

Motivational Interviewing to support patients with TIA or ischemic stroke to change their lifestyle on an nurse led secondary prevention clinic.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39323

Source

ToetsingOnline

Brief title

MOTIVE

Condition

- Other condition
- Vascular hypertensive disorders

Synonym

stroke

Health condition

neurovasculaire aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lifestyle behavior change, motivational interviewing, prevention, TIA or ischemic stroke

Outcome measures

Primary outcome

Primary outcome measures will be lifestyle behavior change, defined as smoking cessation and/ or increase of physical activity of 30 minutes and increase of 5 points at the Food Frequency Questionnaire after 6 months.

Secondary outcome

Secondary outcome measures will be motivation to change lifestyle, applicability and feasibility of motivational interviewing on our nurse led out-patient prevention clinic and change in weight, waist, blood pressure, cholesterol and blood glucose at 6 months.

Study description

Background summary

Patients with Transient Ischemic Attack (TIA) or ischemic stroke carry an increased risk of recurrent stroke of 6% each year. Stroke recurrence is a consistent and independent prognostic factor of disability, institutionalization and death. Much higher is the risk of other vascular conditions after stroke or TIA, this can raise to 50%. Hence, secondary prevention is an important part of stroke care.

Pharmacological and surgical interventions lower the risk of recurrent stroke

and other cardiovascular conditions. Little is known about the contribution of lifestyle behavior changes at this risk reduction. Epidemiological studies showed unhealthy lifestyle, like physical inactivity, smoking, overweight and unhealthy diet can increase the risk on stroke and other vascular conditions. Healthy lifestyle can influence vascular risk factors positively, for instance, modest weight loss in the obese can improve hypertension and hyperglycemia. Moreover, in patients with coronary artery disease the benefits of lifestyle management on vascular risk factors as well as the incidence of vascular death and myocardial infarction have been clearly demonstrated. Therefore, lifestyle management can be an effective way to reduce stroke recurrence.

Over 400 patients with TIA or ischemic stroke visit our nurse-led secondary prevention clinic each year. Informing and advising patients about healthy lifestyle is an important part of stroke care. Changing lifestyle is difficult and can be hampered by the cognitive and functional impairment and old age of our population. Motivation is essential to change lifestyle and maintaining this change. We are investigating other determinants which can influence intention and motivation to change at this moment in a prospective cohort study.

Motivational interviewing can be an effective way to help patients with TIA or ischemic stroke to change their unhealthy lifestyle. Earlier research and meta-analysis showed positive effects of motivational interviewing on changing unhealthy lifestyle at patients with chronic conditions and patients with cardiovascular conditions. Motivational interviewing appears a useful method to change health behavior by nurses. This method is particularly effective in short (15 minutes) conversations and more than one encounter with the patient ensures the effectiveness of motivational interviewing.

Little is known about the effects of motivational interviewing on lifestyle behavior change in patients with TIA or ischemic stroke. Hopeful effects on physical activity, diet, blood pressure, self-efficacy and compliance were showed in two small studies. However the duration of the conversations and the intensity of the intervention aren't reported.

In this study we will investigate if motivational interviewing can motivate and stimulate patients with recent TIA or ischemic stroke to change their lifestyle and maintain this healthy lifestyle. Moreover we will investigate applicability and feasibility of this intervention on our nurse led out-patient prevention clinic.

Study objective

Primary aim of the study is to investigate if motivational interviewing can be an effective way to motivate and stimulate patients with recent TIA or ischemic stroke to change their lifestyle and maintain this healthy lifestyle. Moreover we will investigate applicability and feasibility of this intervention on our

nurse led out-patient prevention clinic.

Study design

Randomized controlled trial with blinded outcome assessment

Intervention

One nurse specialist will follow a motivational interviewing training of 4 days. This specialist will patients of the interventiongroep. Patients who receive the intervention will have 3 extra visits of 15 minutes, 1 month, 2 months and three months after discharge following the principles of motivational interviewing. Patients in the controlegroup will only have standard conversations being admitted to the stroke unit or visiting the outpatient clinic. During this conversations lifestyle will be discussed, but no advise or motivational technics will be applied. This patients will visit the outpatient clinic after 4 weeks en 3 months after discharge. The will be done bij the untrained nurse specialist.

Study burden and risks

There are no risks of participation. Patients in the interventiongroup can experience some benefits.

Patients will be assessed during regular visits. Patients in the interventiongroup will have one extra visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients will be eligible for inclusion if they are 18 year or older, and have a clinical diagnosis of TIA or ischemic stroke

Exclusion criteria

Patients will be excluded if they are discharged to a nursing home, are non-Dutch speaking or notably aphasic.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-12-2012
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO	
Date:	22-05-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL39881.078.12