Using an app with timely information to support hypercholesterolemia patients. A randomised controlled trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22965

Source
NTR

Brief title
N/A

Health condition

Cardiovascular diseases Hypercholesterolemia

Sponsors and support

Primary sponsor: No
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Increased level of knowledge about the condition in patients with hypercholesterolemia due to the use an app (The Patient Journey App).

Secondary outcome

There isn't a secondary outcome

Study description

Background summary

On average, the Dutch population is getting older, but the number of people with cardiovascular disease is rising (RIVM, 2018; Hartstichting, 2019). As a result, healthcare costs will double from 8.3 billion to 17.4 billion in the upcoming 20 years (RIVM, 2018). Atherosclerosis is the main cause of cardiovascular disease in which lifestyle and hypercholesterolemia play an important role. Almost a quarter of the Dutch population has hypercholesterolemia.

According to the Heart Foundation (2019), the number of potential patients with atherosclerosis can be reduced if people become more aware of the risk factors. To raise awareness, people need information on how atherosclerosis develops, what influence it has on the heart and blood vessels and, most importantly, how atherosclerosis can be prevented (Catapano, Pirillo, & Norata, 2017). This information is currently given orally to patients during consultation in hospital. However, it is difficult for patients to understand and remember the information. In addition, users want to be informed in advance about the condition, the risk factors, lifestyle, treatment and the consequences by means of simple visual information.

The aim of this study, a randomised control trial, is to compare the control group receiving the conventional oral information during consultation with the intervention group receiving an application (app) that provides daily information in the period before their consultation. The app, actively alerts patients to immerse themselves in de information, supported with images and videos. The assumption is that dosed information, prior to the consultation, contributes to the level of knowledge about the condition hypercholesterolemia. All patients receive information on the following topics: what is cholesterol, atherosclerosis, risk factors for elevated cholesterol, lifestyle and drug treatment options.

During the study the Patient Journey App developed by Interactive Studios will be used. This app has already proved effective in several studies in educating patients in various stages of various diseases (Rathbone & Prescott, 2017; Kim & Xie, 2017; Piette et al., 2015).
Study type: RCT
Population: hypercholesterolemia patients
Sample size: 68 (34 intervention, 34 control)
Questionnaires and timing:

- Seven days before the hospital consultation, baseline measurement:
Questionnaire about demographic characteristics (self-designed questionnaire)

Questionnaire about subjective knowledge about hypercholesterolemia (self-designed questionnaire)
Mobile skills questionnaire (validated questionnaire)

- Immediately after the hospital consultation, follow-up measurement:
Questionnaire about subjective knowledge (self-designed questionnaire)
Questionnaire about absolute knowledge about hypercholesterolemia (self-designed questionnaire)

Study objective

The primary hypothesis assumes an increase in the level of knowledge about the disorder in patients with hypercholesterolemia through the use of the intervention, that actively offers timely information to patient through push notifications.

Study design

Six months duration of the study

Intervention

The Patient Journey App

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with hypercholesterolemia based on secondary causes, such as obesity, a high-

calorie/fat diet or excessive
alcohol consumption.
• Men and women between ages of 18-75 years.
• In possession of an e-mail address for sending questionnaires.
• In possession of an Apple or Android smartphone or tablet before using the app.
• Good command of and ability to express the Dutch language.
• Respondents need a good command of the Dutch language in order to be able to consider signing for informed
consent.
A good command of the Dutch language is also necessary to use the application and to understand the information in
the application.

Exclusion criteria

• Patient with hypercholesterolemia on the basis of a gene mutation.
• Patients who have previously been treated for hypercholesterolemia at the vascular clinic at Bravis Hospital. This can
lead to a distorted picture, because patients who have previously been treated for hypercholesterolemia at Bravis
Hospital may have more knowledge about the condition hypercholesterolemia.
• Men and women under 18 years and over 75 years.
• Not in possession of an e-mail address.
• Not in possession of an Apple or Android smartphone or tablet.
• Not a good mastery or ability to express him/herself in the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	03-02-2020
Enrollment:	68
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8328
Other	ToetsingOnline : 2019/DT/0036

Study results

Summary results
N/A