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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27117

Source
Nationaal Trial Register

Brief title
Vitalum

Health condition

1. No condition, healthy participants;

2. Hypertensive participants.

Sponsors and support

Primary 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
Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Quality of life will be assessed with the Short Form 36.

Determinants of physical activity, fruit and vegetable consumption and fat intake will also be assessed in the baseline and 12 month follow-up questionnaires.

Study description

Background summary

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 usefull 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 interventino 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.

Study objective

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.

Intervention

The Vitalum study has 4 trialarms:

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	1500
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2007
Application type:	First submission

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	NL1035
NTR-old	NTR1068
Other	: 2200.0120 (ZonMw)
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A