Real-time monitoring the occurrence of gout flares in patients by incorporation of the 2017 gout flare definition into an eHealth platform: a feasibility study.

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Purpose of this descriptive study is to gauge the feasibility of the Q1.6 app as platform to measure gout flares in real time. Primary research question: What is the perceived patients* value of thirty patients of app-based platform Q1.6 for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Purine and pyrimidine metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON45981

Source
ToetsingOnline

Brief title
Gout app study

Condition

- Purine and pyrimidine metabolism disorders
- Joint disorders

Synonym
gout

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: AbbVie;Menarini

Intervention

Keyword: eHealth, gout, mobile application, self-diagnosis

Outcome measures

Primary outcome

The main study parameter will be the score provided by the System Usability Scale (SUS) [Brooke J. Usability Evaluation in Industry 1996] as a measure for *perceived ease of use*. The SUS is a ten item questionnaire with five response options, generating a score between zero and forty. This score is multiplied two and a half times to adjust the score to a zero and one hundred point score. Finally, this score is categorised in concordance with Bangor et al:

Score = >80 Continue research on Q1.6 gout app without adjustments

Score = 50 * 80 Adjust Q1.6 gout app before continuing

Score = <50 Abolish or redesign platform applying gout flare measurement

The other main parameter is the *perceived usefulness*. This is a descriptive measure and assessed using the translated and adapted version of the questionnaire by Davis Jr.

Secondary outcome

To be able to answer the secondary research questions, the following secondary study parameters will also be collected:

- Number of gout flares reported by patients during three months

- Proportion of gout flares reported by patients that last longer than three

consecutive days.

- Uptake: number of patients that have been approached to commit to the

feasibility study in order to reach thirty inclusions

- Period of use: the time period that the subject actively uses the app

- Application adherence: percentage of days that questions have been answered

- All contact with the Q1.6 helpdesk of included subjects will be documented

using a case report form

Study description

Background summary

Uncontrolled gout is characterized by recurrent arthritis attacks in patients with gout, also named gout flares. The occurrence and frequency of flares are important outcome measures in clinical practice and clinical trials assessing the response of new treatments. Furthermore, frequency of gout flares is an important indicator for initiation of urate lowering therapy. However, measuring gout flares and flare frequency is difficult. Patient reported flare and physician observed flare are not always in accordance. Also, serum urate is not a well correlating proxy for flares. Use of anti-inflammatory drugs as proxy for flares has been described but has not been validated.

In current practice gout flares are recorded during outpatient clinic visits when flares have long past and thus are subject to recall bias. In the ideal situation gout flares are recorded while occurring. Recently, a four-criteria gout flare definition has been validated. Patients recording the presence of three or more criteria is associated with a positive prediction of 88% for a gout flare as defined by the diagnostic standard investigator. This definition has primarily been developed and validated for use in clinical studies. At present no studies have investigated the use of these criteria in daily clinical practice. In this study we want to test if it is feasible to apply the gout flare definition at home using a mobile app.

The Q1.6 app is a newly developed smartphone PRO-platform (patient reported

outcome-platform), based on pushing questions on smartphone login with predefinition of the type of question, question timing and frequency. Additionally, questions can be adjusted according to answers given. Data are transferred in real-time to the healthcare professional. This allows for stricter monitoring of gout patients with avoidance of therapeutic delay, thus improving patient outcome and quality of care.

The setup of Q1.6 using the gout flare definition has been designed by healthcare professionals with patients in mind. In order to know if patients value the chosen design for applying the gout flare definition, their attitude towards the application has to be determined. The Technology Acceptance Model (TAM) devised by Davis Jr describes user motivation as a combination of perceived usefulness and ease of use which affects the attitude towards using and which will eventually lead to actual system use. In the past decades, TAM has become a widely accepted model in the field of information technologies and has readily been applied to health care. Therefore the TAM will also be applied to the Q1.6 app loaded with the gout flare definition.

We hypothesize that by combining the recently validated gout flare criteria with a patient-friendly app and real-time monitoring, we can implement a gout flare measure that can be used by patients at home. With this feasibility study we want to assess what the perceived patients* value is of the Q1.6 gout app.

Study objective

Purpose of this descriptive study is to gauge the feasibility of the Q1.6 app as platform to measure gout flares in real time.

Primary research question:
What is the perceived patients* value of thirty patients of app-based platform Q1.6 for identification of gout flares as operationalized by the perceived usefulness and ease of use?

Secondary research questions:
a) What is the adherence to the Q1.6 gout app?
b) How often are gout flares reported per patient per 3 months?
c) What proportion of flares lasts longer than three days?

Study design

After inclusion, subjects install the app and record gout-activity daily, guided by the app. One to four questions a day are asked over a period of three months (see intervention for details). This information is encrypted and directly send to a database that is only accessible to the researchers.

In case of a recorded gout flare in patients without a crystal proven diagnosis

(question 4: are you currently experiencing a gout flare answered by yes) they will be invited by the rheumatology department, for an interim visit within 48 hours to obtain synovial fluid aspiration and confirm the gout flare. This is the gold standard for diagnosis of gout and in accordance with the local gout protocol.

Patients with a proven diagnosis will receive a telephone call from their healthcare professional if the patient reported a pain score over 3 and at least one warm or swollen joint for three consecutive days. The investigator will support the patient with therapeutic advice according to local gout protocol.

If subjects do not respond to the questions during a minimum of 5 consecutive days, the subject will receive a phone call from the investigator. Purpose of the call is to verify whether there is a technical problem or the subject has willingly stopped using the Q1.6 application. Technical issues will be resolved where possible. If the subject has willingly stopped the study will be brought to an end.

When the period of 90 days has passed or the subject has prematurely stopped using the Q1.6 application, the research will be brought to an end. Subjects will receive the 'System Usability Scale' and 'Perceived Ease of Use' questionnaires through email. Once completed the study will be terminated for this particular subject.

Intervention

App-based platform Q that will daily ask the user one to four questions (depending on the answers) for 90 consecutive days.
These four questions are:

What is your current pain level? (rated 0 - 10)

If pain is rated >3 then the following questions will also be asked:

Are one or more of your joints swollen? (yes/no)
Are one or more of your joints warm? (yes/no)
Are you currently experiencing a gout flare? (yes/no)

Study burden and risks

The burden of participation in this research consists of one to four questions asked through a mobile phone app for three consecutive months. The benefit that participants receive is that there will be acted upon this generated output if the patient reports a gout flare for at least three consecutive days.
Consequence of the use of the app-based platform Q is that the patient is

pro-actively asked to report symptoms instead of reactively. A possible medical treatment will always follow usual care as defined by the local gout protocol. Patients will not receive additional medication or invasive treatment (like a venapunction) because of inclusion in this study. As such, burden for patients is minimal and non-invasive. With this study, we hope to add a possible monitoring step to the diagnosis and treatment of gout flares and as such help to improve the health outcomes for patients with (high suspicion) of gout.

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

- Patients aged *18 years
- A diagnosis of crystal proven gout or a high clinical suspicion of gout
- At least one (possible) flare reported in the last three months

- Possession of an Android or iOS-based smartphone or tablet

Exclusion criteria

- Stable gout with no flares over the last year
- Life expectancy less than 3 months

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2018
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	mobile application Q1.6
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-10-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21867
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65917.091.18
OMON	NL-OMON21867