eMate - Intelligent online monitoring and support for chronic patients

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Patients with chronic diseases require long-term adherence. Adherence can be improved by patient counseling as is common in disease management programs. However, personal counseling is expensive, especially given the fact that chronic patients will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON37933

Source
ToetsingOnline

Brief title
eMate

Condition

- Diabetic complications
- Viral infectious disorders

Synonym
HIV and Diabetes Mellitus type II

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMW programma Disease Management

Intervention

Keyword: mobile phone support, self-management, therapy adherence

Outcome measures

Primary outcome

Adherence to therapy 1) for medication as measured by the system (% of medication intakes taken) and 2) lifestyle aspects measured via questionnaires (number of gym visits, amount of physical activities and their intensity, healthy and unhealthy food consumption).

The ultimate goal is that the system provides an improved adherence to therapy (both to medication intake and life style changes), eventually resulting in a reduction in the risk of developing late-stage complications.

Secondary outcome

N.A.

Study description

Background summary

Treatment for chronic diseases often consists of a combination of lifestyle advices and medication. Many patients experience difficulties in following treatment recommendation. Adherence to these recommendations is often far from optimal, especially in patients with chronic diseases. Therapy adherence of patients with chronic diseases ranges between 70-80%. As a result of this widespread adherence problem, substantial numbers of patients do not get the maximum benefit of their medical treatment - with poor health outcomes, lower quality of life and
increased health care costs as a result.

Study objective

Patients with chronic diseases require long-term adherence. Adherence can be improved by patient counseling as is common in disease management programs. However, personal counseling is expensive, especially given the fact that chronic patients will often require treatment for the rest of their life. Permanent personal counseling is therefore often not realistic. However, adherence is not a static property and as such, it is likely to decline when counseling is ended.
In this study, we will evaluate an intelligent online self-monitoring and self-support system, with the aim of improving adherence to therapy, both with respect to lifestyle changes and medication intake. This system can be used within disease management programs as a new element or as long-term follow-up to support retaining the effects of personal counseling. The objective of this study is to determine to what extent adherence to oral medication and healthy lifestyle that comprises physical exercises and healthy food in patients with type 2 diabetes and HIV patients can be improved with ICT tools: Real Time Medication Event Monitoring System (electronic monitoring of medication use), model of behaviour change, combined with an SMS interaction system and Internet technologies. The elements of the model and the system are meant to be generally applicable to chronic diseases.

Study design

First, a pilot study with 40 patients will be done to validate the model and fine-tune the application. Then the hypothesis of improved therapy adherence with the help of the electronic system will be tested in two controlled studies, in which the adherence to therapy of 150 chronic patients that use the system is compared to the adherence of 150 patients that receive the usual treatment. Both chronic patients group as the control group will consist of 75 HIV patients and 75 diabetes type 2 patients.

Intervention

The intervention groups use the complete system (mobile phone app, website, electronic pillbox) and get tailored information; the control groups use the electronic pillboxes and get a link to general information about the importance of therapy adherence for their disease.

Study burden and risks

The patients will fill two times questionnaires on physical activity and diet: one time in the beginning of the study and one time in the end. They will also answer short questions via a mobile phone or a web-site during the intervention maximum. The maximal number of questions per day will be determined by the preferences of each individual participant.

The burden of the study is very low: the participants have to read the messages

sent by the system via a mobile phone or on the web-site and periodically answer the questions posed by the system.

There are no risks involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for diabetes patients are: 1) using oral antidiabetics >1 year; 2) using an Android-based smart phone; 3) using a personal computer with the Internet connection. Inclusion criteria for HIV-patients are: 1) using combination antiretroviral therapy for > 1 year; 2) using an Android-based smart phone; 3) using a personal computer with the Internet connection.

Exclusion criteria

Exclusion criteria for both patients groups are: 1) age > 65 years; 2) age < 18 years; 3) not speaking Dutch; 4) analphabetic

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2012
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO

Date:	10-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL34393.029.11