Reducing Metabolic risk associated with coronary artery disease; controlling dietary components in diabetes patients.

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controlling diet will reduce metabolic syndrome in diabetes patients controlling metabolic syndrome will reduce the risk of coronary artery disease risk score.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28875

Bron
NTR

Verkorte titel
MSDC-PAK

Aandoening

Diabetes mellitus Type 2

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Arterial Blood Pressure
Lipid Profiling
Risk of Coronary Artery disease score

Toelichting onderzoek

Achtergrond van het onderzoek

Pending

Doel van het onderzoek

controlling diet will reduce metabolic syndrome in diabetes patients
controlling metabolic syndrome will reduce the risk of coronary artery disease risk score.

Onderzoeksopzet

0 - 2 - 4 - 6 months

Onderzoeksproduct en/of interventie

Control Arm

Participants randomized into the control group did not receive unsolicited feedback but will continue to receive their usual medical care as per usual when visiting their doctors but are allowed to contact the research facilitator as necessary. Participants in all three groups were required to monitor their blood glucose at least once daily (as per schedule). Glucose readings were taken daily as per schedule and performed 5 days a week throughout the six-months of study duration. At the end of study (six-months) participants of control arm were compared with Pharmacist intervention arm and telemonitoring arm for glycemic control and other relevant outcomes.

Pharmacist Intervention Arm:

Participants were referred through their primary physician or clinic nurses. Further screening was conducted to ensure eligibility for participation in this study.

Diabetes education that includes (i) diabetes disease process (ii) nutrition and physical exercise (iii) self-monitoring (iv) diabetes complications will be provided to participants who have provided a written informed consent. Participant baseline assessment included (i) past medical history (ii) demographic questionnaire and symptom questionnaire (iii) concomitant medication (iv) physical examination such as weight, height (v) blood specimen including HbA1c, etc.

Eligible participants were provided with a systemic booklet and home-work book to record their daily activities. Also researcher has developed a weekly glucose-monitoring schedule. Participants have to report daily physical activity and eating habits as well. A registered pharmacist provide once weekly visit to participant home for monitoring and evaluation (also provide counselling).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

individuals over the age of 18, of both genders, with at least one of the Metabolic Syndrome components and/or comorbities

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

without metabolic or motor disabilities that would limit physical exercise

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	20-12-2016
Aantal proefpersonen:	500
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	17-11-2016
Soort:	Eerste indiening

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	NL6064
NTR-old	NTR6211
Ander register	PML:280916 : Protocol ID

Resultaten

Samenvatting resultaten
Pending