

Regional collaboration to improve atrial fibrillation care

Citation for published version (APA):

Cremers, H. P., Hoorn, C., Theunissen, L., van der Voort, P., Polak, P., de Jong, S., van Veghel, D., & Dekker, L. R. C. (2019). Regional collaboration to improve atrial fibrillation care: preliminary data from the Netherlands heart network. *Journal of Arrhythmia*, 35(4), 604-611. <https://doi.org/10.1002/joa3.12197>

DOI:

[10.1002/joa3.12197](https://doi.org/10.1002/joa3.12197)

Document status and date:

Published: 01/06/2019

Document Version:

Publisher's PDF, also known as Version of Record (includes final page, issue and volume numbers)

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

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Regional collaboration to improve atrial fibrillation care: Preliminary data from the Netherlands heart network

Henricus-Paul Cremers PhD¹  | Cassandra Hoorn MSc² | Luc Theunissen MD³ |
Pepijn van der Voort MD² | Peter Polak MD⁴ | Sylvie de Jong MD⁵ |
Dennis van Veghel MSc¹ | Lukas Dekker PhD, MD^{2,6}

¹Netherlands Heart Network, Veldhoven, The Netherlands

²Catharina hospital, Eindhoven, The Netherlands

³Máxima Medical Center, Veldhoven, The Netherlands

⁴St. Anna hospital, Geldrop, The Netherlands

⁵Elkerliek hospital, Helmond, The Netherlands

⁶Department of Electrical Engineering, Technical University, Eindhoven, The Netherlands

Correspondence

Henricus-Paul Cremers, Netherlands Heart Network, Veldhoven, The Netherlands.
Email: paul.cremers@nederlandshartnetwerk.nl

Abstract

Background: Guideline non-adherence and variations in therapeutic and diagnostic trajectories result in suboptimal atrial fibrillation (AF) treatments. Large academic and referral hospitals demonstrated positive effects of dedicated outpatient AF clinics. Although similar results have not been indicated in (small) non-academic hospitals yet, ample opportunities are present when collaboration is initiated on a regional level. Therefore, this study assesses the effectiveness of outpatient AF clinics in a collaborative region in the Netherlands.

Methods: For this study baseline and 6 months follow-up data of a prospective cohort including newly or recently diagnosed AF-patients of 4 hospitals involved in the Netherlands Heart Network are used. From January'15 to March'16 patient relevant outcome measures (ie EHRA score, stroke, major bleedings, hospitalizations, serious adverse effects of medication, and mortality) are gathered. Descriptive and regression analyses are performed to assess the effectiveness of outpatient AF clinics.

Results: In the analyses 448 AF-patients were included. After 6 months, significant improvements regarding EHRA score ($P < 0.01$), hypertension ($P < 0.01$), and type of AF ($P < 0.01$) were indicated. Results of the patient relevant outcomes showed that AF-patients were hospitalized 23 times, no major bleedings and 2 strokes occurred. Furthermore, 0 AF-patients reported serious adverse effects of medication and no AF-patients deceased.

Conclusions: Collaboration between cardiologists in a regional setting permits further improvement of AF care. Therefore, such quality targets are not exclusively reserved to large academic or referral hospitals. Although promising, future research should put effort in measuring the effectiveness of the outpatient AF clinics also on the long run.

KEYWORDS

atrial fibrillation, nurse-led care, outpatient atrial fibrillation clinic, patient relevant outcomes, regional collaboration

1 | INTRODUCTION

Atrial fibrillation (AF) is the most frequently diagnosed arrhythmia,¹⁻⁴ affecting only in Europe over 6 million patients⁵ and leading to approximately 583 million Euros of the Dutch annual healthcare expenditure.⁶ Due to the aging population, the expectation is that both the number of AF-patients and healthcare costs will increase rapidly during the coming years,¹ if no further action is taken.

Optimal treatment with less cardiovascular events in AF care can be established when adherence to guidelines is increased,⁷⁻⁹ and variations in therapeutic and diagnostic trajectories are reduced. Prior research indicated that improved guideline adherence and providing extensive information to patients is an achievable target in cardiac care.⁹⁻¹¹ More specifically, an integrated approach for AF has shown to be an effective^{9,12} and cost-effective¹³ solution in the treatment of AF-patients by introducing “nurse-led care”. Compared to usual care, in nurse-led care specialized nurses perform activities to treat AF-patients using protocolled procedures supervised by a physician. Until now most nurse-led care is operationalized and assessed for effectiveness in large academic hospitals,¹⁴ assuming that this procedure is solely feasible in similar settings. However, opportunities for outpatient AF clinics in (small) non-academic hospitals may be created when collaboration is initiated on a regional level.

Regional collaboration in healthcare involves adapting similar procedures and activities between cooperating partners (ie cardiologists, nurses, and general practitioners (GPs)), increasing the potential of collective improvements of outcomes that are most relevant for patients. However, to establish collaboration between hospitals regarding specific cardiac conditions, patient care pathways need to be aligned. Subsequently, those patient care pathways should be implemented and evaluated for effectiveness by using similar parameters.

The aim of this study was to assess if the nurse-led care in a collaborative region of 4 non-academic hospitals in the Netherlands is effective in improving outcomes for AF-patients after 6 months of diagnosis. To assess the registration density of the nurse-led care, completeness of registrations was also evaluated as a quality measure of AF care.

2 | METHODS

2.1 | Population and design

Data for this study was gathered at baseline (T0) and 6 months follow-up (T6) of the prospective intervention group of the AF-NET study imbedded in the Netherlands Heart Network (NHN), between 1 January 2015 and 1 March 2016. In essence, the NHN is a regional, joint effort of all relevant healthcare providers in primary, secondary, and tertiary care (ie cardiologists, GPs, nurses, ambulance service, thrombosis service, home care organizations, pharmacists, and diagnostic centers) to improve the quality of care for cardiac patients by organizing the total healthcare chain in an

optimal way. To achieve this purpose 4 hospitals and 4 GP organizations collaborate in a densely populated area in the Netherlands (761,763 inhabitants in 2017¹⁵). The participating hospitals vary in size considerably, ranging from a 5 cardiologists' practice to a high-volume heart center.

Patients included in this study originated from the outpatient AF clinics of the 4 hospitals involved in the NHN. Patients were included in the study when they were ≥ 18 years, newly or recently diagnosed with atrial fibrillation, were competent to read and agree on the informed consent, and had provided written informed consent.

2.2 | AF-NET study

2.2.1 | Outpatient AF clinic

A regional care standard has been developed for AF-patients visiting the outpatient AF clinic. This standard includes a description of the care pathway, uniform definitions for AF, initial conditions, process and structural measures, aligned protocols to treat AF-patients, and patient relevant outcome measures. Using this regional care standard, the same procedures for AF-patients were applied in the 4 collaborating hospitals. Additionally, identical patient relevant outcome measures were registered at T0 and T6.

Within the outpatient AF clinic the AF-nurse performs the required registrations and provides education for the AF-patients during a consultation of approximately 45–60 minutes. During the consultation, the AF-nurse makes an inventory of complaints and the general health status of the patients. The education strategy includes information about AF and the treatment options, in order to make informed decisions concerning the treatment. Furthermore, the AF-nurse explains the relevance of treatment compliance and clarifies to the patients how the follow-up procedure will continue via the cardiologist. By using this procedure cardiologists receive more detailed information regarding the patients' conditions, supporting the decision-making process and the adherence to guidelines by medical specialists. The outline of the AF-NET study is shown by the flowchart in Figure 1. In prior research^{9,11} nurses made decisions regarding AF care themselves, leading to an essential different process than the AF-NET study.

2.2.2 | Procedure

Patients meeting the inclusion criteria visited an AF-nurse in any of the 4 hospitals. At the first visit the AF-nurse discussed the onset date of symptoms, type of symptoms, type of AF, medical history, and medication. Also, patient demographics, vital signs, stratification scores (ie EHRA, HAS-BLED, and CHA₂DS₂-VASc), physical exam, and ECG were noted. During the first visit the AF-NET study was explained and written informed consent of the AF-patient was obtained. All procedures at the outpatient AF clinic were supervised by a cardiologist.

AF-patients included in the AF-NET study consult the outpatient AF clinic at baseline and 6 months to evaluate the initiated treatment

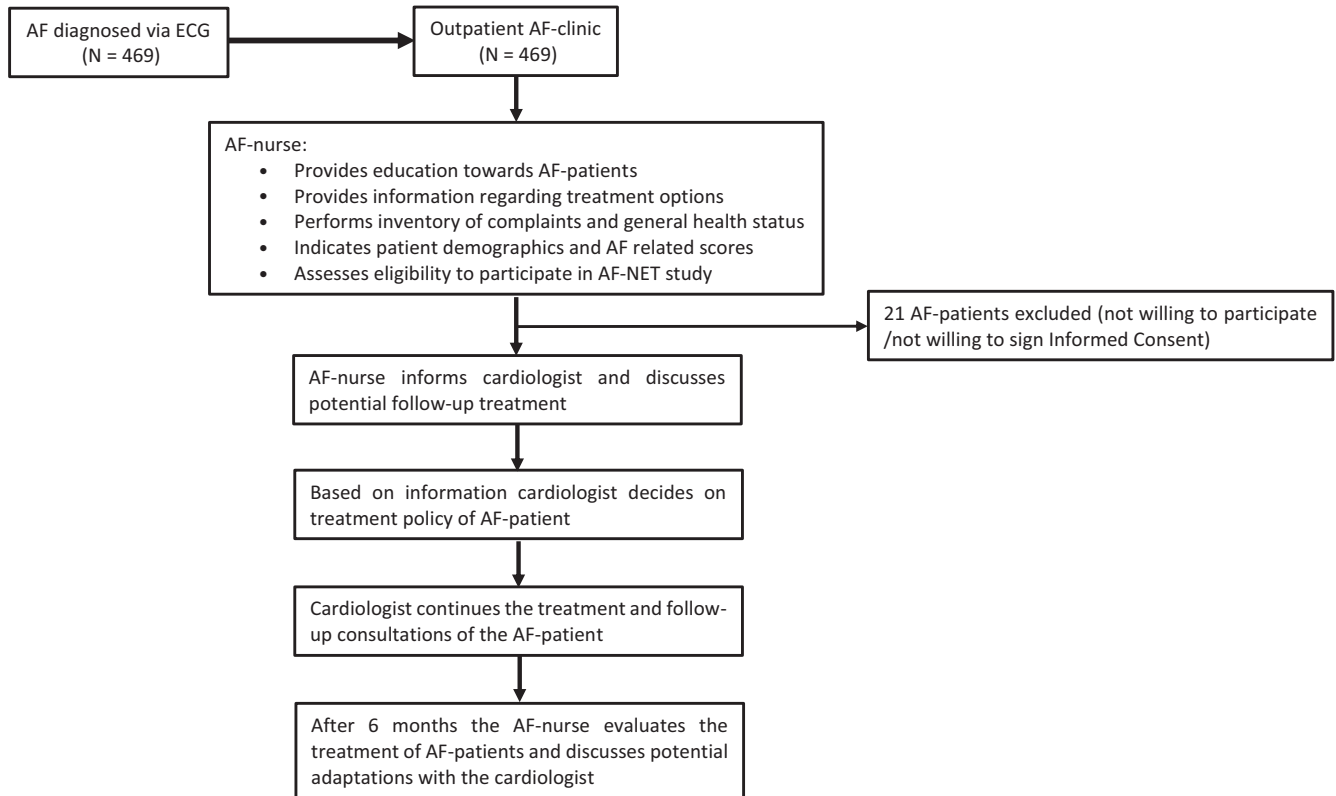


FIGURE 1 Flowchart of the AF-NET study

and the patient relevant outcome measures. During the consultations the AF-nurse registered the required data in the Medical Health Record (MHR).

2.2.3 | Ethical approval

The protocol of the AF-NET study was submitted for approval to the Medical research Ethics Committee United (MEC-U) in the Netherlands (reference number: 14.083). The MEC-U confirmed that the Medical Research Involving Human Subjects Act does not apply to the AF-NET study and that therefore an official approval of this study by the MEC-U is not required.

2.3 | Measurements

In this study the *patient relevant outcome measures*, *background variables*, and the *potential comorbidities* were assessed as the main measurements.

2.3.1 | Patient relevant outcome measures

The patient relevant outcome measures constitute the primary end-point of this study and are defined by Meetbaar Beter (<http://www.meetbaarbeter.com/>) (ie a Dutch organization that indicates, measures, and validates patient relevant outcome measures for cardiac patients). It includes EHRA score, stroke, major bleedings, hospitalization, adverse effects of medication, and cardiovascular death.

All patient relevant outcome measures are (at least) measured after 6 months of follow-up.

EHRA score

The EHRA score, indicated by a mean score, provides an indication of the AF related symptoms during an AF episode and is indicated by 1 = "EHRA I *No symptoms*"; 2 = "EHRA II *Mild symptoms, normal daily activities not affected*"; 3 = "EHRA III *Severe symptoms, normal daily activity affected*"; 4 = "EHRA IV *Disabling symptoms, normal daily activity discontinued*".¹⁷ Both at T0 and T6 the EHRA score is indicated by the AF-nurse.

Ischaemic stroke

The number of sudden thrombo-embolic events or focal deficits caused by focal cerebral, spinal, or retinal infarction registered in the MHR and validated by a neurologist based on computerized tomography or magnetic resonance imaging.¹⁸ The amount of ischaemic strokes of every AF-patient are measured between T0 and T6 and indicated by the AF-nurse.

Major bleedings

Percentage of patients that suffer a clinically overt bleeding associated with any of the following: fatal outcome, involvement of a critical anatomic site (intracranial, spinal, ocular, pericardial, articular, retroperitoneal, or intramuscular with compartment syndrome), fall in haemoglobin concentration >2 g/dL, transfusion of >2 units of whole blood or packed red blood cells during hospitalization, or

permanent disability. All bleedings are registered by the AF-nurse between T0 and T6 using the BARC-index,¹⁹ and were only indicated as major bleedings if the BARC-index corresponded to a score of 3a, 3b, 3c, 4, 5a, or 5b.

Cardiovascular hospitalization

Percentage of patients that require inpatient hospital admission for symptomatic AF, decompensation, heart failure, myocardial infarction or coronary artery disease, hypertension, ischaemic stroke, TIA, systemic embolism, major bleeding, heart valve disease, syncope, sustained VT, or life-threatening adverse effects of drugs. Cardiovascular hospitalization and the days of hospitalization are indicated by the AF-nurse between T0 and T6. In this study hospitalization is defined as unscheduled hospital admissions with an overnight stay.

Cardiovascular death

Percentage of patients that pass away due to any cardiovascular cause, such as symptomatic AF, decompensation, heart failure, myocardial infarction or coronary artery disease, hypertension, ischaemic stroke, TIA, systemic embolism, major bleeding, heart valve disease, syncope, sustained VT, or adverse effects of drugs. Cardiovascular death and the date of death are indicated by the AF-nurse between T0 and T6.

Serious adverse effects of medication

Percentage of patients that report serious adverse events due to rate or rhythm control medication, resulting in hospitalization with an overnight stay. The serious adverse effects of medication are registered by the AF-nurse between T0 and T6.

2.3.2 | Background variables

The background variables in this study include the *age* (in years), *gender* (1 = male; 2 = female), *Left Ventricular Ejection Fraction* (LVEF) (in %), *CHA₂DS₂-VASc* score to estimate the stroke risk (indicated by a mean score), *HAS-BLED* score to estimate major bleedings (indicated by a mean score), the *type of AF* (1 = first diagnosed AF; 2 = paroxysmal AF; 3 = persistent AF; 4 = permanent AF), *rate-control medication* (1 = Yes; 2 = No), and *rhythm-control medication* (1 = Yes; 2 = No). *Rate-control medication* involved all medication used to reduce the rapid ventricular heart rate in AF-patients, whereas *rhythm-control medication* includes all medication to convert AF episodes to normal sinus rhythm and/or to maintain normal sinus rhythm in AF-patients.

2.3.3 | Potential comorbidities

Potential comorbidities are measured by 1 = "Yes"; 2 = "No" and registered by the AF-nurse at T0 and T6 in the MHR. The potential comorbidities in this study are:

Hypertension is defined as systolic blood pressure ≥ 140 mm Hg and/or diastolic blood pressure ≥ 90 mm Hg measured during 2 or

more consecutive moments (during rest), and or current use of anti-hypertensive medication.²⁰

Coronary Artery Disease (CAD) is characterized as previous myocardial infarction (MI) (either ST-elevation MI or non-ST-elevation MI), percutaneous coronary or surgical coronary revascularization, or evidence of coronary atherosclerosis with the presence of a stenosis in at least 1 coronary artery. The stenosis should lead to a reduction in at least 50% diameter or a pressure drop (FFR) $< 80\%$.^{21,22}

Heart failure is characterized by typical symptoms (eg breathlessness, ankle swelling, and fatigue) that may be accompanied by signs (eg elevated jugular venous pressure, pulmonary crackles, and peripheral oedema) caused by a structural and/or functional cardiac abnormality, resulting in a reduced cardiac output and/or elevated intracardiac pressures at rest or during stress.²³

Peripheral Artery Disease (PAD) is indicated by the presence of 1 of the following: claudicatio intermittens, amputation due to arterial insufficiency, vascular reconstruction (bypass surgery or percutaneous intervention of extremities), or documented aortic aneurysm.

Diabetes Mellitus (DM) is characterized by recurring or persistent hyperglycaemia and is diagnosed by demonstrating sober plasma glucose level ≥ 7.0 mmol/L (≥ 126 mg/dL), or plasma glucose ≥ 11.1 mmol/L (≥ 200 mg/dL) after 2 hours of 75 g oral glucose, or symptoms of hyperglycaemia and a plasma glucose of ≥ 11.1 mmol/L (≥ 200 mg/dL), or glycosylated haemoglobin (HbA1c) $\geq 6.5\%$.^{24,25}

Severe renal dysfunction is characterized as chronic dialysis, renal transplantation, or a serum creatinine of ≥ 200 mmol/L.

Severe hepatic disease is characterized as a chronic liver disease, liver cirrhosis, or biochemical indicated liver dysfunction (ie bilirubin over twice the normal value).

2.3.4 | Completeness of registrations

Additionally the *completeness of registrations* (in %) of the patient relevant outcome measures, background variables, and potential comorbidities is indicated as a quality measure of the outpatient AF clinic at T0 and T6. For the patient relevant outcome measures at T0 only the EHRA score is used since the other variables are not measured at T0.

2.4 | Statistical analyses

To describe the study population general descriptive analyses were performed on the background variables and the potential comorbidities to indicate mean scores and percentages at T0. To assess whether the various types of AF differ regarding the background variables or potential comorbidities independent sample t-tests and chi-square tests were carried out. For the analyses the various types of AF were indicated separately as a reference group.

In addition, linear and logistic regression analyses were performed to assess potential differences between EHRA score, hypertension, and type of AF at T0 and T6. Age, gender, CHA₂DS₂-VASc, HAS-BLED, EHRA score at T0, hypertension at T0, and type of AF at T0 are included as potential confounders for these analyses. To

TABLE 1 Baseline characteristics

	Total (N = 448)	First diagnosed AF ^A (n = 104)	Paroxysmal AF ^B (n = 175)	Persistent AF ^C (n = 135)	Permanent AF ^D (n = 34)	Significant difference*
Age (years ± SD)	68.3 (±10.6)	67.3 (±12.1)	66.2 (±9.9)	69.7 (±9.7)	76.2 (±8.2)	D > A,B,C
Gender (% male)	56.7	51.9	49.1	68.1	64.7	C > A,B
LVEF (% ±SD)	59 (±11.0)	62 (±9.6)	62 (±9.7)	54 (±12.4)	57 (±8.5)	A,B > C/ B > D
CHA ₂ DS ₂ -VAsc-score (mean)	2.60	2.62	2.26	2.90	3.09	B < C,D
HAS-BLED (mean)	1.40	1.30	1.25	1.67	1.41	C > A,B
Hypertension (% yes)	55.4	54.8	53.1	61.5	44.1	N.S.
CAD (% yes)	9.4	12.5	5.7	11.1	11.8	B < A
Heart failure (% yes)	3.1	1.9	0.6	7.4	2.9	B < C
PAD (% yes)	5.6	1.9	6.3	8.2	2.9	C > A
DM (% yes)	13.6	16.3	8.0	14.8	29.4	B < A,D/ C < D
Severe renal dysfunction (% yes)	0.2	0.0	0.0	0.7	0.0	N.S.
Severe hepatic disease (% yes)	0.2	1.0	0.0	0.0	0.0	N.S.
Rate-control medication (% yes)	35.3	26.0	27.4	47.8	55.9	A,B < C,D
Rhythm-control medication (% yes)	39.5	45.6	48.6	33.6	0.0	D < A,C/ B > C,D

Abbreviations: SD, standard deviation; N.S., no significant differences.

*Significant difference if $P \leq 0.05$.

assess potential differences in type of AF at T0 and T6, persistent AF was indicated as the reference group. For the completeness of registrations, percentages were indicated on both background variables, potential comorbidities, and patient relevant outcome measures at T0 and T6. At T6 only data were used for AF-patients of which the type of AF was registered. All analyses were performed in SPSS 21.0 and differences were indicated to be significant if $P \leq 0.05$.

3 | RESULTS

3.1 | Basic characteristics

A total of 448 AF-patients met the inclusion criteria (95.5% of the complete sample) and were used in the analyses for this study, also indicated in the flowchart in Figure 1. At baseline (Table 1) the mean age of the patients visiting the outpatient AF clinic was 68.3 years and most patients were male (56.7%). At inclusion the mean CHA₂DS₂-VAsc-score of the AF-patients was 2.60 and the HAS-BLED-score was 1.40. In the AF-NET study hypertension is the most frequent co-morbidity (55.4%).

3.2 | Characteristics of AF-patients

The differences in characteristics among the AF types are also indicated in Table 1. Patients diagnosed with permanent AF (n = 34) were of higher age (mean age = 76.2 years), received rate-control medication more frequently (55.9%), and had DM more often (29.4%)

as compared to patients with other types of AF. Furthermore, paroxysmal AF-patients (n = 175) were male less frequently (49.1%), were diagnosed with CAD (5.7%), heart failure (0.6%), and DM (8.0%) less regularly. However, compared to other AF types, rhythm-control medication (48.6%) was most frequently prescribed to paroxysmal AF-patients.

3.3 | Patient relevant outcome measures after 6 months of follow-up

In Table 2 the data on EHRA score, hypertension, and type of AF are illustrated between T0 and T6, taking into account potential confounders. As indicated in the table the EHRA score at T0 (mean = 1.93) significantly decreased ($B = 0.17$; SEM = 0.04; $P < 0.01$) after 6 months of follow-up (mean = 1.36). At T0 the percentage of patients with hypertension was 55.4%, which declined significantly ($B = 7.71$; SEM = 0.96; $P < 0.01$) to 52.7% after 6 months of follow-up. At inclusion 30.1% of the AF-patients was diagnosed with persistent AF. The number of patients with persistent AF significantly decreased ($B = 2.93$; SEM = 0.40; $P < 0.01$) to 12.5% at T6.

Within 6 months AF-patients were hospitalized 23 times for cardiovascular causes (of which 5 hospitalizations for symptomatic AF), 2 strokes occurred, no major bleedings were reported, and no AF-patients died due to confirmed cardiovascular causes. Furthermore, no serious adverse effects of medication were reported between T0 and T6.

TABLE 2 Difference in EHRA score, hypertension, and type of AF (persistent) between T0 and T6

	B	SEM	P-value*
Age	<-0.01	<0.01	0.29
Gender	0.07	0.07	0.30
CHA ₂ DS ₂ -VAsC-score	0.02	0.03	0.57
HAS-BLED	-0.09	0.05	0.11
EHRA score (T0)	0.17	0.04	<0.01
Age	0.05	0.04	0.22
Gender	-0.29	0.65	0.65
CHA ₂ DS ₂ -VAsC-score	0.53	0.33	0.11
HAS-BLED	-0.99	0.65	0.13
Hypertension (T0)	7.71	0.96	<0.01
Age	<0.01	0.02	0.74
Gender	-0.06	0.37	0.88
CHA ₂ DS ₂ -VAsC-score	-0.04	0.17	0.80
HAS-BLED	-0.03	0.28	0.90
Type AF (persistent AF) (T0)	2.93	0.40	<0.01

Abbreviations: B, Unstandardized beta; SEM, standard error of the mean.

*Significant P-value (≤ 0.05) are presented in bold.

3.4 | Completeness of registrations after 6 months of follow-up

The completeness of registrations by the AF-nurses at T0 and T6 is presented in Table 3. At T0, the completeness ranged from 99.1% to 99.8%. At T6, a high percentage of data was registered ranging from 98.6% (patient relevant outcomes), 99.0% (potential comorbidities) to 99.8% (background variables). As indicated in Table 3, 33 AF-patients were lost to follow-up between T0 and T6 (ie unable to reach despite multiple attempts, referred to their GP without further planned contact with the AF-nurse, or withdrew their participation before T6).

4 | DISCUSSION

4.1 | Interpretation of findings

The primary aim of this study was to assess if the nurse-led care in a collaborative region of 4 non-academic hospitals of various sizes in the Netherlands is effective in improving patient relevant outcomes after 6 months of follow-up. Due to the joint development of the regional care standard for the outpatient AF clinic significant improvements were indicated in EHRA score, hypertension, and the percentage of persistent AF-patients. Furthermore, the completeness of registrations by the AF-nurses was high ranging from 98.6% to 99.8% at both T0 and T6.

The positive influence of the outpatient AF clinic, as presented in this study is comparable with prior research regarding outpatient AF clinics assessed in a clinical trial (academic) setting⁹ and in

TABLE 3 Percentages of completeness of registrations at T0 and T6

	T0 (N = 448)	T6 (N = 415)
Patient relevant outcome measures (%)	99.8%	98.6%
Background variables (%)	99.6%	99.8%
Potential comorbidities (%)	99.1%	99.0%

a real-world setting.¹¹ Although, these prior studies reported more hospitalizations (48⁹ and 50¹¹), more major bleedings (6⁹ and 5¹¹), higher mortality rates, and a higher number of serious adverse effects of medication, the difference in measurement periods should be taken into account. While the AF-NET study presented 6 months follow-up data, the results in the study of Hendriks et.al (2012) were indicated after 22 months and in the study of Qvist et.al (2016) after 14 months of follow-up. Hence it will be most interesting to compare the data regarding the outcome measures after 12 and 24 months of follow-up. However, the preliminary data of the AF-NET study indicate that the findings are in line with prior research which endorses the hypothesis that outpatient AF clinics in collaborating, smaller hospitals may be as effective as those in (larger) academic settings.

In regular care (ie patients periodically consulting a medical specialist) adherence to guidelines is known to be limited.^{7,9,16} Prior research⁷⁻⁹ reported that guideline adherence results in better outcomes for AF-patients. In this study, adherence to the prevailing guidelines is assessed by performing audits in the participating hospitals. Based on the audit results, it was concluded that the participating hospitals comply with the (inter)national AF guidelines. In addition, the effectiveness of the nurse-led care is assessed in which nurses follow protocolled procedures and inform cardiologists more in-depth regarding AF-patients' medical status. Besides a positive trend of the outcome measures, this study also reports a high registration density resulting in better decision-making support for medical specialist. Although this information is often absent in previous studies, it underscores the notion that outpatient AF clinics employed by AF-nurses is both an effective as well as an applicable setting in non-academic hospitals.

4.2 | Implication of findings

The findings of this study indicate that multiple non-academic, and smaller hospitals are able to develop outpatient AF clinics leading to improved patient outcomes when they collaborate in a regional setting. Important aspects for achieving this improvement is (i) close collaboration between general cardiologists and electrophysiologists to define state of the art (regional) care pathways, (ii) training of AF-nurses for adequate registration of relevant outcome measures and educating AF-patients, and (iii) intensive cooperation with regional GPs. It is advisable for other (small) non-academic hospitals to reinforce their collaboration with referral hospitals to share knowledge and experience, and initiate outpatient AF clinics to improve and secure the quality of AF care.

4.3 | Limitations

A limitation of this study is that only a prospective intervention group was analyzed. Therefore, the results should be interpreted as mere associations between T0 and T6 regarding the efficacy of the outpatient AF clinic. Although the results indicate a positive trend of the outpatient AF clinic as compared to an equivalent research in an academic setting,⁹ it should be taken into account that the regular AF care may have improved during the last years. Second, data concerning the patient relevant outcome measures are only measured at T6 in this study. Therefore, no conclusion can be drawn regarding significant improvements over longer time periods. Despite significant differences in follow-up periods, the procedure and positive influence of the outpatient AF clinic on AF-patients outcomes as demonstrated in this study are comparable with previous studies.^{9,11} Nevertheless, future research should put effort in analyzing the patient relevant outcomes at 12 and 24 months, or comparing follow-up data with similar retrospective data. A final limitation of this study may be that the renal function was measured with the serum creatinine level instead of the currently used eGFR. Since the eGFR was not available in the participating hospitals at the moment of inclusion, this measure was not indicated in this study. Even though the eGFR is the preferred indicator to assess renal dysfunction, the expectation is that this indicator has not affected the conclusions of the research under study.

5 | CONCLUSIONS

Based on the provisional findings presented in this study it can be concluded that the quality of AF care can be improved in smaller and non-academic hospitals when collaboration between hospitals is reinforced by uniform standards and intensive education of AF-patients. To continuously improve AF care collaboration with surrounding healthcare professionals (including referral hospitals and GPs) seems to provide a practicable approach by developing and implementing regional care standards for specific heart conditions.

ACKNOWLEDGEMENTS

The Netherlands Heart Network is supported by various medical industries (i.e. Medtronic, BMS Pfizer, Bayer, Boehringer Ingelheim, Daiichi-Sankyo, St. Jude Medical, and Stichting Vrienden van het Hart). However, the sponsors of the Netherlands Heart Network were not in any way involved in the AF-NET study or in analyzing and writing this manuscript.

CONFLICT OF INTEREST

Besides the funding of the medical industries, the authors declare there are no conflicts of interest.

ORCID

Henricus-Paul Cremers  <https://orcid.org/0000-0003-3059-296X>

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How to cite this article: Cremers H-P, Hoorn C, Theunissen L, et al. Regional collaboration to improve atrial fibrillation care: Preliminary data from the Netherlands heart network. *J Arrhythmia*. 2019;35:604–611. <https://doi.org/10.1002/joa3.12197>