Understandable drug information

Gepubliceerd: 19-10-2015 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25593

Bron
Nationaal Trial Register

Aandoening

Hypertension; (health) literacy

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is change in blood pressure
control between baseline and the first standard control measurement compared between the control and intervention group.

Toelichting onderzoek

Doel van het onderzoek

We expect that, compared to a standard text-only, a leaflet with pictograms leads to better perceived comprehensibility, utility and design quality of the leaflet
by consumers. This could lead to better recall and understanding of the drug information, increasing patients' self-efficacy, and in turn intention to adhere and actual adherence, which could lead to better blood pressure control. Additionally, we aim to gain insight into the question as to whether such intervention is especially beneficial for low-literate people, who are not sufficiently helped with a text-only leaflet format.

Onderzoeksopzet

Blood pressure control means that the patient has achieved the target blood pressure that was set out by their treating physician. Values at baseline (last measurement by HCP before first prescription of
antihypertensive drugs) will be compared to blood pressure measurements of the first routine check-up (usually three weeks after start of medication).

The secondary outcomes will be measured during two interviews - one at t=2-3 weeks and one at t=4-5 weeks after the patients have received the leaflet in the pharmacy.

Onderzoeksproduct en/of interventie

The control group will receive a secondary patient information leaflet that is text-only; the intervention group will receive the same information with pictograms added.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients who get prescribed antihypertensive medication for the first time, or for the first time after at least a year of not having received this medication.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- unable to verbally communicate in Dutch

- blind

- under 18 years of age

- incapacitated

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	28-10-2015
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-10-2015
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	NL5593
NTR-old	NTR5699
Ander register	: P15.209

Resultaten