

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

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“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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20643

Bron

NTR

Verkorte titel

INTEGRATE study

Aandoening

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

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

Ondersteuning

Primaire 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

Overige ondersteuning: 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)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 characteristics of participating practices. Several response-enhancing strategies will be tested in different subgroups.

COUNTRY OF RECRUITMENT: The Netherlands

Doel van het onderzoek

“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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	28500
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A