

# An integral Pro-Active Multicomponent Approach (PAMA) to optimize and tailor smoking cessation strategies for the primary health care (PHC) setting

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**HYPOTHESES:** We hypothesize that the PAMA condition in comparison to the Usual Care condition will: 2. Lead to more high risk smokers engaging to quit 3. Lead to more informed decision to quit smoking by smoking patients 4. Lead to more evidence...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aanpak</b>          | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20094

### Bron

Nationaal Trial Register

### Verkorte titel

PAMA/StopWijzer

### Aandoening

smoking cessation, smoking cessation guideline; primary healthcare, tailored approach, shared decision making

### Ondersteuning

**Primaire sponsor:** ZonMW

**Overige ondersteuning:** ZonMW

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Assess program appreciation, level of informed decision making and smoking cessation.

## Toelichting onderzoek

### Achtergrond van het onderzoek

The PAMA project (the ProActive Multicomponent Approach) is aimed at developing and evaluating an intervention (the StopWijzer) aimed at motivating smokers to quit smoking and making use of effective cessation methods. The smoker will be supported by the practice assistant (POH) or General Practitioner. The POH will inform the smoker about the available cessation methods and by talking together, a choice will be made for a cessation method that best suits the individual smoking patient. Examples of cessation methods are behavioral (personal counseling, eHealth, telephone counseling or group counseling), but also nicotine replacement agents (such as patches) or pharmacological agents (such as varenicline). To ensure that the smoker and practice supporter gain sufficient knowledge about the different options, a tool will be developed for both the smoker and the POH. To increase the final implementation and adoption, close cooperation with smokers, general practitioners and POHs were initiated. For example, an extensive needs assessment was conducted through a Delphi study and several interview rounds. Based on this needs assessment and scientific literature, an intervention has been developed that has been tested by means of a pilot study under 13 general practices. The pilot study has demonstrated the added value of the intervention within the field. The final intervention will be developed on the basis of the feedback from the pilot study and will be tested through an effectiveness study accompanied by an economic analysis. The project will be concluded with an appreciation and adoption study.

### Doel van het onderzoek

HYPOTHESES: We hypothesize that the PAMA condition in comparison to the Usual Care condition will:

2. Lead to more high risk smokers engaging to quit
3. Lead to more informed decision to quit smoking by smoking patients
4. Lead to more evidence based smoking strategies chosen by smoking patients
5. Be more effective to realize smoking cessation in smoking patients
6. Be more appreciated by smoking patients<

- 7. Be more cost-effective
- 8. Is appreciated by GPs, PNs and other stakeholders
- 9. Be more likely to become adopted in the GP setting

### **Onderzoeksopzet**

baseline questionnaire and six and twelve month follow-up questionnaire

### **Onderzoeksproduct en/of interventie**

The StopWijzer counseling method including supporting materials (online and on paper).

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen**

## (Inclusiecriteria)

Patients are reporting to smoke, providing informed consent and being able to read and understand the Dutch language.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Non-smokers

## Onderzoeksopzet

### Opzet

|                  |                        |
|------------------|------------------------|
| Type:            | Interventie onderzoek  |
| Onderzoeksmodel: | Parallel               |
| Toewijzing:      | Gerandomiseerd         |
| Blinding:        | Enkelblind             |
| Controle:        | Actieve controle groep |

### Deelname

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 01-05-2019            |
| Aantal proefpersonen:   | 900                   |
| Type:                   | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

|                 |            |
|-----------------|------------|
| Positief advies |            |
| Datum:          | 30-01-2018 |

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        | NL7020                |
| NTR-old        | NTR7218               |
| Ander register | METC MUMC : Submitted |

## Resultaten