatient setting is that patients in primary care usually have a less severe prognostic profile concerning their psychiatric disorder and CVD risk than patients in a mental health care setting. Therefore, results from studies performed in a psychiatric outpatient setting are unlikely to be generalizable to the primary care setting. Based on these considerations we decided to investigate the possibility of a MLI specifically for patients with depression in general practice. Since January 2019, four MLIs in the Netherlands are reimbursed by health insurance companies. (https://puc.overheid.nl/nza/doc/PUC_236692_22/). However, these MLIs do not meet the specific needs of patients with depression and in some MLIs mental health problems are even an exclusion criterion for participation. Therefore we developed our own MLI. To this end, we extended and adapted the widely used Coaching on Lifestyle (CooL)-program (van Rinsum 2018), which is recommended by the Dutch Healthcare Authority, to the disease-specific problems and needs of patients with depression. Depressed patients often have motivational and self-management problems (American Psychiatric Association 2013). Therefore, the substantial adaptations to the program include, for example, the highly recommended (but not mandatory) involvement of a person in the vicinity of the patient (*buddy* or *trustee*) and combining group and individual formats. This MLI has been piloted (N=42) in a mental health care (GGZ Drenthe) and general practice setting (N=8) with promising results. More information on the development and content of our MLI can be found in chapter 5.1.

Before proceeding with a full-scale randomized study to evaluate the cost-effectiveness of our MLI in general practice, it is essential to gain a better understanding of its implementation feasibility in this setting. Although we have previously tested our MLI among eight patients with depression and obesity in primary care , many questions about a larger scale implementation remain unanswered. The present real-world implementation feasibility study aims to provide answers to these questions.

Study objective

Primary Objective:
Our primary goal is to investigate the feasibility of a large pragmatic study of the effectiveness of a tailored MLI for patients with depression in general practice and to evaluate potential barriers and facilitators in a process evaluation. This enables us in primary care to estimate the feasibility of conducting such a study in real-world scenarios and identify key factors that may influence its successful implementation.

Secondary Objective:

Get an impression of the variance in the outcome measures on mental health, lifestyle factors, functioning, recovery, well-being, sleep quality, self-esteem, quality of life, health care costs, anthropometry and blood pressure for the future sample size calculation.

To meet these objectives, we will use the RE-AIM framework, which evaluates the feasibility of implementing an intervention in practice using five dimensions: (1) Reach, (2) Effectiveness, (3) Adoption, (4) Implementation and (5) Maintenance (Glasgow et al., 1999). In this study, we will only assess the Reach, Adoption and Implementation dimensions of the RE-AIM framework to evaluate the feasibility of future large-scale (cost-)effectiveness research. We believe that evaluating the effectiveness (2) and maintenance dimension (5) are more appropriate for a randomized controlled trial to be performed in the future.

Study design

The Lifestyle InterVEntion Study-GP (LIVES-GP) is an observational prospective single-group cohort study among patients with prevalent depression in primary care who also fulfil the criteria of at least overweight according to the NHG-richtlijn *Obesitas*. Individual patients are included in this implementation feasibility study and assessed for 42 weeks (including an intervention of 18 weeks and 24 weeks of follow-up. In order to address our research questions, we implement an MLI that was tailored specifically for patients with comorbid depression and metabolic abnormalities in a mental healthcare setting. The implementation will be done in patients with depression and overweight who are treated in general practices in the Northern Netherlands. Parameters of Reach, Adoption, and Implementation will be documented next to measurements of outcomes to assess variance herein. These measurements will be performed at baseline, end of treatment (18 weeks after baseline), and six months after the completion of the intervention (week 42). Alongside quantitative data we will collect qualitative data based on interviews. These interviews will be conducted at baseline, at the end of the intervention (after 18 weeks) and at follow-up (6 months post intervention). The interviews will be conducted amongst approximately 8-12 patients, depending on the number needed to achieve data saturation..

Intervention

The starting point is the CooL intervention recommended by the Dutch Healthcare Authority. This is complemented by innovations that can be assumed to make this GLI suitable for patients with depression who have difficulty with initiative and self-management. The possible adjustments are made on the basis of literature exploration into the most theoretical augmentation strategies in lifestyle interventions. Preliminary results show that, in addition to being sufficiently intensive and long-term, the intervention can be made suitable for

depression by adding innovations:

a) Involvement of a buddy from the immediate living environment of the patient (a friend, or family member) in the lifestyle intervention: augmentation with social support. This will provide extrinsic motivation and can ensure that the patient receives support in changing the living environment. Involving a buddy is not mandatory but is strongly recommended.

b) Support activity level increase: augmentation of the active movement module. With the help of an activity tracker during the entire treatment period, patients set personal goals in the field of exercise.

c) Strengthening of motivation and belief in the successful completion of the intervention, by supplementing the group sessions with exercises from positive psychology and from competitive memory training;

d) Increasing health knowledge and skills by adding *hands-on* practical lessons in buying and cooking healthy food: augmentation of the healthy food module).

GL-LEEF is personalized based on specific lifestyle problems in a given patient. The person sets his/her personal goals at the start of the training, and is also followed during the training based on these personal goals. GLI_LEEF focuses on physical activity, diet, stress, sleep, and alcohol and tobacco use. In principle, GLI-LEEF is carried out in a multidisciplinary manner, with practice nurses and lifestyle coaches under the direction of the general practitioner. The prototype of GLI-LEEF has already been made by GGZ Drenthe.

The lifestyle intervention is designed to last six months, with 14 weekly 1.5-to 2 hour group sessions and four 45 to 60 -minute individual sessions (1, 6, 12 and 18) with at least one person from the patient*s support network of friends or family (preferably sharing the same household). All sessions will end with individual homework exercises, and each session will start with a 10 to 15-minute positive psychology intervention (PPI) focussed at improving self-esteem, and 5 to 15 minutes of physical activity. These sessions will be followed by two booster sessions after about two and six months, depending on the patient*s individual needs.

Study burden and risks

The current lifestyle intervention feasibility study is quite extensive with a substantial number of visits, questionnaires and homework in between. On the other hand, the study poses minimal risks on the subject. In different module hands on experience is given to promote a healthier lifestyle, but the intervention has an advisory and not compulsory character. Measurements are questionnaire type or non-invasive anthropometry. Patients will be asked to

wear an activity tracker (Fitbit), but the main goal of this is to motivate the patient, not to control him.
On the other hand the study could have positive effects, namely an improved lifestyle, which may contribute to a better physical and mental health.
Eventually we hope to improve the life expectancy and quality of life of the target population.
For the buddy, participation is also quite extensive and may evoke some tension between the participant and the buddy. However, this will be closely monitored.
Moreover, the buddy may profit from the intervention in a similar way as the participant.

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

- Aged 18 years or older - Diagnosis of depressive symptoms or depressive disorder in the past year as registered in the general practice electronic health record and coded according to the International Classification of Primary Care (ICPC) as P03 and P76, respectively, or currently treated for depressive symptoms or depressive disorder in general practice. - At least mild depressive symptom level according to the Quick Inventory Depressive Symptomatology-Self-Report (QIDS-SR) (score >=6) - Body mass index >= 25 kg/m2 or increased waist circumference (>88cm (women) of >102cm (men)).

Exclusion criteria

- Current treatment in mental health care (GGZ in Dutch)
- Severe somatic / neurological disease at the discretion of the GP
- Currently participating in another lifestyle intervention
- Insufficient proficiency in Dutch
- Unability to read and write

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	20-11-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL84134.099.23