# Serum urate home monitoring for gout using a Point-of-Care Testing Meter and nurse-led treat-to-target approach: A feasibility study

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This research aims to examine the feasibility of home monitoring of serum uric acid for both patients and stakeholders, using a digital home measuring device in conjunction with a nurse-led T2T approach.Primary research question:What is the…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Purine and pyrimidine metabolism disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56711

**Source**
ToetsingOnline

**Brief title**
Home Monitoring Gout

### 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:** Projectgebonden financiering van de Sint Maartenskliniek

## Intervention

**Keyword:** eHealth, gout, Point-of-care-testing, self-monitoring

## Outcome measures

**Primary outcome**

The main outcome to answer the primary research question is patient and stakeholder feasibility of sUA home monitoring and nurse-led T2T, which will be assessed on the following domains:

Acceptability (How individuals involved react to the program):
Patient acceptability of the POCT-device itself and sUA home monitoring and nurse-led T2T as a whole will be studied according to the Technology Acceptance Model (TAM) using questions included in both the 12 week and 24 week questionnaire. Ease of use of the POCT device will be assessed by the system usability scale (SUS, Dutch version), in which 10 questions are asked on a 5-point Likert scale (Appendix 1, Part 1, Question 1-10). Perceived usefulness of sUA home monitoring and nurse-led T2T will be assessed by 9 questions on a 5-point likert scale (Appendix 1, Part 2, Question 1 - 9). Attitude towards using and intention to use the POCT device itself will be assessed by 5 questions relating to the overall satisfaction with and rating of the device, and intention to use the device in the future (Appendix 1, Part 2, question 10 - 15). Furthermore, acceptability of the POCT-device is evaluated by two

ques-tions related to attractiveness and appropriateness of the POCT-device (Appendix 1, Part 1, Question 11 - 12), and the physical and mental burden of home monitoring sUA (Appendix 1, Part 3, Question 5 - 8).
Stakeholders* acceptability for sUA home monitoring and nurse-led T2T will be evaluated through semi-structured interviews (Appendix 2) and weekly journal entries describing their barriers/facilitators and other remarks.

Demand (Use and/or need for the intervention):
Patients* demand for sUA home monitoring and nurse-led T2T will be assessed by two ques-tionnaire items related to actual use of the POCT-device (Appendix 1, Part 2, Question 16 -17), included in both the 12 week and 24 week questionnaire. Additionally, the adherence to the communication of sUA measurements towards the hospital is indicative for demand. The number of patients approached to reach 30 included patients can also provide information regarding demand for home monitoring of sUA and nurse-led T2T.
Stakeholders* demand for sUA home monitoring and nurse-led T2T will be evaluated through semi-structured interviews (Appendix 2).

Practicality (the extent to which an intervention can be delivered when resources, time, commitment, or some combination thereof are constrained in some way):
Patients* ability to carry out intervention activities, i.e. sUA home monitoring, is assessed using four questions related to using the POCT-device and communicating the values digitally (Appendix 1, Part 3, Question 1 - 4),

included in both the 12 week and 24 week questionnaire. Questions regarding usage of the POCT-device received by patients and answered by nurses will also be collected to provide insight into practicality. Also, patient*s ability to carry out the intervention activities will be assessed by the proportion of and possible reasons for withdrawal.
Stakeholders* perspectives on the practicality of sUA home monitoring will be collected through semi-structured interviews (Appendix 2). Additionally, weekly journal entries from HCPs will provide additional insight into intervention practicality.

Implementation & Integration (The extent, likelihood, and manner in which an intervention can be implemented as planned and the level of system change needed to integrate a new program or process into an existing infrastructure):
Stakeholders* perspectives on implementation and integration of sUA home monitoring and nurse-led T2T will be collected using semi-structured interviews (Appendix 2). Finally, in this domain, weekly journal entries will also provide additional insight into barriers and facilitators for implementation of the intervention.

Limited efficacy (effect of intervention on outcomes in a limited way):
Serum urate levels (percentage on target), gout flares, ULT usage and doses are collected from the 4-weekly questionnaire. Health care use will also be extracted and is defined as number of consultations with all types of healthcare providers and lab testing for gout registered in the electronic

patient file. Patient activation will be assessed at baseline and after 24 weeks, using a validated questionnaire: the patient activation measure (PAM). This measure includes 13 questions on a 5-point likert scale (Appendix 1, part 4). Quality of life will be assessed at baseline, and 24 weeks using the EQ-5D-5L, which measures 5 dimensions of everyday life and patient*s self-rated health on a vertical visual analogue scale (Appendix 1, part 5). Beliefs about medication using the Beliefs About Medication questionnaire (BMQ) 23 will be assessed at baseline and 24 weeks (Appendix 1, part 6).

**Secondary outcome**

Not applicable

# Study description

**Background summary**

Gout is one of the most common inflammatory rheumatic disorders, with an expected prevalence of 580,000 in the Netherlands by 2030, corresponding to 3.3% of the current Dutch population of 17.5 million. The disease arises from the deposition of sodium urate crystals when serum urate (sUA) consistently exceeds saturation. Deposition of these crystals can lead to intense joint pain, joint damage, and subcutaneous nodules. Fortunately, gout can be effectively treated, with a central role for urate-lowering therapy (ULT). A 'treat-to-target' (T2T) approach, titrating doses of urate-lowering therapy until a target value of sUA below 0.36 mmol/L is achieved, prevents the occurrence of future attacks.

Unfortunately, some gout patients are inadequately treated with ULT, resulting in unnecessary attacks. Research indicates that 1) patients with an indication for ULT sometimes do not receive this treatment, and 2) the T2T approach is not always (sufficiently) employed to effectively control sUA levels. Lastly, adherence to ULT is generally low among gout patients, leading to uncontrolled disease.

In their groundbreaking research, Doherty et al. demonstrate that nurse-led care and a strict T2T strategy (with intensive monitoring and support) can lead

to 95% of gout patients achieving treatment goals, followed by a significant reduction in gout attacks after two years. Other studies also show promising results with nurse-led care. However, this form of care is labor-intensive. The increasing prevalence of gout and the resulting pressure on healthcare professionals underscore the need to integrate innovative solutions to ensure the accessibility and affordability of healthcare.

Supporting patient self-management via eHealth can be a promising addition to gout care, providing the opportunity for additional information, education, and monitoring, possibly in a more automated manner. An intervention with a nurse-led T2T strategy, combined with self-monitoring using a digital uric acid meter and digital communication with nurses, can increase patient engagement and adherence. Greater patient engagement, adherence, and task delegation to specialized nurses can improve the efficiency of care while maintaining its quality. In secondary care, efficiency is crucial, as the greatest gains can be achieved in the efficiency of care, as opposed to quality. Patients and healthcare providers were positive about a nurse-led T2T strategy combined with home uric acid monitoring after a pilot project at the Sint Maartenskliniek, and important considerations for the use of such a strategy in clinical practice were obtained.

However, more scientific evidence is needed on the feasibility of using home monitoring to better understand how the intervention can add value and meet the needs of patients and healthcare providers, improving the chances of successful implementation.

The current research aims to evaluate the feasibility of home monitoring of sUA using a digital uric acid meter and a nurse-led T2T approach in secondary care.

**Study objective**

This research aims to examine the feasibility of home monitoring of serum uric acid for both patients and stakeholders, using a digital home measuring device in conjunction with a nurse-led T2T approach.

Primary research question:
What is the feasibility of home monitoring of sUA and nurse-led care for both patients and stakeholders in secondary care?

Secondary research questions:
a) How often do patients achieve the sUA goal after 24 weeks?
b) What is the average dose of uric acid-lowering therapy after 24 weeks?
c) How many attacks do patients experience on average after 24 weeks?
d) What is the adherence to the intervention after 24 weeks?
e) What is the average healthcare utilization after 24 weeks?
f) How does patient activation change before and after the intervention (24 weeks)?

g) How does health-related quality of life change before and after the intervention (24 weeks)?
h) How do beliefs about ULT medication change before and after the intervention (24 weeks)?

## Study design

A prospective descriptive study will be conducted at the Sint Maartenskliniek in Nijmegen to evaluate the feasibility of home monitoring of sUA in combination with a nurse-led T2T approach. We will use Bowen's feasibility framework to guide data collection in this study, as we aim to assess multiple feasibility focus areas. The included areas are acceptance, demand, implementation, integration, practicality, and limited effectiveness (Table 2 in the protocol).

We will have two types of participants: (1) patients (n = 30) and (2) stakeholders (n ~ 7). Included patients will receive instructions to use a digital uric acid meter for home monitoring of serum urate and digitally communicate values through a questionnaire sent every 4 weeks. This questionnaire will also collect data on side effects, attacks, and any questions or comments. The specialized nurse will coordinate care, provide explanations and instructions on home monitoring, advise patients on medication dosage and lifestyle, and may decide to refer patients to other healthcare providers (e.g., rheumatologist). Additional questionnaires will be sent to assess feasibility and secondary outcomes at baseline, 12 weeks, and 24 weeks. A review of medical records will provide insight into clinical results and patient characteristics during the research period. All participants are part of the intervention group, and the experiences of patients and stakeholders with the intervention are the primary outcome of the study. Therefore, no control group is included in this study. Finally, stakeholders, including healthcare providers (HCPs) and management personnel involved in the use and implementation of sUA home monitoring, will be invited to participate in interviews. Healthcare providers will be asked to keep a diary in which they report obstacles/problems they encounter or any other comments.

## Intervention

Intervention for Patient Participants:

An overview of the intervention and procedures can be seen in Table 1 of the protocol. Patients wishing to participate (see section 12.2 for the consent procedure) are instructed on the use of the digital meter, which reads the uric acid level through a small finger prick, and the remote communication of the measured values. When obtaining informed consent, patients are asked whether they prefer personal instruction (Face-to-Face, (F2F)) for using the device, or if the instructional manual and a digital video would be sufficient. In the

latter case, the device is sent by mail. Information is digitally sent, including written and video instructions explaining self-measurement, information about home monitoring of sUA and its objectives, contact details of healthcare providers, and a troubleshooting page in case of issues during self-measurement. If a patient wishes to receive personal instructions, an instruction session with a medical assistant is scheduled before the first home measurement.

Patients are instructed to measure their sUA levels at home every four weeks using the digital uric acid meter and digitally communicate their measured value, any (health) issues, symptoms, potential side effects, questions, and comments in a questionnaire that is sent every 4 weeks. The same 4-weekly questionnaire digitally obtains information about gout attacks. Reminders are automatically sent twice after 3 and 7 days if a patient does not communicate their value within 3 days of the intended measurement date. Additionally, patients can present more urgent medical questions or issues to the specialized nurse via email contact or by calling the usual phone number.

Medication Treatment Strategy:
The local protocol will be followed, with allopurinol as the first drug of choice. In case of toxicity or treatment failure, uric acid-lowering therapy will be switched to benzbromarone or febuxostat according to the local protocol. There are no differences in the medication treatment strategy compared to usual care.

Monitoring Medication Toxicity:
Regular laboratory tests, including sUA, complete blood count, creatinine, and ALT (alanine transaminase), are performed every 4-6 weeks through venous puncture in usual care. In this study, regular laboratory tests are conducted in week 8 and at the end of the study (week 24) to monitor the toxicity of uric acid-lowering therapy. If deemed necessary by the treating physician, toxicity tests will be conducted more frequently, for example, in patients at higher risk for medication toxicity, such as those with reduced kidney function, i.e., CKD-EPI between 0.45 and 0.90 ml/min/1.73m$^2$. Lab tests are reviewed by the study rheumatologist (MF), and the advice is communicated to the patient by a specialized nurse. In case of suspected acute toxicity and the need for acute changes in the medication regimen, the study physician will directly contact the patient.

All provided care will follow the recommended treat-to-target approach for gout. Completed values, questions, and other parts of the 4-weekly questionnaire are reviewed by specialized nurses every Tuesday and Friday. At these times, emails are also answered by specialized nurses. For very urgent questions, such as experiencing a gout attack, patients are advised to call the hospital, as in usual care. In case of questions, the nurse (possibly in collaboration with the rheumatologist) will take appropriate actions, as applicable in usual care. After 24 weeks, the study ends, and the final

measurements are conducted. The intervention places more emphasis on scheduling the first (lengthy) consultation with a specialized nurse within 8 weeks of starting ULT. Consultations with specialized nurses will occur more frequently than in usual care, namely at 5 weeks, with the possibility of healthcare provider and patient initiated contact outside these moments. During the intervention, patients do not have standard appointments with a rheumatologist, unlike in usual care. Therefore, patients in this intervention will have approximately 2 fewer consultations with a rheumatologist than in usual care.

Intervention for Stakeholders:

In this study, the specialized nurse coordinates care and treatment, advises patients on medication dosage and lifestyle, and refers to other healthcare providers (medical assistant (for finger prick instructions) or the rheumatologist if necessary).

**Study burden and risks**

Patient subjects will be asked to record their sUA at home every four weeks using a fingerpick device for 24 weeks. While the intervention is invasive, the burden on patient subjects is considered low. Compared to usual care, subjects will experience a finger prick seven times in total, resulting in approx. 2-3 less lab visits and venapunctures compared to usual care. The intervention is expected to lead to improved adherence to ULT medication and thereby reduced sUA levels and improved clinical outcomes. Additionally, fewer face-to-face visits, less rheumatologist contact and lab tests are expected which will reduce patient burden, travel time and costs. Patients have more frequent and easily accessible contact with the specialized nurse. Patients have more frequent and easily accessible contact with the rheumatology nurse.Small risks that might be associated with participation in this study are 1) burden of the finger prick 2. responsibility to perform POCT at home, 3. Less therapy adherence due to additional patient responsibility. However for the latter, patients that consistently do not comply will be referred back to usual care. Additionally, subjects have to fill in questionnaires at baseline (30 min.), 12 weeks (20 min.) and 24 weeks (40 min). No extra visits will be planned for this study.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (16-17 years)
Adults (18-64 years)

## Inclusion criteria

Patients:
In order to be eligible to participate in this study, a patient subject must meet all of the following criteria:
• Have a clinical diagnosis of gout
• Are older than 16 years of age
• Not at sUA target of 0.36 mmol/L (or 0.30 for tophaceous gout, chronic arthropathy and frequent attacks), based on lab results not older than 6 weeks.
• Starting ULT (allopurinol, benzbromarone, febuxostat, probenecid or pegloticase) or using ULT but not at sUA target
• Able and willing to sign informed consent
• Possession of a digital device (e.g. smartphone, laptop, tablet), email address and in-ternet connection
• Willing to use a POCT at home
• Sufficient understanding of the Dutch language

Stakeholders:
In order to be eligible for the stakeholder interviews, a stakeholder must have been involved in involved in carrying out, or managing the current study.

### Exclusion criteria

Patients who have contra indications for using urate-lowering therapry (ULT) and not being able to measure sUA at home. Patients with mild kidney disease (CKD-EPI between 0.45 and 0.90 ml/min/1.73m2) can be included but patients with severe kidney disease (CKD-EPI < 0.45 ml/min/1.73m2) or severe liver function problems (i.e. ALAT 3 times higher than normal range, liver cirrhosis etc.) will be excluded.

## Study design

### Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Health services research |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 16-05-2024 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Wellion LUNA Trio |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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| Date: | 10-04-2024 |
| 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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL86160.091.24 |