

# The effect of a pictogram-guided antihypertensive drug leaflet on patients\* recall and understanding of information, self-efficacy, adherence and blood pressure control.

Published: 03-09-2015

Last updated: 19-04-2024

Our objective is to determine if, 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42631

### Source

ToetsingOnline

### Brief title

Understandable drug information/UDI

### Condition

- Other condition

### Synonym

patient communication/education

### Health condition

communicatie

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

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

## Intervention

**Keyword:** adherence., patient information, pictograms, self-efficacy

## Outcome measures

### Primary outcome

The main study parameter is change in blood pressure control between baseline and the first standard control measurement (usually three weeks after start of medication) compared between the control and intervention group.

### Secondary outcome

Other measures are differences in overall understanding of the information provided in the leaflet, satisfaction with the information, self-efficacy, and (intention to) adherence between the control and intervention group.

## Study description

### Background summary

Previous studies have shown that use of pictograms can improve the quality of written drug information, in particular for people who have difficulty reading and understanding health information. We have developed targeted pictograms, based on visual needs and preferences of people with low literacy levels. The aim of this study is to evaluate the effect of these pictograms in the context of existing patient leaflets for antihypertensive drugs.

### Study objective

Our objective is to determine if, 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.

## **Study design**

Cluster randomised design

## **Intervention**

The control group will receive a standard care, text-only drug information leaflet with their medication. The test group will receive the leaflet enriched with pictograms.

## **Study burden and risks**

A participating patient will experience standard care, with the additional burden of signing informed consent and answering questions in an interview. The interview will be planned at a time that is convenient for the patient to limit additional burden. The drug leaflets used in the study are currently in use at the LUMC outpatient pharmacy. Participants\* (health) literacy will be assessed, so that there is a risk of labelling the participant as literate or low-literate. To minimize this effect it will be explained that the literacy test provides insight into the gap between the level at which health information is offered and the level that matches the information needs of its target group. Direct benefits for participants include receiving potentially more user-friendly information on their medication, and contributing to the general advancement of patient drug information and safe medication use.

## **Contacts**

### **Public**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

### **Scientific**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: to get an antihypertensive prescribed for the first time and to not have used an antihypertensive the year before.

### Exclusion criteria

- unable to verbally communicate in Dutch
- blind

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose: Other

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 18-11-2015  
Enrollment: 180  
Type: Actual

## Ethics review

Approved WMO  
Date: 03-09-2015  
Application type: First submission  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)  
Approved WMO  
Date: 01-03-2017  
Application type: Amendment  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL53876.058.15