

Vitalum: development and evaluation of two innovative health communication technologies aimed at a combination of diet and physical activity changes among patients with high blood pressure and the general population.

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1. Compared to participants in the control group, people receiving either Telephone Motivational Interviewing (TMI) or Tailored Print Communication (TPC): a) increase fruit and vegetable intake by 10% from the expected mean at baseline; b)...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27117

Bron

Nationaal Trial Register

Verkorte titel

Vitalum

Aandoening

1. No condition, healthy participants;
2. Hypertensive participants.

Ondersteuning

Primaire sponsor: Maastricht University
Faculty of Health, Medicine and Life Sciences

Department of Health Education and Health Promotion
P.O. Box 616
6200 MD Maastricht
The Netherlands

Overige ondersteuning: ZonMw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Physical activity, fruit and vegetable consumption and fat intake will be assessed with self-report questionnaires. At baseline and 47 and 73 weeks after baseline questionnaires will be filled out.

Toelichting onderzoek

Achtergrond van het onderzoek

Tailored Print Communications (TPC) and Telephone Motivational Interviewing (TMI) are both innovative and promising communication technologies that are being used to change regular physical activity and diet behaviour. Altering these behaviours is useful when aiming at the reduction of elevated blood pressure, which continues to be a widespread major impediment to health. The 2 strategies are applied as instruments in the primary and secondary prevention of cardiovascular disease, i.e. participants include a sample of the general population and patients with hypertension, all recruited from databases of General Practitioners. The RCT will use a factorial design to test the (cost-) effectiveness of TPC, TMI and the combined effects of TPC and TMI, compared to the control group, who will receive a tailored letter after follow-up data are collected. Furthermore, the potential surplus value of TMI for lower SES groups will be tested. Four intervention actions are spaced over a one-year period. Cost effectiveness analyses focus on the most cost-effective method for achieving at least 10% improvement in at least one behavior and for achieving at least 1 guideline. This data will help policy makers to decide which approach deserves future dissemination.

Doel van het onderzoek

1. Compared to participants in the control group, people receiving either Telephone Motivational Interviewing (TMI) or Tailored Print Communication (TPC):

a) increase fruit and vegetable intake by 10% from the expected mean at baseline;

b) decrease fat intake by 5%;

c) increase physical activity by 13%.

2. People receiving TMI+TPC have resulting behavioural changes which exceed the sum of the changes that are expected given each intervention.

3. Lower socio economic status groups benefit most from TMI.

4. Hypertensive patients are expected to be more motivated to change compared to the general public.

Onderzoeksproduct en/of interventie

The Vitalum study has 4 trial arms:

1. Tailored Print Communication (TPC) group: this group receives four tailored letters;

2. Telephone Motivational Interviewing (TMI) group: this group receives four motivational interview phone calls;

3. Combined (TPC+TMI) group: this group receives two tailored letters and two telephone motivational interviews in turns;

4. Control group: this group receives a tailored letter after the second follow-up questionnaire.

Intervention activities are delivered in week 5, 13, 30 and 43 after the baseline questionnaire.

Contactpersonen

Publiek

Maastricht University
Faculty of Health, Medicine and Life Sciences
Department of Health Education and Health Promotion
P.O. Box 616

Hilde Keulen van
Maastricht 6200 MD
The Netherlands
+31 43 3882448

Wetenschappelijk

Maastricht University
Faculty of Health, Medicine and Life Sciences
Department of Health Education and Health Promotion
P.O. Box 616

Hilde Keulen van
Maastricht 6200 MD
The Netherlands
+31 43 3882448

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Participants aged 45-70;
2. Maximal one person per address;
3. Not participating in other studies according to the database of general practitioners;
4. 50% of the participants is hypertensive;
5. 50% of the participants is male;
6. Participants who are included fail to meet at least two public health guidelines: one of them is physical activity, the other is fruit or vegetable consumption.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Physically not able to comply with healthy lifestyle;
2. Unknown address/removed;
3. Not able to speak/read Dutch;
4. Life threatening or malignant disorder;
5. Intellectual disability;

6. Cerebral vascular or cardiac event in the last 6 months;
7. Disorders in which the health of individuals will be harmed if they alter their lifestyle.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	1500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	06-09-2007
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	NL1035
NTR-old	NTR1068
Ander register	: 2200.0120 (ZonMw)
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A