

# The iVitality Proof-of-Principle Study

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In the present project we aim to develop a first working platform for interactive, home-based blood pressure screening and monitoring by using internet and smartphone technology in middle-aged offspring of patients with dementia.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Dementia and amnestic conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39067

### Source

ToetsingOnline

### Brief title

The iVitality-POP study

### Condition

- Dementia and amnestic conditions
- Vascular hypertensive disorders

### Synonym

high blood pressure, hypertension

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Netherlands Genomics Initiatieve / Netherlands Consortium for Healthy Aging

## Intervention

**Keyword:** bluetooth, Digital communication (internet, Healthy aging, Home-based blood pressure monitoring, Interactive, smartphone)

## Outcome measures

### Primary outcome

Technical feasibility.

### Secondary outcome

We will assess satisfaction and motivation of the user of the platform.

Other parameters are measurements of

blood pressure physical activity, sleep patterns, cognitive function and mood

status.

## Study description

### Background summary

Randomized controlled trials are the cornerstone of evidence-based medicine, but elderly are structurally excluded from these trials, because of the high prevalence of multi-morbidity and poly-pharmacy among them. Therefore, alternative research methods to test effectiveness of interventions in such populations are needed. Innovative technologies such as the Internet, mobile phones and home-based health sensors are easy to use, even in the ageing population, and offer new study opportunities. The basis of such an approach is the "need" of participants to control (aspects of) their own health. Offspring of patients with dementia are at higher risk of dementia and have higher blood pressure at middle age, which is poorly controlled using conventional strategies. Therefore, we will develop a platform that can 1) prove the concept that such a platform can help control blood pressure and 2) generate user data that can aid in assessing the effect of interventions.

### Study objective

In the present project we aim to develop a first working platform for

interactive, home-based blood pressure screening and monitoring by using internet and smartphone technology in middle-aged offspring of patients with dementia.

### **Study design**

A feasibility study in which we will assess the technical feasibility and usability of the platform, together with the satisfaction and motivation of its users. In this first phase, no interventions will be applied.

### **Study burden and risks**

Since the iVitality-POP study is non-invasive and home-based, the burden for the participant is minimal. Participants will benefit of participation because their blood pressure will be strictly monitored.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

- Diagnosis of dementia (vascular/ Alzheimer\*s) in one of their parents
- Familiar with the use of internet, e-mail and mobile phone

## Exclusion criteria

- Medical history of any form of dementia and / or any other cognitive disorder.
- Medical history of stroke and / or transient ischemic attack.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-09-2012

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 22-05-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 22-01-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 01-05-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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	NL37384.058.11