

The effectiveness and cost-effectiveness of an integrated cardio-metabolic risk assessment and treatment program in primary care: the INTEGRATE study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20643

Source

NTR

Brief title

INTEGRATE study

Health condition

Cardiometabolic disease, prevention, screening, non-participation, primary care, effectiveness, economic evaluation.

Cardiometabole ziekten, preventie, screening, non-participatie, eerstelijns gezondheidszorg, effectiviteit, economische evaluatie.

Sponsors and support

Primary sponsor: - NIVEL, Netherlands Institute for Health Services Research

- University Medical Center Utrecht, Julius Center,

- VU University Medical Center, EMGO Institute for health and care research, Amsterdam

Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for - Health Research and Development

- Dutch Diabetes Research Foundation, in collaboration with: Dutch Heart Foundation, and Dutch Kidney Foundation (LekkerLangLeven)

- Healthcare Insurance Innovation Fund (Innovatiefonds Zorgverzekeraars)

Intervention

Outcome measures

Primary outcome

1. The number of newly detected patients with a CMD in one year follow-up.
2. Change in individual risk factor (smoking, physical inactivity, obesity, unhealthy diet, blood pressure and cholesterol levels) for CMD between baseline and one year follow-up.
3. The expected number of newly detected patients with CMD and mortality after 5, 10, 20 years and lifetime.
4. Costs-effectiveness of PPA CMR
5. Non-participation and compliance in different stages of PPA CMR.

Secondary outcome

1. Difference in primary outcome 5 after implementation of different response-enhancing strategies.
2. Change in willingness to change lifestyle between baseline and one year follow-up.
3. Change in health status between baseline and one year follow up

Study description

Background summary

The increasing prevalence of cardiometabolic disease (CMD) asks for an effective program for early detection and management of individuals at risk. In the INTEGRATE study we evaluate the effectiveness and cost-effectiveness of the integrated prevention program 'Personalized Prevention Approach for CardioMetabolic Risk' (PPA CMR). In addition, determinants for participation and compliance are established. The INTEGRATE study is designed as a stepped-wedge randomized controlled trial with a waiting list control group. We will invite all listed patients without CMD aged 45-70 years of approximately 40 general practices to participate in PPA CMR. PPA CRM starts with an online risk estimation. Patients with a score above risk threshold are invited to the GP for additional measurements, detailed risk profiling and tailored treatment of risk factors through medication and/or lifestyle counseling. Follow

-up will be one year, necessary data are collected by questionnaires and extraction from and the GPs' electronic medical records. To determine factors for non-participation we will send non-participants questionnaires and we will assess all characteristics of participating practices. Several response-enhancing strategies will be tested in different subgroups.

COUNTRY OF RECRUITMENT: The Netherlands

Study objective

"Personalized Prevention Approach for CardioMetabolic Risk" (PPA CMR), a prevention program for cardiometabolic disease (CMD) combined with an individualized lifestyle intervention, is effectiveness and cost-effectiveness when implemented in primary care.

Study design

Intervention group:

- T=0 months: baseline measure for all patients
- T=6 months: follow-up measure for patients with increased risk
- T=12 months: follow-up measure for all patients

Control group:

- T=0 months: baseline measure for all patients
- T=12 months: follow-up measure for all patients
- T=18 months: follow-up measure for patients with increased risk
- T=24 months: follow-up measure for all patients

Intervention

The intervention is the CMD prevention program "Personalized Prevention Approach for CardioMetabolic Risk" (PPA CMR). We use an online risk estimation as screening tool for patients with an increased risk for CMD. Patients with a score above risk threshold are offered additional measurements by their GP. The GP gives individual tailored lifestyle advice and treatment when indicated. Treatment will be a lifestyle program and/or drug treatment.

Contacts

Public

Postbus 85500, 3508 GA Utrecht, Huispostnummer 6.131
Ilse Badenbroek
Centrum voor Gezondheidswetenschappen en Eerstelijns geneeskunde, UMC Utrecht
Universiteitsweg 100, 3584 CG Utrecht
Utrecht 3508 GA
The Netherlands
088-7568164

Scientific

Postbus 85500, 3508 GA Utrecht, Huispostnummer 6.131
Ilse Badenbroek
Centrum voor Gezondheidswetenschappen en Eerstelijns geneeskunde, UMC Utrecht
Universiteitsweg 100, 3584 CG Utrecht
Utrecht 3508 GA
The Netherlands
088-7568164

Eligibility criteria

Inclusion criteria

Inclusion criteria for practices:

- The use of an Electronic Medical Record (EMR) system, from which electronic data extraction is possible, covering approximately 90% of all Dutch general practices.

Inclusion criteria for patients:

- Age between 45 and 70 years, according to the guideline of the Dutch College of GPs

Exclusion criteria

Exclusion criteria for practices:

- Previously performed systematic CMD screening of the entire or a non-random sample of the practice population.

Exclusion criteria for patients:

- Previous diagnosis of CMD according to EMR
- Receiving antihypertensive and/or lipid-lowering treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	28500
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL4126
NTR-old	NTR4277
Other	METC UMC Utrecht : Protocolnumber: WAG/om/13/055866
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A