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Original article

Management of patients with rheumatoid arthritis by telemedicine: connected monitoring. A randomized controlled trial



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ABSTRACT

Objectives: Rheumatoid arthritis (RA) is a prevalent and disabling disease that is the source of significant direct and indirect costs. The current recommended therapeutic strategy is based on the rapid introduction of therapy with conventional Disease-Modifying Anti-Rheumatic Drugs (DMARDs) combined with regular disease monitoring by the rheumatologist. The onerous nature of such intense monitoring has motivated the development of new, less demanding strategies such as telemedicine. This study aimed to estimate the cost-effectiveness of the connected monitoring of RA patients initiating a new DMARD therapy versus conventional monitoring.

Methods: An economic evaluation based on a randomized controlled trial of 89 patients was conducted. The patients in the intervention group ($n=45$) were monitored using a connected monitoring interface on a smartphone, while patients in the control group ($n=44$) were conventionally monitored. Health outcomes were measured as the gain in quality-adjusted life-years (QALYs), assessed using the EuroQol-5D questionnaire. Resource use and health outcomes were collected alongside the trial and at the six-month follow-up using application data and the related clinical case manager time, visits, hospitalisations, and transport records. These outcomes were valued using externally collected data on unit costs and QALY weights.

Results: Compared to conventionally monitored patients, patients receiving connected monitoring had a slightly greater but not significant gain in the average QALY of 0.07. The economic analysis found that connected monitoring resulted in a significant cost reduction of 72€ (2927€ vs. 2999€, $P<0.01$). The incremental cost-utility ratio of the intervention was equal to $-1,029$ € per QALY (95% CI: $-32,033$; $+24,625$) with a 97.8% chance of being cost-effective at a threshold of 30,000€ per QALY gained.

Conclusion: Implementing EULAR recommendations for RA patients initiating a DMARD treatment using connected monitoring is more efficient and less expensive than conventional care.

Clinical trial registration number: ClinicalTrials.gov (NCT03005925).

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1. Introduction

In recent years, rheumatoid arthritis (RA) prevalence has been estimated at between 0.3% and 1.3% worldwide [1]. RA adversely affects the quality of life (QoL) and causes disability due to joint damage. RA has become an economic burden on society due to

the direct and indirect costs of the disease. A recent review estimates worldwide annual direct costs of patients with RA ranged from US\$401 to US\$67,306, and annual indirect costs ranged from US\$595 to US\$22,444 [2]. In France, the annual cost for RA is between 5.7 to 7.1 billion euros and continues to grow with the addition of biotherapy [3–5]. Indeed, the European League against Rheumatic diseases (EULAR) emphasizes that individual, social, and medical costs be considered when choosing to initiate new treatments [6].

The treat-to-target (T2T) strategy for RA, with guidelines developed by both the American College of Rheumatology (ACR) and

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the EULAR designed to avoid the appearance of joint destruction and improve the quality of life of patients, is based on the rapid introduction of therapy with conventional Disease-Modifying Anti-Rheumatic Drugs (DMARDs) combined with regular disease monitoring by the rheumatologist every 1–3 months in patients with active disease to achieve sustained remission or maintain low disease activity [7]. Such relatively intense monitoring is onerous to many patients, requiring frequent travel to consultations that can impact physical, mental, and social (including economic) well-being. Indeed, in industrialized countries there is an incongruity between recommendations for care and the capacity of the health system to meet these guidelines stemming from a general lack of patient access to rheumatologists and an irregular distribution of medical services, particularly in rural areas [8,9]. Consequently, alternatives to conventional prescheduled outpatient follow-ups, such as telemedicine, could potentially support RA self-management and strengthen the implementation of the EULAR recommendations [10].

Nowadays, telemedicine is recognized as a tool to assist patient management and optimize the monitoring and adaptation of treatment [11]. Telemedicine is also attractive from a financial point of view as it reduces hospital visits, travel time, and related stresses [8]. A few studies have analysed the effectiveness of telemedicine follow-up in RA [12,13]. Digital health technologies, including electronic health records, virtual visits, mobile health, wearable technology, digital therapeutics, artificial intelligence, and machine learning, have the potential to improve the quality of RA care. These technologies will undoubtedly enable new clinical practice models [10]. Currently, the presence of the health professional is essential for objective and relevant monitoring of RA disease activity (e.g., establishing DAS28 scores). However, it is often difficult in the routine care of many patients to follow T2T recommendations due to the insufficient availability of health professionals. Thus, telemedicine may provide another practical benefit of facilitating close patient follow-up through smartphone or online self-assessment devices [14].

We previously evaluated patient satisfaction with a monitoring interface connected to a smartphone (SATIE-PR) application over six months following the initiation of DMARD therapy in RA patients with high to moderate disease activity [15]. This study highlighted the benefits of telemedicine in managing RA patients, resulting in a decreased number of physical visits while continuing to control disease activity. In addition, the QoL (SF-12 score) of patients who received connected monitoring improved compared to conventionally monitored patients. In the present study, we aimed to estimate the medico-economic results of the connected monitoring and assess the model's cost-effectiveness compared to conventional monitoring.

2. Methods

2.1. Study design and participants

The economic evaluation was conducted alongside a two-arm randomized, pragmatic, controlled, prospective, monocentric, and open-label clinical trial in the rheumatology department, Montpellier university hospital, France. The protocol has been published elsewhere [15]. Patients were included if they fulfilled the following criteria:

- RA according to the 2010 ACR/EULAR classification;
- aged between 18 and 75 years;
- indication to initiate DMARD therapy with a moderate/high disease activity (DAS28 > 3.2);

- agreed with the concept of using a connected monitoring interface;
- willingness to participate in this study and provide informed consent.

Patients were not included if they had an insufficient level of understanding to perform the measurements and self-questionnaires on a smartphone correctly, lacked an internet connection to transfer data, or if they were pregnant, protected by law, or included in another interventional study.

Equal numbers of patients were randomly allocated to receive either connected monitoring via the “SATIE-PR” application on a Smartphone or conventional monitoring (“control”).

2.2. Interventions

Each patient was trained to use the “SATIE-PR” application installed on a dedicated smartphone in the connected monitoring arm. All data were sent remotely to the investigative team composed of several academic or private-practice rheumatologists and one clinical case manager (CCM). Each week, patients completed and electronically returned responses to self-questionnaires evaluating disease activity (RAPID-3, auto-DAS 28), general condition, and quality of life. The patient could address questions directly to the CCM via the app or by phone for technical issues. In addition, the CCM was automatically notified if the data fill rate was less than 75% from weeks eight to ten or upon a report of high disease activity (RAPID-3 score greater than 12/30 at two successive online assessments). In such cases, the CCM would call to schedule a 3-month physical visit and/or inform the attending rheumatologist, who would determine whether a physical or a phone-call visit was required.

Patients in both groups received an on-site physical visit at the beginning and the end of the study. In addition, all patients could directly access the CCM by phone or physical visit if needed. Finally, in case of emergency, patients, general practitioners, or the rheumatologist could request a physical visit with the rheumatologist at any time by contacting the CCM.

This trial was approved by the French ethics committee (CPP Sud-Méditerranée IV-2016-A01373-48) and by the national competent authority (*Agence Nationale de Sécurité du Médicament et des produits de santé*). The study was registered on ClinicalTrials.gov (NCT03005925). Written consent was obtained from each subject before enrolment.

2.3. Costs

The estimated direct medical costs considered all inpatient and outpatient hospital services (including in-person and phone-based visits), the use of the application and the related CCM time, and transportation to and from the hospital during the six months of the study. Costs were assessed from a societal perspective, were not discounted, and were expressed in euros.

2.4. Hospital services

Outpatient in-person and phone-based visits were retrieved from the study case report form (CRF). Inpatient admissions were retrieved from the CRF and checked for consistency against the local hospital inpatient database PMSI (*Programme de Médicalisation des Systèmes d'Information*) of Montpellier university hospital. In-person visits were valued using the 2020 tariff. Since phone-based visits are not reimbursed in the French system, they were valued using the actual average duration measured during the study (i.e., 20 minutes) and the gross salary of the CCM in charge of these visits (1514€ per month). Thus, the unit cost of a phone-based

visit amounted to 3.30€. Inpatient admissions were valued using the national reference production costs according to the French classification of Diagnosis Related Groups (DRGs).

2.5. Application

In the intervention arm, we calculated three separate costs of the SATIE smartphone app: the application per se, the initial training at inclusion provided by the CCM, and the support and coordination provided during the study by the same clinical CCM. The vendor set the cost of the application. It included the fixed costs of hardware (€1400 for 24 months) and software and licensing (€8000 per hospital for 24 months), and the variable costs of data housing and maintenance per patient (€50 per month) and system maintenance and administration (€500 per hospital per month). Considering the number of patients and the participation time of each patient during the period of the study, the average cost of the application per se amounted to €888 per patient. To estimate the cost of training, we multiplied the training duration (45 minutes per patient) by the gross salary of the CCM to come to the value of €7.50 per patient. Lastly, the time spent in support and coordination of the application was determined (81 hours, or 1.8 h per patient) and multiplied by the gross salary of the CCM, which came to a cost of €19.30 per patient.

2.6. Transportation

Travel costs were estimated using the e-CRF. For each patient, we used Google Maps to determine the distance traveled between their home and Montpellier university hospital and the resulting costs associated with various modes of transport (non-medicalized ambulance, taxi, public transportation, and personal vehicle). Transportation costs were valued using the 2020 tariff of each mode of transportation.

2.7. Preference-based outcomes

Quality-Adjusted Life-Years (QALYs) were assessed using the EQ-5D questionnaire, administered at each physical visit in both groups, namely at months 0 and 6. Utility scores were calculated using values from the EQ-5D-3L questionnaire by the crosswalk method for each health condition [16,17]. Utility scores were relative to the reference value set for the general French population [18], and individual QALYs were calculated using a multiple linear regression method [19]. This method generates estimates of differential mean QALYs while controlling for potential differences in baseline mean utility between groups.

2.8. Economic analysis

The economic analysis was performed according to French and international reporting guidelines [20]. Given the importance of quality of life in RA patients, we conducted the cost-utility analysis over a 6-month time horizon. The study focused on the comprehensiveness of patient follow-up, and the amount and costs of care for patients in the two groups ($n = 89$), during the study period.

The qualitative variables are described using frequencies and percentages of each category. The mean, standard deviation, median and range, and extreme values by distribution are reported for quantitative variables. The two groups were compared using either a Student's *t*-test or Wilcoxon test for continuous variables and the chi-square or Fisher's exact test for qualitative variables. The alpha risk was set at 5% for all tests. The cost-utility analysis was carried out according to international recommendations for medical and economic evaluations of health interventions. The EQ-5D health-state questionnaires were retrieved from the patients.

The incremental cost and QALY were used to estimate the incremental cost-utility ratio (ICUR). The ICUR is the ratio between the difference in mean cost (cost with connected monitoring – cost without connected monitoring) and the difference in mean QALYs (QALYs with connected monitoring – QALYs without connected monitoring). The 95% confidence intervals were estimated using non-parametric bootstrapping [21]. Cost-utility planes and acceptability curves were drawn. Cost-utility planes plot between-group differences in costs and QALYs, with QALYs plotted on the x-axis and costs on the y-axis. The control group (i.e., without connected monitoring) is plotted at the origin. Acceptability curves were used to estimate the probability that the intervention is cost-effective considering various willingness-to-pay threshold values [22]. The statistical analysis was performed at the department of medical information of the CHU de Montpellier using SAS EG v7.1 software (SAS Institute). Costs are presented in euros (€).

2.9. Role of the funding source

The funders had no involvement in the writing of the manuscript or the decision to submit it for publication. The funders had no role in the study design, data collection, data analysis, or data interpretation. The corresponding author had full access to all of the study data and had final responsibility for the decision to publish the findings.

3. Results

3.1. Study population

A total of 89 patients was enrolled in this study. Of these, 45 participants were randomized to the connected monitoring arm and 44 to the conventional monitoring arm. Baseline patient characteristics are summarized in Table 1. No differences were found between the two groups.

3.2. Resource use

Patients assigned to connected monitoring had significantly fewer in-person visits (2.4 vs. 3.9, $P < 0.01$), and more phone visits

Table 1
Descriptive baseline characteristics in both group.

Demographics/characteristics	Conventional monitoring ($n = 44$)	Connected monitoring ($n = 45$)
Age (years)	55.5 (12.9)	55.9 (11.8)
Female, n (%)	34 (77.3%)	33 (73.3%)
Disease duration, median (IQR) years	6 (2.0; 21.0)	6 (1.0; 18.0)
Concomitant initiated therapy		
Steroids, n (%)	18 (40.9)	17 (37.8)
csDMARDs, n (%)	31 (70.4)	31 (68.9)
bDMARDs or tsDMARDs, n (%)	32 (72.7)	30 (66.7)
DAS28 score, mean \pm SD	4.4 \pm 0.8	4.5 \pm 0.8
RAPID-3 score/30, mean \pm SD	10.8 \pm 5.6	10.1 \pm 4.7
EQ-5D-5L, mean \pm SD	0.5 \pm 0.2	0.5 \pm 0.2
Distance from home to hospital, mean \pm SD, km	87.5 (79.9)	119.4 (126.5)

n: number; IQR: interquartile range; SD: standard deviation; csDMARDs: conventional synthetic disease modifying anti-rheumatic drugs; bDMARDs: biologic DMARDs; tsDMARDs: targeted synthetic DMARDs; DAS28: disease activity score in 28 joints; RAPID-3: routine assessment of patient index data 3. No statistically significant differences between groups were found.

Table 2
Healthcare resource use over 6-months.

Resource use	Conventional monitoring (n = 44)	Connected monitoring (n = 45)
In-person visits	3.9 (0.6)	2.4 (0.6)*
Phone visits	0.4 (1.2)	2.7 (2.6)*
Total visits	4.3 (1.3)	5.1 (2.7)
Hospitalisations	2.3 (3.0)	1.3 (1.4)
Length of stay (days)	3.6 (8.9)	1.6 (2.6)
Total travel distance (km)	698 (667)	563 (566)

All results are represented with means and standard deviation (S.D)

* $P < 0.01$.

Table 3
Cost over 6-months (euros) per patient.

Costs elements (€)	Conventional monitoring (n = 44)	Connected monitoring (n = 45)
In-person visits	98.3 (13.6)	60.6 (14.6)**
Phone visits	1.4 (3.9)	8.9 (8.6)**
Total visits	99.7 (14.5)	69.4 (17.6)**
Hospitalisations	2464.6 (4371.7)	1606.8 (1993.9)
SATIE smartphone app.	0 (0)	888.1 (67.9)**
SATIE CCM (Inclusion)	0 (0)	7.5 (0)**
SATIE CCM (Coordination)	0 (0)	19.3 (0)**
Total SATIE	0 (0)	914.9 (67.9)**
Transport	435.5 (440.3)	336.5 (307.9)
Total	2999.7 (4375.3)	2927.7 (2107.8)*

All results are represented with means and standard deviation (S.D). CCM: clinical case manager.

* $P < 0.01$.

** $P < 0.001$.

(2.7 vs. 0.4, $P < 0.01$) (Table 2). In addition, they travelled an average of 563 km to seek care during the study period, compared to 698 km in the conventional group.

3.3. Costs

On average, patients in the connected monitoring group experienced significantly lower costs of hospital visits (69.4€ vs. 99.7€, $P < 0.01$) and nonsignificant reductions in transportation costs (336.5€ vs. 435.5€) and inpatient admissions (1,606.8€ vs. 2,464.6€). Lastly, the 914.9€ cost of the SATIE PR application was restricted to patients in the connected monitoring group (Table 3). Thus, overall costs were significantly lower in the connected monitoring group (2927.7€ vs. 2999.7€, $P < 0.01$).

3.4. Health outcomes

Mean EQ-5D scores increased throughout the 6-month study period in both the conventional and connected monitoring arms, indicating that improvement in health status was unaffected by the type of monitoring. QALYs derived from the EQ-5D scores were not significantly different between the connected and the conventional monitoring groups (Table 4).

Table 4
Cost-utility analysis.

	Conventional monitoring (n = 44)	Connected monitoring (n = 45)
Costs,€	2999.7 (4375.3)	2927.7 (2107.8)*
QALYs	0.56 (0.39)	0.63 (0.35)

QALY: quality adjusted life year.

* $P < 0.01$.

3.5. Cost-utility

The SATIE-PR intervention was associated with a significant reduction in the average cost of monitoring of 72€ and a non-significant increase in the average QALY of 0.07. The estimated incremental cost-utility ratio was $-1,029€$ per QALY (95% CI: $-32,033$; $+24,625$) (Fig. 1). At a willingness to pay threshold of $€30,000$ per QALY, the probability of the SATIE-PR intervention being cost-effective was 97.8% (Fig. 2) [23].

4. Discussion

To our knowledge, this is the first study supporting the cost-effectiveness of telemedicine monitoring in RA patients initiating DMARD therapy. Indeed, only a few studies have analysed the cost-effectiveness of telemedicine in rheumatic diseases, mainly in osteoarthritis [24–26]. It would appear that e-health interventions are cost-effective, but additional and more rigorous studies are needed [27,28]. Our study evaluated the cost-effectiveness of connected monitoring with the implementation of the EULAR recommendations and close follow-up of patients initiating DMARD therapy. We showed that the combination of an e-health digital approach, assisted by contact with the case manager, resulted in more efficient monitoring. By guiding patients using the remote interface, the CCM optimised the use of the medical device, evaluated its limits, and was on hand to relay communication with a specialist when necessary. Indeed, it is important to emphasize the role of the CCM in patient management in the connected monitoring arm. The CCM ensured that the questionnaires were filled out regularly and had a positive influence on communication and motivation.

In addition, our results show an increase in EQ-5D scores in both groups throughout the six-month monitoring period, with a slightly greater (although not significant) increase in the connected group. Over the six-month study, the number of visits in the conventional arm was on average 3.9 versus 2.4 in the connected arm. Two mandatory visits at baseline and six months were required for all patients. Thus, most patients in the conventional arm complied with the intermediate scheduled visits with their referent rheumatologist at visits at 1 and 3 months. In the connected arm, intermediate assessments were performed remotely or on request, which reduced the number of in-person visits. Such close monitoring of RA patients initiating DMARD therapy is standard practice in France and is in accordance with international recommendations. Reducing the number of visits in the conventional arm could conceivably reduce the overall medico-economic benefit of connected monitoring. With fewer visits in the conventional arm, we could expect a poorer control of RA disease activity, leading to a higher risk of hospitalization, which would increase costs and possibly impair patients outcomes, including quality of life.

The cost-utility analysis showed that connected monitoring is more efficient and less expensive than conventional monitoring. The cost-utility ratio was much lower than the reference value per QALY commonly accepted in high-income countries [29]. This corresponded to a highly cost-effective intervention where there appeared to be no trade-off involving the quality of care. Indeed, adopting connected monitoring of patients reduced costs with no change, or perhaps even a slight increase in patient well-being, increasing the likelihood of adopting the technology. For instance, at a cost-effectiveness threshold of $€30,000$ per QALY, the probability that connected monitoring with the SATIE PR application would be cost-effective is 97.8%. This result highlights the exceptional efficacy of our intervention, which allowed for a clear improvement in the health status of patients while reducing costs.

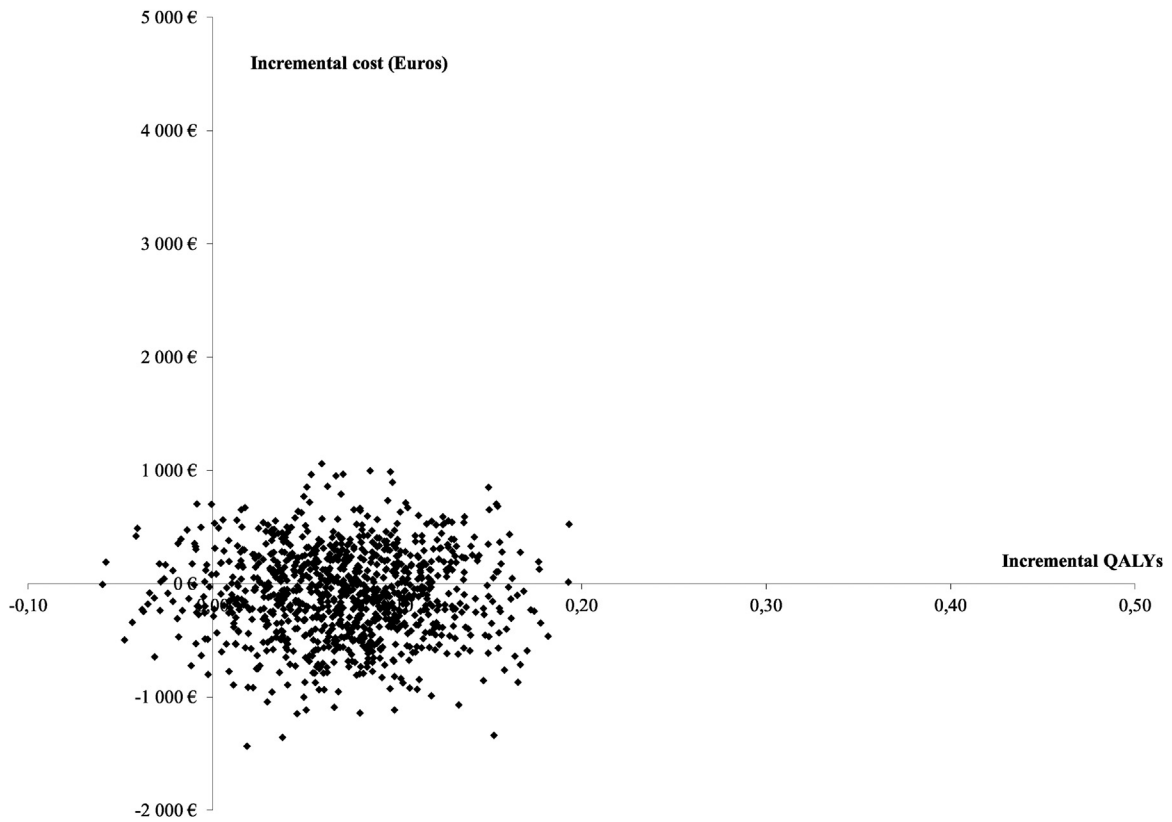


Fig. 1. Cost-effectiveness plane (conventional vs connected monitoring). Cost-effectiveness plane showing the iterations from the probabilistic sensitivity analysis. The y-axis represents the cost difference while the x axis represents the effectiveness difference between the connected and conventional group. Cost effective strategies are depicted with black points.

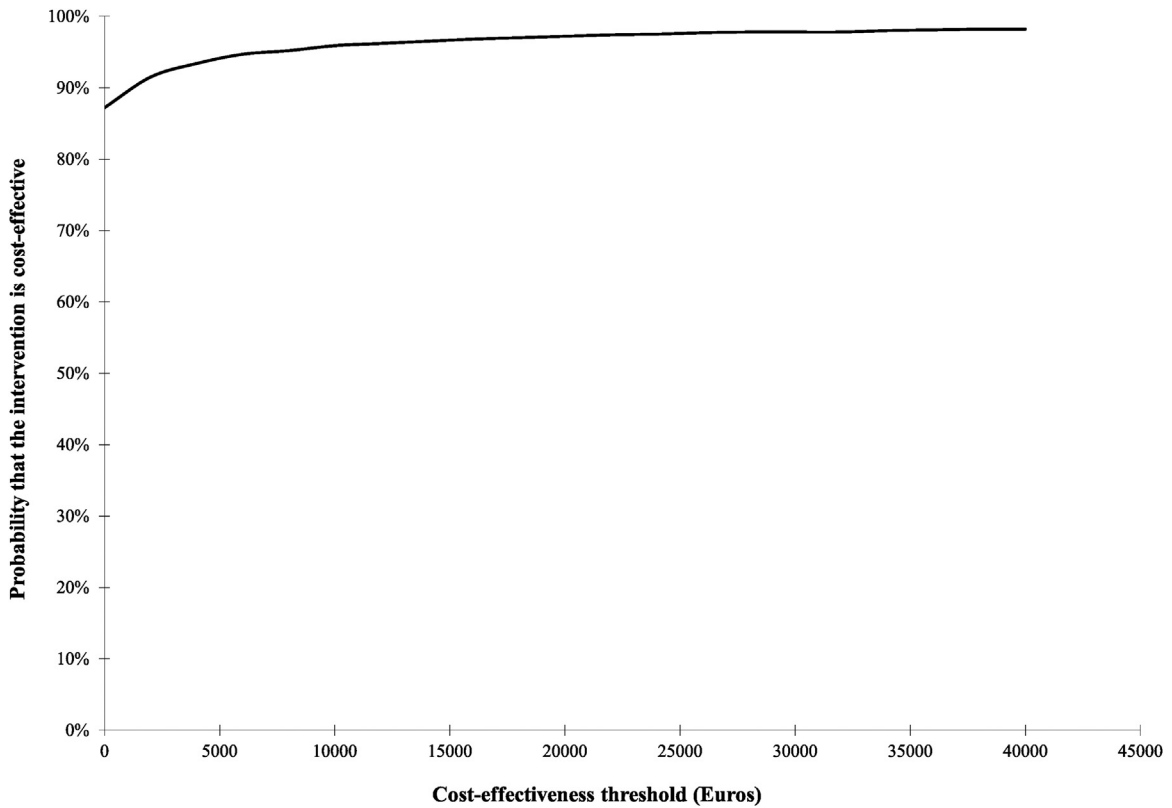


Fig. 2. Acceptability curve. Acceptability curve showing the probability that the connected monitoring is cost-effective compared to conventional monitoring for a range of cost-effectiveness thresholds.

Thus, as an option for digitally aware patients, connected monitoring could be a good recommendation. The use of digital technologies in healthcare may become increasingly important in the future practice of rheumatology. The explosion of telemedicine also brings new challenges for the organization of care and requires that rheumatologists learn how to use the technology to maximize patient benefit. The growth of telemedicine will also necessitate a major change in the doctor-patient relationship since an additional partner (a nurse, a professional trained in monitoring chronic diseases, etc.) will need to establish a new confidence-based relationship. Other “pragmatic” factors must also be considered, such as the legal framework, reimbursement conditions, and the hosting of medical data.

We must acknowledge some limitations in our study. A six-month follow-up period may be considered too short to address longer-term health and economic impacts. However, once treatment is established, and the disease is better controlled, it is reasonable to expect the benefits of remote monitoring to increase. Due to the magnitude of the fixed costs, the cost of the SATIE-PR application is highly dependent on the number of patients involved and on the duration of the study. These fixed costs are related to the development of the application, the secure housing of the medical data, the digital tablets, and the maintenance of the system. In this study, the cost per patient was quite high because the sample size was relatively small. Unit costs would be significantly lowered in future studies or with the implementation of SATIE-PR connected monitoring on a much larger group of patients. Another bias of this study is its monocentric design and a possible centre effect related to the involvement of the CCM in patient follow-up and system adherence. Thus, the evaluation of the SATIE PR application using a multi-centre approach would be relevant. The study's open-label design may also have influenced responses to health status assessments. Lastly, the fact that participants completed many questionnaires raises the issue of the Hawthorne effect. However, since the number of EQ-5D measurements is the same in both groups, the validity of the main outcome is unlikely to be threatened.

Altogether, the use of connected monitoring, following EULAR recommendations for RA patients with uncontrolled disease initiating a DMARD treatment, was highly cost-effective, resulting in similar health outcomes at a lower cost than conventional monitoring. Further studies are needed to confirm and implement these results.

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Author contributions

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Y-M. Pers and L. Bernard wrote the first draft of the manuscript, had full access to all of the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Pers, Jorgensen, Mura, Mercier.

Acquisition of data. Pers, Valsecchi, Jorgensen, Ferreira.

Analysis and interpretation of data. Bernard, Pers, Valsecchi, Mura, Mercier, Aounti, Pastor, Padern, Ferreira, Jorgensen.

Disclosure of interest

The authors declare that they have no competing interest.

Data sharing

All of the individual participant data collected during the trial, after de-identification might be made available upon request. Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code will be available. Data are accessible immediately following publication; at least for 15 years. Proposals should be directed to the promotor and principal investigator. For further information, contact the corresponding author.

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