

## Original article

# Tele-monitoring flares using a smartphone app in patients with gout or suspected gout: a feasibility study

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## Abstract

**Objectives.** Gout flares are painful and disabling. We developed a smartphone application (app) for patients to tele-monitor gout flares surveyed by clinicians. The aim of this study was to assess patient acceptability and technical and clinical feasibility.

**Methods.** Adult patients with either established gout or high suspicion thereof were recruited if they possessed a smartphone and reported a recent arthritis attack. A smartphone application was used to identify gout flares by asking during 90 consecutive days: (1) what is your pain score (0–10); (2) are your joints warm; (3) are your joints swollen; and (4) are you currently experiencing a gout flare? The clinician was alerted via email if a flare occurred. Patient acceptability was assessed using the technology acceptance model. Technical feasibility consisted of reported technical issues and clinical feasibility of actions taken by the clinician regarding gout flare alerts.

**Results.** Twenty-nine included patients completed the study. The mean age of participants was 57 years, and all but one were male. The adherence rate was 96% (110 of 2910 queries were missed). Patients had a positive attitude toward app use, found the app very easy to use (mean usability score 81 out of 100) and were neutral to positive on its usefulness. There were four minor technical issues. A total of 100 gout flare alerts were generated that led to 18 proactive contacts with patients.

**Conclusion.** A smartphone app to monitor gout flares was developed and tested, showing high adherence, good acceptability and clinical feasibility for established gout patients.

**Trial registration.** Netherlands Trial Register, <https://www.trialregister.nl>, NL6435.

**Key words:** gout, flares, e-Health, tele-monitoring, smartphone application

## Key messages

- Patients with gout or suspected gout are highly adherent to tele-monitoring flares using an app.
- Tele-monitoring can help to provide clinical care to gout patients with a persistent flare.
- The patient-reported gout flare definition needs modification to be suited for patients with suspected gout.

## Introduction

Patients with gout, one of the most frequent inflammatory arthritic diseases, may experience recurrent flares, which are intensely painful and disabling in the case of

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uncontrolled disease [1]. Recurrent and chronic inflammation in gout impairs quality of life [2]. As a result, patients care most about the frequency and intensity of flares when considering treatment efficacy over time [3]. In addition, independent of hyperuricaemia, gout severity is associated with cardiovascular disease risk [4, 5]. Hence, the frequency of gout flares is an important clinical gout outcome. For optimal gout management, timely identification of flares and initiation of pharmacological treatment are needed according to European guidelines [6]. However, patients often flare at home, without the knowledge of the clinician, which limits the timely and accurate monitoring of gout flares.

Ideally, flares are identified at onset by patients and reported to the clinician to allow for fast and accurate diagnosis and early pharmacological treatment to subdue pain and increase daily functioning of the patient. Recently, Gaffo *et al.* [7] validated a patient-reported gout flare definition. This flare definition was incorporated into a smartphone application (app) to tele-monitor gout flares at home during clinical trials [8]. That study showed that it was feasible to capture gout flares at onset using the app and was deemed very convenient by patients. Nonetheless, tele-monitoring of gout flares has not been applied to routine clinical practice.

Incorporation of the gout flare definition into a smartphone app might have several advantages for clinical care. It facilitates standardized monitoring between visits, giving insight to both patients and treating physicians regarding gout flare frequency and duration. One can act upon reported outcomes immediately or at later scheduled visits. Studies in RA have shown that the implementation of standardized monitoring improves both disease monitoring and clinical outcome when combined with protocolized treat-to-target therapy [9].

To study the possibility of using a smartphone app to monitor gout flares between outpatient visits in patients with uncontrolled or suspected gout, we incorporated the patient-reported flare definition into a smartphone query app. Monitoring reports were sent to a clinician's dashboard for surveillance and to allow timely provision of appropriate treatment strategies. To ascertain that gout flares can be detected using this smartphone app for the use in routine gout care, insight is needed into patients' opinions on its use and its burden in daily practice. The primary aim of this study was to assess patient acceptability and technical feasibility of a smartphone app for tele-monitoring gout flares. Secondary outcomes were to explore the clinical feasibility of the app and the possibility to act upon reported flares.

## Methods

### Study design and setting

This intervention study was conducted during 2018 and 2019 at the Sint Maartenskliniek in Nijmegen, The Netherlands. The study was approved by the ethics committee of Arnhem–Nijmegen under registration number NL65917.091.18 and registered in the Dutch Trial Register as NL6435 (<https://www.trialregister.nl/trial/7217>). The study complies with the Declaration of Helsinki.

### Participants

Adult patients visiting the rheumatologist with established gout or a high clinical suspicion of gout were invited to participate until 30 patients gave written informed consent. Patients were considered to have established gout if crystals were confirmed on microscopic analysis, if tophi were present or if the patient fulfilled the ACR/EULAR criteria [10]. Patients with an unclassified arthritis in the last 3 months and suspicion of gout, as regarded by the rheumatologist, could be enrolled as patients with high clinical suspicion. Furthermore, patients were eligible for participation if they had at least had one self-reported arthritis attack in the past 3 months, possessed an Android or iOS-based smartphone and were able to communicate in Dutch.

### Intervention

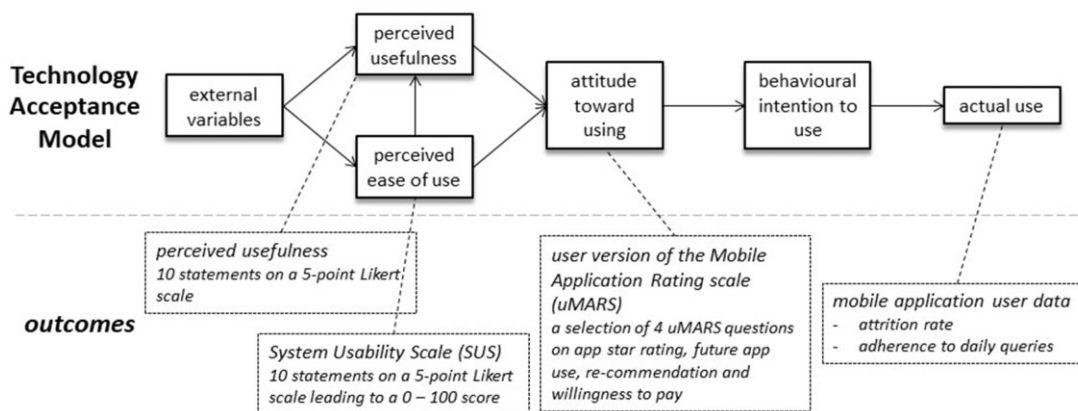
A smartphone application for queries (Q1.6) was used to incorporate elements of the patient-reported gout flare definition by Gaffo *et al.* [7] (see [Supplementary Data S1](#), available at *Rheumatology Advances in Practice* online, for screenshots). The definition gout flare is met if three of the following four questions score positive.

- What is your current pain score on a 0–10 level? (Positive if  $\geq 4$ .)
- Do you have warm joints?
- Do you have swollen joints?
- Are you currently experiencing a gout flare?

The tele-monitoring process is depicted in [Fig. 1](#). Patients installed the app, which was programmed to query the user on a daily basis for 90 days consecutively. To optimize user-friendliness, questions were asked in the Dutch language, and the regression tree definition as defined by Gaffo *et al.* [11] was applied. This means that the first question was a screening question, where scoring pain  $< 4$  (indicating minimal pain) terminated the query; otherwise, the patient had to answer the remaining questions. In the pilot phase, patients could not view their responses. Encoded responses were transmitted in real time to a hospital dashboard that could be accessed by the research team consisting of two rheumatologists and one pharmacist. This dashboard showed a list of all patients, whether questions



Fig. 2 Technology acceptance model and the outcomes of this study



captured the overall feeling of the app and its potential use were selected by B.P.H.P. and B.J.F.v.d.B. All other questions were omitted because they related to other aspects of mobile applications and even overlapped with ease of use and usefulness.

Perceived ease of use was scored using the Dutch version of the system usability scale (SUS) [14]. The SUS consists of 10 statements scored on a five-point Likert scale (from totally agree to totally disagree). Taken together, the SUS items yield a single score representing a composite measure of the overall usability. Bangor *et al.* added an adjective scale to the SUS score ranging from worst (0–25) to best imaginable (90–100) [15, 16].

Perceived usefulness was assessed with the perceived usefulness questionnaire by Davis [12], which was translated and adjusted to fit the purpose of the gout query app. This resulted in 10 usefulness statements on a five-point Likert scale (from totally agree to totally disagree).

See [Supplementary Data S2](#), available at *Rheumatology Advances in Practice* online, for the complete questionnaire.

### Measurements: exploring feasibility

Feasibility is the assessment of the practicality of, in this case, a health-care innovation. There are many domains that can be assessed, among which are technical, operational, clinical, resource and financial feasibility. Given that the patient is the one who should benefit most from the current innovation, we chose to explore the feasibility of two domains: technical and clinical.

Technical feasibility was assessed by collecting all technical issues. These issues were either reported directly by patients or noted by the researcher when checking whether inactivity was attributable to technical issues.

Clinical feasibility was stratified for suspected and established gout patients because clinical follow-up differed. All patients received standard care according to

the care protocols of the Sint Maartenskliniek. Patients with a suspicion of gout are instructed to telephone the clinic when flaring to make an appointment for a visit to the clinic within 48 h to try and obtain joint fluid for uric crystal detection. Patients with established gout are instructed to start anti-inflammatory therapy at the onset of flare symptoms (or increase in the case of anti-inflammatory prophylaxis) and to telephone if a flare persists despite adequate treatment. When the clinician received an email alert from the tele-monitoring system, he decoded the patient research identity and looked into the patient's status. Patients with a high suspicion of gout were contacted on the day the email alert was received. This allowed the clinician to invite the patient to the clinic within 48 h to establish the gout diagnosis. Patients with established gout were contacted only if the flare lasted >3 days, because a flare lasting >3 days despite treatment was defined as an inadequately treated gout flare for the purpose of the present study. During the telephone call, the clinician enquired on flare severity and evaluated treatment strategy. To obtain a general idea of how alerts of the app related to the care provided, clinical feasibility was expressed with process parameters such as the number of alerts generated, the number of (timely) clinician–patient contacts and actions taken by the clinician. Given that the care provided could differ between patients, no end-of-prompt was set for generated alerts. Therefore, one flare could generate multiple alerts, and alert generation could continue even after the patient was consulted.

### Sample size

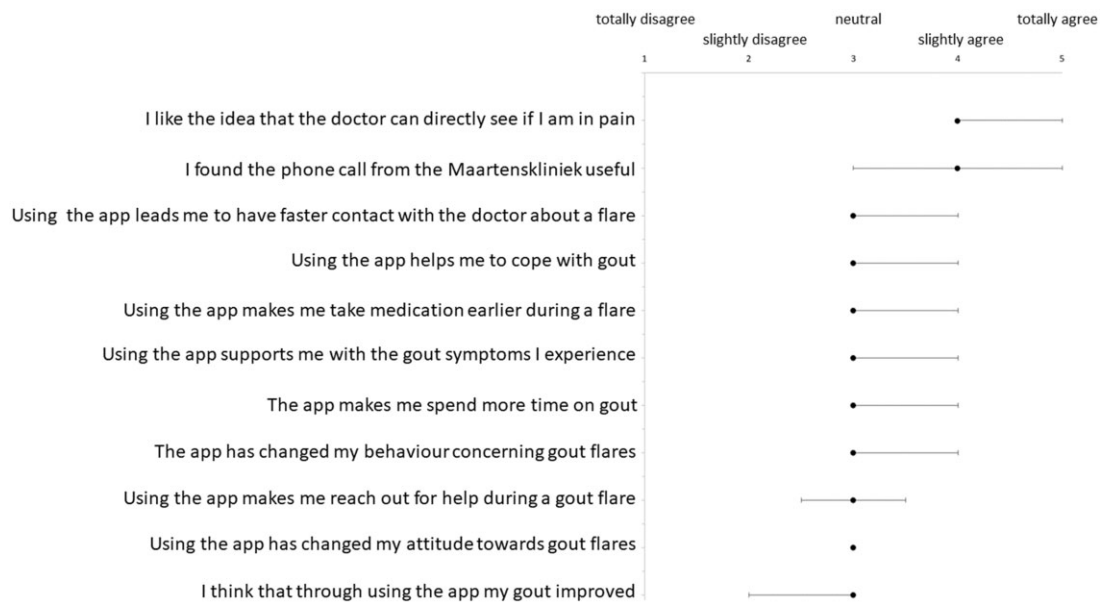
In this feasibility study, we based our sample size on earlier publications by Kieser & Wassmer [17] and Julious [18] showing that a pilot sample of 20–40 with  $\geq 12$  patients per sample suffices [17, 18]. As a consequence, the sample size was set at 30 patients to ensure the minimum of 12 patients with established and 12 with suspicion of gout.

TABLE 1 Characteristics of study participants

Characteristic	All (n = 29)	Established gout (n = 17)	Suspicion of gout (n = 12)
Age, mean (s.d.), years	57 (13)	59 (14)	54 (13)
Male sex, n (%)	28 (97)	17 (100)	11 (92)
Established gout, n (%)		17 (100)	
Time since diagnosis <sup>a</sup> , median (IQR), months		3.5 (2.4–14.1)	
Crystal proven, n (%)		9 (53) <sup>c</sup>	
Tophi present, n (%)		7 (42) <sup>c</sup>	
Flares in the previous 3 months <sup>b</sup> , n (%)			
One	26 (90)	16 (94)	10 (83)
Two	2 (7)	–	2 (17%)
Three or more	1 (3)	1 (6)	–
Use of urate-lowering therapy, n (%)	20 (69)	16 (94)	4 (33)
Allopurinol	16 (80)	13 (81)	3 (75)
Benzbromaron	3 (15)	2 (13)	1 (25)
Febuxostat	1 (5)	1 (6)	–
Use of anti-inflammatory drugs, n (%)	29 (100)	17 (100)	12 (100)
Colchicine, cont., n (%) / proph., n (%)	18 (62) / 7 (24)	13 (76) / 2 (12)	5 (42) / 5 (42)
Prednisone, cont., n (%) / proph., n (%)	2 (7) / 5 (17)	1 (6) / 3 (18)	1 (8) / 2 (17)
NSAID, cont., n (%) / proph., n (%)	6 (21) / 11 (38)	3 (18) / 7 (41)	3 (25) / 4 (33)
Coxib, cont., n (%) / proph., n (%)	1 (3) / –	1 (6) / –	–
Urate level, mean (s.d.), mg/ml	0.39 (0.11)	0.36 (0.10)	0.42 (0.11)
CKD-EPI, mean (s.d.), ml/min	85 (16)	84 (27)	86 (14)

<sup>a</sup>As confirmed by the rheumatologist. <sup>b</sup>Self-report by patients as documented by the rheumatologist. <sup>c</sup>Four patients had neither crystal-proven gout nor tophi present but did fulfil the ACR/EULAR criteria for gout. CKD-EPI: glomerular filtration rate estimate from serum creatinine using the Chronic Kidney Disease Epidemiology Collaboration formula; cont.: continuous use; Coxib: selective cyclo-oxygenase-2 inhibitor; IQR: interquartile range; proph.: prophylactic or use in case of a flare.

FIG. 3 Results of the perceived usefulness statements



A dot represents the median and a line the interquartile range.

### Statistical analysis

Analysis was performed using descriptive statistics. Continuous variables were described using the mean (s.d.) or, in the case of non-nominally distributed data, the median and interquartile range (IQR). Categorical variables were expressed as percentages. All data were analysed using STATA v.13.1 (StataCorp, College Station, Texas).

## Results

### Participants

Thirty patients gave consent, but one patient was excluded because he received a diagnosis of RA before starting the study. Participants had a mean age of 57 (13) years, and almost all (97%) were male (see Table 1). Seventeen patients had a diagnosis of established gout [disease duration after diagnosis 3.5 (IQR 2.4–14.1) months], of whom 16 patients (94%) used urate-lowering therapy. Twelve patients with a suspicion of gout participated, of whom four (33%) used urate-lowering therapy and all used anti-inflammatory drugs.

### Patient acceptability

#### Actual use

The attrition rate was 0%, because no patients quit prematurely. Overall adherence to queries was 96%, because 110 of 2710 queries were missed. Three patients were responsible for 60% of the missing queries ( $n = 66$ ), whereas 16 patients never missed a query.

#### Attitude toward using

The median overall rating of the app was four out of five stars [IQR four to five]. Fifteen patients (52%) would use the app daily. Twenty-four patients (48%) would recommend the app to others. Eleven patients (38%) would consider paying for the app.

#### Perceived ease of use

The mean SUS score was  $81 \pm 8$ , and 27 (93%) patients rated usability as good to excellent.

#### Perceived usefulness

Overall, patients perceived the usefulness of the app as neutral to slightly positive (Fig. 3). The statement 'I like the fact that the doctor can immediately see when I'm in pain' scored best (IQR four to five).

### Exploring feasibility

Regarding technical feasibility, four technical issues were reported during the study. Two patients had trouble installing the app, and two issues involved a temporary disruption of the queries and led to 13 missed queries. All issues were considered minor and resolved by the research team.

Eleven of the 17 patients (65%) with established gout experienced a total of 20 flares during the 3-month period. The median flare duration was 1.5 days (range

1–8 days). Five flares lasted >3 days, generating an alert, of which one flare was discussed during an already planned consultation. The remaining four alerts were followed up with a telephone call within 4 days of symptom onset. No action was deemed necessary for three patients, whereas one patient was invited to the clinic the next day, where an IA injection was placed and medication adjusted.

In the 12 suspected gout patients, seven patients (58%) generated 95 alerts out of 630 queries (15%), with three patients responsible for 79 alerts (83%). In line with the protocol, 14 patient contacts with the clinician followed, of which 7 (50%) were within 48 h (weekends excluded). These contacts led to two alternative diagnoses (one RA and one PsA), four medications being started, one medication adjustment and three emergency visits to the clinic, where one IA injection was placed and one diagnostic screening performed. During follow-up, the following clinical problems were encountered that led to repeated alert generation: non-adherence to gout flare therapy, alternative diagnoses and co-morbidity (OA).

## Discussion

This feasibility study aimed to assess the patient acceptability and feasibility of tele-monitoring of gout flares using a smartphone app as part of routine gout care. The app was used continuously, with few minor technical issues. Patients had a positive attitude toward app use, found the app easy to use and were neutral to positive on its usefulness. Clinically, it was feasible to contact all patients with established gout in a timely manner, but not actionable to contact patients with suspicion of gout at each alert.

### Patient acceptability

The adherence found in the present study is very high compared with that reported in similar literature [19]. It is possible that the high adherence is a result of the easy and short patient definition, because Elmagboul *et al.* [8], who used the same definition, showed similar adherence rates when monitoring gout flares on a weekly basis for 6 months using a smartphone app and interactive voice response. Additionally, in a qualitative study patients stressed that flare monitoring should be included in a gout self-management app [20]. These results comply with the theory of the technology acceptance model that high app use is a result of high usability and usefulness, which was also found in our study.

High adherence could also have been the result of selection bias, because patients participated after invitation by their rheumatologist, and no record was held of patients who were not eligible or who declined invitation. The included participants were relatively young, and it has been shown that a younger age leads to higher e-Health adherence; hence, it is possible that we selected early adopters [19]. Adherence rates in clinical practice

can be lower, especially when tele-monitoring exceeds our 3-month study period. Colls *et al.* [19] found adherence rates to be highest in the first month, followed by a decline over a period of 6 months. The use of a short, low-key screening question (pain score) instead of the full questionnaire might be an important factor in maintaining high adherence over time in the present study. Fortunately, lower adherence rates could still suffice for the purpose of catching flares, because patients do not flare on a daily basis.

### Technical and clinical feasibility

Our findings demonstrated technical and clinical feasibility of the gout app. Few technical issues were encountered, and these were easy to resolve.

At the clinical level, the app functioned as expected in monitoring the occurrence and duration of gout flares. However, regarding alert generation several issues were identified, especially in translating alerts into clinical action. One flare was able to generate multiple alerts, because we did not build an end-of-prompt definition into the alert algorithm. Therefore, alerts did not terminate upon action, which can be built in as a future improvement.

Furthermore, we included suspected gout patients to increase generalizability by encompassing the full range of patients who are seen during routine clinical practice, although the flare definition is not validated for patients with a suspicion of gout. In retrospect, this group might not be suitable for using the gout flare criterion on a daily basis, because alternative diagnoses might lead to repeated alerts in the case of a more chronic form of arthritis. In patients with established gout, the app alerts functioned as a valuable monitoring tool. However, the additional value of pro-active contact was considered low, because for only one of five alerts the patient was invited to the clinic for consultation and IA injection. In further research, the query frequency could be optimized by using an algorithm that lowers query frequency when flares subside, especially with longer use of the app.

### Clinical implications

The present study shows high patient adherence to tele-monitoring symptoms using a smartphone app. In clinical practice, tele-monitoring of gout flares would provide a real-time between-visits overview of the frequency and duration of gout flares in patients with uncontrolled gout. The use of a standardized gout flare patient-reported outcome makes comparison within population and between patients an insightful possibility for both clinicians and patients. Furthermore, anonymized tele-monitoring data combined with clinical outcomes gives valuable insight in gout flare prognostics and treatment options. There is a case for acting upon flares in patients with a suspicion of gout, but in patients with established gout the additional value of a pro-active intervention remains to be seen.

### Future work

Given that this is a feasibility study, there are steps to take before full implementation of tele-monitoring of gout flares in clinical practice. Firstly, acceptability from the clinician's perspective should be assessed because participation of all concerned parties is crucial for implementation; even more so because clinicians should guarantee continuous monitoring of the dashboard and take appropriate clinical actions. Secondly, the value of the app as a diagnostic tele-monitoring tool for facilitating routine gout care could be increased. In its current form, the app is most useful for established gout patients with active disease, and we do not advise use of the app in patients with a suspicion of gout. Adjustment and validation of apps like this one might result in a more useful eHealth tool in this patient group [21]. Lastly, the effectiveness of tele-monitoring gout flares should be evaluated on clinical outcomes such as those described by Day *et al.* [22]. Such a study will provide a better estimate of patient acceptability because inclusion will extend beyond the early adopters.

### Conclusion

Taken together, a smartphone app to tele-monitor gout flares was developed and tested. Tele-monitoring was technically feasible and had high adherence and good patient acceptability. Clinically, our application made it feasible to act on flares as they occurred in established gout patients during the present study. The present patient-reported definition for gout flares is not suitable for patients with a suspicion of gout.

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### Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

### Supplementary data

Supplementary data are available at *Rheumatology Advances in Practice* online.

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