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ORIGINAL RESEARCH

Effectiveness of the AF-EduCare and AF-EduApp approach to improve atrial fibrillation knowledge and risk factor awareness in patients with atrial fibrillation: a randomized controlled trial

Lieselotte Knaepen [1,2,3,4]*†, Lien Desteghe [1,2,3,4,5]†, Michiel Delesie [1,2,4], Rana Önder [3,4], Johan Vijgen [3,4], Paul Dendale [3,4], Joris Ector [6], and Hein Heidbuchel [1,2,3]

[1]Antwerp University Hospital, Cardiology Center, Drie Eikenstraat 655, Edegem 2650, Belgium; [2]Research Group Cardiovascular Diseases, University of Antwerp, Prinsstraat 13, Antwerp 2000, Belgium; [3]Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, Hasselt 3500, Belgium; [4]Heart Center Hasselt, Jessa Hospital, Stadsomvaart 11, Hasselt 3500, Belgium; [5]Centre for Research and Innovation in Care (CRIC), Department of Nursing and Midwifery Sciences, University of Antwerp, Prinsstraat 13, Antwerp 2000, Belgium; and [6]Department of Cardiology, University Hospitals Leuven, Herestraat 49, 3001 Leuven, Belgium

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Aims Developing an integrated care pathway for atrial fibrillation (AF) patients is of pivotal importance, given the different treatment strategies. Moreover, knowledge about the condition is an important factor in engaging patients in their care. Patient education formed the core of the integrated AF-EduCare/AF-EduApp approach. The main aim of this manuscript is to report the impact of this approach on AF and risk factor (RF)–related knowledge and self-care awareness.

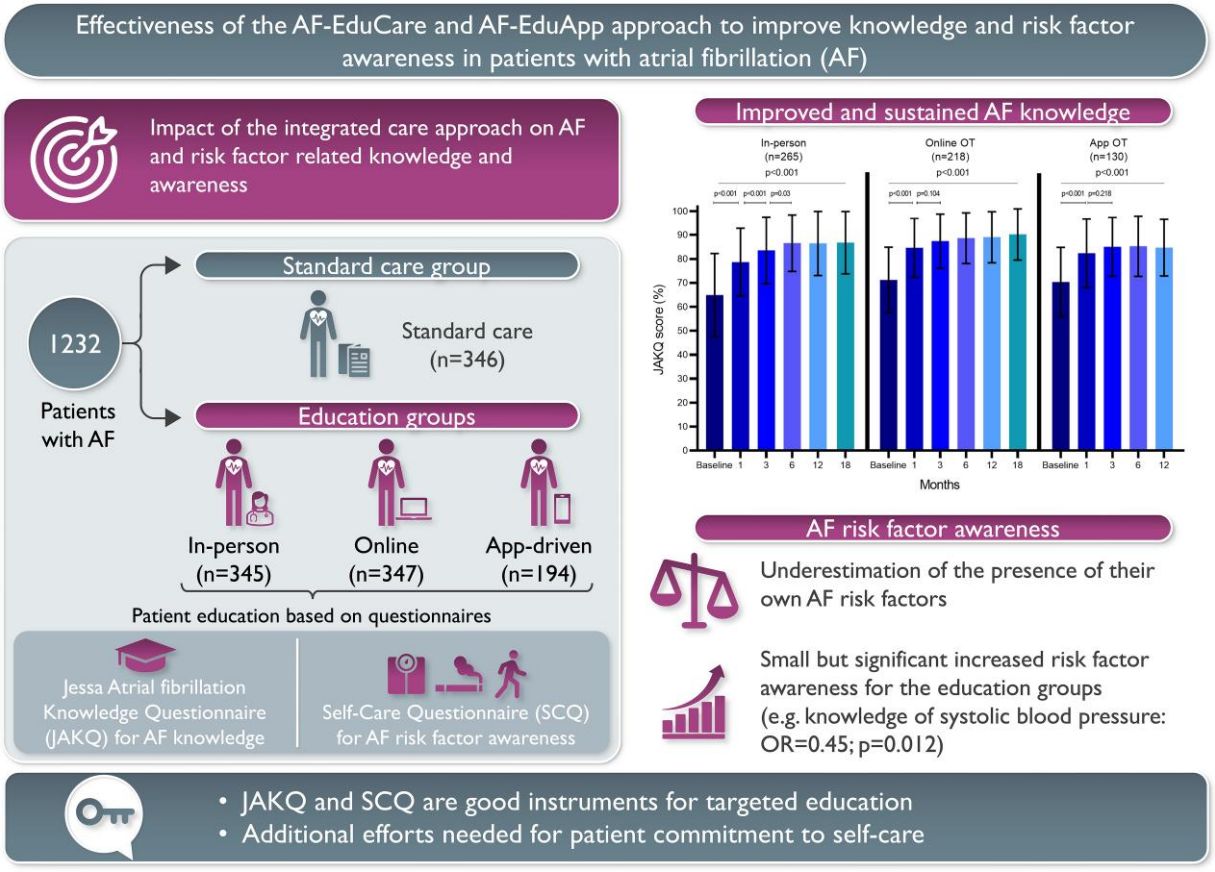
Methods and results Atrial fibrillation patients ($n = 1232$) were randomized to standard care (SC) or three educational interventions: in-person, online, or app-based education. Patients in the intervention groups received targeted education based on their responses to the Jessa Atrial fibrillation Knowledge Questionnaire (JAKQ) and a Self-Care Questionnaire (SCQ) presented at different time points. Patients who received educational follow-up reached a significantly higher knowledge score (in-person: 86.5 ± 13.2%; online: 82.5 ± 19.3%; app: 80.1 ± 15.0%) than the SC group (65.3 ± 16.6%) after 12/18 months ($P < 0.001$). The knowledge rapidly improved with the first sessions (i.e. 3 months) and remained sustained in all education groups. Patients with RF at baseline showed a slight but significant increase in awareness about their RF through education [e.g. no knowledge of last measured systolic blood pressure compared between education vs. SC: odds ratio of 0.45 ($P = 0.012$)], a change that was not seen in SC patients. Nevertheless, patients keep under-estimating the presence of their own RFs compared with objective documentation in their medical record (e.g. hypertension).

Conclusion The JAKQ and SCQ are good instruments to provide targeted education to AF patients in daily clinical care. Knowledge level increases clinically significantly, but the impact on awareness about personal risk factors remains unsatisfactory.

Registration ClinicalTrials/gov: NCT03707873NCT03788044.

* Corresponding author. Tel: +3211 33 70 88, Email: lieselotte.knaepen@uhasselt.be
† Shared first author.

Graphical Abstract



Keywords Atrial fibrillation • Education • Integrated care • mHealth

Novelty

- The results show that targeted education improves patients' AF knowledge. However, targeted education did not affect patients' perception on self-care capabilities. There exists a difference between educational efforts to increase risk factor awareness and patients actively using this knowledge to improve their own well-being.
- Overall, users of the app performed less than the other education groups. The simplicity of digital follow-up with smartphone applications could be a pitfall in quickly completing tasks without actively engaging patients, which needs further study.

Introduction

The 2016 and 2020 European Society of Cardiology (ESC) guidelines on atrial fibrillation (AF) management recommend a patient-centred, multi-disciplinary, structured, integrated care approach for AF patients.[1,2] To succeed with an integrated care approach, patient involvement and empowerment are needed, which requires adequate education about the arrhythmia, its risk factors (RFs), and management. Several studies have been performed on integrated AF care, although in selected AF patient populations, with different management strategies and with variable results.[3–6]

Atrial fibrillation is the most common cardiac arrhythmia, affecting 8 million people in Europe, and it is expected to rise drastically by 2060.[7] It is linked to high morbidity and mortality, leading to a significant health and socioeconomic burden.[8,9] The management of AF is based on three pillars or the so-called ABC pathway: i.e. (A) avoiding stroke with oral anticoagulation (OAC) therapy, (B) better symptom control with rate and/or rhythm control, and (C) cardiovascular RF management. This makes the management complex and patient specific. To effectively manage AF patients, they must thoroughly understand the arrhythmia, RFs, outcomes, treatment, and self-management opportunities.

Previous integrated AF care studies included education as part of their intervention. However, this was often not in a structured and patient-tailored manner.[3–6] Our research group already showed that

short targeted education sessions based on patients' knowledge gaps assessed with the Jessa Atrial fibrillation Knowledge Questionnaire (JAKQ) significantly improved their knowledge both via in-person and online education.[10–12] This type of education was the cornerstone of the AF-EduCare/AF-EduApp study (NCT03707873/NCT03788044). With the AF-EduCare study, the impact of a new integrated care approach, with education delivered either in-person or via an online platform with intermittent prompts, was evaluated on clinical outcome parameters.[13] The AF-EduApp study was set up to evaluate the effect of an additional education pathway, i.e. via in-house developed educational smartphone application, implemented as an additional study arm in the AF-EduCare trial. The new AF-EduCare/AF-EduApp approach delivers integrated care based on the following components: (i) patient education on the arrhythmia and its treatment as the cornerstone to ensure patient involvement and commitment, (ii) assessment of AF RFs and education on how to manage those, (iii) improving adherence to OAC therapy, and (iv) providing patients with easy access to a specialized AF team in case of AF-related questions or problems.

The main aim of this manuscript is to evaluate the effect of the AF-EduCare/AF-EduApp approach on the evolution of the knowledge level and self-care capabilities of patients with AF compared with standard care (SC).

Methods

The AF-EduCare/AF-EduApp study was a prospective randomized controlled trial (RCT) performed at Antwerp University Hospital (UZA), Jessa Hospital Hasselt, and University Hospital Leuven. A total of 1232 patients were randomized between September 2018 and March 2021 to in-person, online, or app-driven education or SC and had a follow-up of 12–42 months.[14]

Study population and design

Atrial fibrillation patients hospitalized at the cardiology ward or AF patients coming for an outpatient visit were asked to participate. After inclusion, the patients were randomized to one of three intervention groups (in-person, online, app-driven education) or SC. Patients in the in-person group were seen at the hospital, where they received targeted education from a study nurse experienced in AF management (i.e. clinical nurses specialists or master in biomedical sciences with >1 year experience in AF and trained in general AF management, symptom control, and addressing AF-related RFs, who worked under the supervision of the treating cardiologist) at each follow-up moment. In contrast, patients of the online and app groups received access to an online education platform or the in-house–developed AF-EduApp application,[15] respectively. These patients were seen less often in the hospital and received notifications to access their platform for planned targeted education sessions. The groups were stratified for age, highest educational degree, duration of AF, and place of inclusion. Patients randomized to the online or app group, who did not have a personal computer, tablet, or smartphone with an internet connection (or were not able to use it), were considered as a non-suitable group. For this reason, the online and app groups were divided into a part that was suitable and a part that was unsuitable for online or app-driven education, i.e. an extra control group. These groups had the same study procedures as the SC group. This made it possible to perform intention-to-treat (ITT) analyses of the four main study groups: in-person, online (both suitable and unsuitable), app (both suitable and unsuitable), and SC. In addition, on-treatment (OT) analyses were performed for the six separate study groups.

Patients of the in-person, online ITT, and SC groups (AF-EduCare study) had a minimum follow-up of 18 months (i.e. all patients were followed until the last included patient had completed 18 months follow-up). The App and no-App groups were part of the AF-EduApp sub-study, which was implemented in the larger AF-EduCare study due to the same follow-up and study design. However, these patients had a follow-up of 12 months due to the fact that this sub-study had another primary outcome parameter. The full protocol of the AF-EduCare approach has previously been described by Delesie *et al.*[13] However, the methodology for the components focused on within this manuscript (i.e. knowledge level and self-care capabilities) will be described.

A generic brochure regarding AF, which was the SC in all centres at the beginning of AF-Educar study, was distributed to all included patients. This ensured that at the beginning of the trial, every group had access to at least the same standardized information.

Patients' knowledge level about AF was evaluated using the JAKQ, a validated AF-specific questionnaire that measures knowledge gaps.[10] The JAKQ contains 16 questions: 8 questions about AF in general, 5 questions about OAC therapy, and 3 patient-specific questions on vitamin K antagonists (VKAs) or non-vitamin K antagonist oral anticoagulants (NOACs). The JAKQ contains multiple choice questions with one correct answer, two distracters, and an 'I do not know' option. The total number of correct answers was divided by the number of completed questions, which resulted in a percentage. Targeted education of the intervention groups was given at baseline, 1, 3, 6, 12, and 18 months if applicable (i.e. for patients of the AF-EduCare study). However, patients of the SC, not-online, and no-app group only received the knowledge questionnaires at 12 or 18 months if applicable to minimally trigger these patients to search for information based on the questionnaire. The analyses were performed on data until 18 months, except for the ITT app group, which was on 12 months. Time to complete the questionnaire and receive education is registered.

To gain insight into the perception of AF patients on their self-care capabilities, they were asked to fill out the Self-Care Questionnaire (SCQ). This in-house–developed study questionnaire consists of 14 questions about RFs related to AF [i.e. overweight, hypertension, hyperlipidaemia, alcohol consumption, smoking, obstructive sleep apnoea, correct medication intake, and physical (in)activity]. The questionnaire was validated during different one-on-one sessions with a panel of experts (i.e. two electrophysiologists, a cardiologist with expertise in cardiovascular rehabilitation, an AF nurse specialist, and a specialist in AF RF management) who gave feedback on the relevance and content of the questions (content validity) and with 10 AF patients (mean age, 74.7 ± 8.3 years; 60% male; mean AF duration, 47.2 ± 29.6 months) who gave feedback on relevance and clarity of the questions (face validity). The answer options for most questions consist of a 4-point Likert scale (i.e. never, occasionally, sometimes, and often) and an additional 'I do not know' option. Only the questions on systolic blood pressure (i.e. <135 mmHg, <145 mmHg, <155 mmHg, and >155 mmHg) and body mass index (BMI) (i.e. <25 kg/m^2, <27 kg/m^2, <30 kg/m^2, and >30 kg/m^2) have specific answer possibilities besides the 'I do not know' option. All answers were made dichotomous for the analyses (i.e. awareness vs. no awareness). The SC and ineligible groups (online or app) received the SCQ at baseline, at 18 or 12 months, respectively, and at the end of the study. The education groups needed to complete the SCQ at baseline, 3, and 12 months and if applicable at 18 months and end of the study. Data at baseline and 18 months, or 12 months for the ITT app group, were used for the ITT analyses.

Statistical analysis

The statistical analyses were performed using SPSS 29.0 (IBM, Armonk, NY, USA). Normal distribution was assessed using the Shapiro–Wilk test. As appropriate, variables were described as numbers and percentages, as mean ± standard deviation (SD) or median and inter-quartile range (IQR). The χ^2 test was used for categorical variables. For continuous variables, the Kruskal–Wallis was used for unpaired samples. Friedman was used for paired continuous variables. For both tests, post hoc Bonferroni correction was used for pairwise comparison. It is important to note that the Friedman test does not include variables with missing values. The results of the SCQ questionnaire were analysed with a generalized estimating equation model as the answers on the questions were dichotomized and patients were followed over time, which could not be ignored. *P*-values <0.05 were considered statistically significant.

Results

A total of 1232 patients (Centre 1: 433 patients; Centre 2: 455 patients; Centre 3: 344 patients) were included in the AF-EduCare/AF-EduApp

Table 1 Demographic data of included cardiology patients

	Total population (*N* = 1.232)	In-person (*N* = 345)	Online (ITT) (*N* = 347)	App (ITT) (*N* = 194)	SC (*N* = 346)	*P*-value[a]
Age (years), mean ± SD	69.8 ± 8.9	69.5 ± 9.3	69.9 ± 9.2	70.1 ± 7.0	69.9 ± 9.1	0.965
Male, *n* (%)	851 (69.1)	249 (72.2)	230 (66.3)	132 (68.0)	240 (69.4)	0.403
Education degree, *n* (%)						0.169
Primary/secondary school	723 (58.7)	203 (58.8)	206 (59.4)	110 (56.7)	204 (59.0)	
College/university	509 (41.3)	142 (41.2)	141 (40.6)	84 (43.3)	142 (41.0)	
Time since AF diagnosis (years), mean ± SD	5.8 ± 7.2	5.9 ± 6.9	5.8 ± 7.5	5.1 ± 6.4	6.2 ± 7.8	0.458
CHA_2DS_2-VASc score, mean ± SD	3.1 ± 1.7	3.1 ± 1.7	3.3 ± 1.7	3.1 ± 1.6	3.1 ± 1.7	0.578
mEHRA, *n* (%)						0.973
1	514 (41.7)	141 (40.9)	142 (40.9)	84 (43.3)	147 (42.5)	
2a	361 (29.3)	99 (28.7)	104 (30.0)	61 (31.4)	97 (28.0)	
2b	204 (16.6)	59 (17.1)	59 (17.0)	27 (13.9)	59 (17.1)	
3	139 (11.3)	42 (12.2)	37 (10.7)	21 (10.8)	39 (11.3)	
4	14 (1.1)	4 (1.2)	5 (1.4)	1 (0.5)	4 (1.2)	
Anticoagulation therapy						0.408
NOAC	995 (80.8)	276 (80.0)	279 (80.4)	163 (84.0)	277 (80.1)	
VKA	105 (8.5)	33 (9.6)	25 (7.2)	16 (8.2)	31 (9.0)	
LMWH	10 (0.8)	4 (1.2)	1 (0.3)	0 (0.0)	5 (1.4)	
None	122 (9.9)	32 (9.3)	42 (12.1)	15 (7.7)	33 (9.5)	
In possession of, *n* (%)						
PC/laptop	971 (78.8)	265 (76.8)	268 (77.2)	154 (79.4)	284 (82.1)	0.308
Tablet	564 (45.8)	155 (44.9)	152 (43.8)	105 (54.1)	152 (43.9)	0.087
Smartphone	156 (80.4)	183 (53.0)	196 (56.5)	156 (80.4)	194 (56.1)	**<0.001**
Internet accessibility, *n* (%)	1078 (87.5)	297 (86.1)	296 (85.3)	181 (93.3)	304 (87.9)	**0.001**
Cardiovascular risk factors, *n* (%)						
Diabetes mellitus Type I/II	220 (17.9)	59 (17.1)	60 (17.3)	36 (18.6)	65 (18.8)	0.503
Hypertension	759 (61.6)	206 (59.7)	226 (65.1)	125 (64.4)	202 (58.4)	0.210
Hypercholesterolaemia[b]	848 (69.1)	234 (68.4)	233 (67.1)	135 (69.9)	246 (71.1)	0.316
Current smoker	99 (8.0)	23 (6.7)	33 (9.5)	20 (10.3)	23 (6.6)	0.527
Alcohol excess (>8/week)	299 (24.3)	90 (26.1)	66 (19.0)	59 (30.4)	84 (24.3)	0.020
Overweight						0.563
BMI = 25–29.9	508 (41.2)	145 (42.0)	133 (38.3)	88 (45.4)	142 (41.0)	
BMI ≥ 30	358 (29.1)	96 (27.8)	107 (30.8)	59 (30.4)	96 (27.7)	
Documented diagnosis of OSA[c]	152 (12.6)	37 (11.0)	39 (11.5)	27 (4.1)	49 (14.3)	0.351
No. of cardiovascular risk factors, mean ± SD	2.6 ± 1.3	2.6 ± 1.3	2.6 ± 1.3	2.8 ± 1.3	2.6 ± 1.3	0.165

Bold text: $P < 0.05$.
ITT, intention-to-treat, mEHRA: modified European Heart Rhythm Association (mEHRA) score; NOAC: non-oral anticoagulation, VKA: vitamin K antagonist, LMWH: low molecular weight heparin, BMI: body mass index, OSA: obstructive sleep apnea.
[a]Kruskal–Wallis test was used for continuous data, and a χ^2 test was used for categorical data.
[b]3 unknown.
[c]23 unknown.

trial (see Supplementary material online, *Figure S1*). They had a mean age of 69.8 ± 8.9 years, 69.1% were male, and the mean time since AF diagnosis was 5.8 ± 7.2 years. The four groups were well matched, as shown in *Table 1*. The only significant difference was seen in the number of patients with a smartphone ($P < 0.001$) and internet accessibility ($P = 0.001$), as expected per design. Most patients had no symptoms ($n = 514$, 41.7%) or mild symptoms ($n = 361$, 29.3%) at the start of the study, and they had a mean number of 2.6 ± 1.3 known cardiovascular RFs at baseline. More demographical parameters of the 1232 patients were described by Delesie *et al.*[14]

Improved knowledge by targeted education

A total of 1071 patients [86.9%, 288 in-person (83.5%), 302 online ITT (87.0%), 168 app ITT (86.6%), and 313 SC (90.5%)] completed the

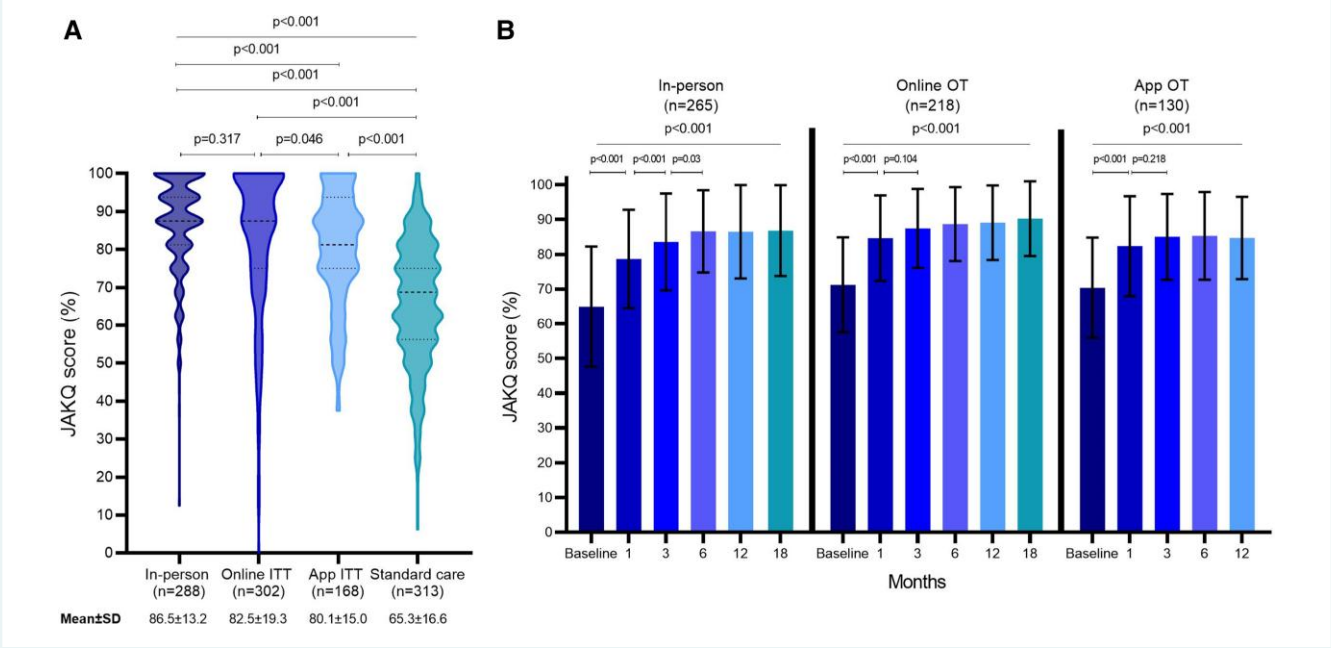


Figure 1 Knowledge scores based on the Jessa atrial fibrillation Knowledge Questionnaire. (*A*) Jessa Atrial fibrillation Knowledge Questionnaire scores in the intention-to-treat groups at 18 months (or 12 months for the app group). (*B*) Mean Jessa Atrial fibrillation Knowledge Questionnaire score over time within the different on-treatment education groups. ITT, intention-to-treat; OT, on-treatment.

JAKQ questionnaire at 18 months (or 12 months for the app group) with a mean score of 78.2 ± 18.5% at this timepoint. There was a significant difference in JAKQ score at 12/18 months between the four study groups (*Figure 1A*; $P < 0.001$), and every intervention group scored significantly higher than the SC group ($P < 0.001$ for all). Moreover, the in-person and online ITT groups also scored significantly higher than the app ITT group ($P < 0.001$ and $P = 0.046$, respectively). Looking at all six OT groups separately (see Supplementary material online, *Figure S2*), it was noted that all education OT groups scored significantly higher than the SC and not-eligible groups ($P < 0.001$ for all). There were no significant differences between the SC and not-eligible groups ($P = 1.00$ for all). Also, no significant difference was seen between in-person and online ($P = 0.214$) or in-person and the app group ($P = 1.00$), but the online group scored significantly higher than the app group ($P = 0.004$).

A total of 613 of the 761 OT education patients [in-person: 265 (76.8%); online: 218 (82.9%); app: 130 (85.0%)] completed all required (i.e. 6 or 5) education moments with the JAKQ. Patients of the in-person group had a significantly lower JAKQ score at baseline (64.7 ± 17.4%) compared with the online (70.9 ± 13.8%; $P < 0.001$) or app group (70.3 ± 14.4%; $P = 0.004$). There was, however, a significant increase over time in all three intervention groups (all $P < 0.001$, *Figure 1B*). Patients of the in-person group significantly increased their knowledge level until month 6, but plateaued earlier in the online and app groups. Patients of all groups maintained their knowledge level over time.

Based on data from all education moments, it took OT education patients only 4.8 min (IQR: 3.4–7.1 min) to complete the JAKQ and 3.1 min (IQR: 1.5–6.9 min) to receive the targeted education. Patients in the OT app group [4.1 (IQR: 3.1–5.8) min] completed the JAKQ questionnaire significantly faster compared with the online [4.8 (IQR: 3.4–7.0) min; $P < 0.001$] and in-person groups [5.1 (IQR: 3.6–7.3) min; $P < 0.001$] but also the time for education received was significantly lower in the app group [1.7 (IQR: 1.1–2.7) min] compared with the in-person [5.6 (IQR: 2.5–10.1) min; $P < 0.001$] and online groups [2.3 (IQR: 1.3–4.2) min; $P < 0.001$]. The time spent on education was significantly higher in the in-person group than in the online group ($P < 0.001$).

Knowledge gaps based on Jessa Atrial fibrillation Knowledge Questionnaire

A sub-analysis was performed on patients in the education groups who received at least three JAKQ education moments (out of a maximum of six) vs. the single completion of the JAKQ in the SC or not-eligible group. *Table 2* shows the percentage of correct answers during the study. Despite repeated education, knowledge gaps remained. More specifically, the general AF-related questions on 'AF is not always associated with symptoms' and 'medication cannot prevent AF permanently; aging increases the risk for relapse' proved to be the most difficult questions, with correct answers by slightly more than half of the education patients (vs. about one-third in the SC patients). General OAC knowledge was high. However, knowledge gaps were still noticeable despite education concerning what patients need to do when they forget to take their VKA (education: 67.3 ± 31.3% vs. SC: 37.5 ± 49.5%; $P = 0.033$) or NOAC (education: 73.7 ± 31.6% vs. SC: 41.8 ± 49.4%; $P < 0.001$) and when to show the NOAC blood thinner card (education: 47.3 ± 33.8% vs. SC: 30.3 ± 46.1%; $P < 0.001$).

Assessment of self-care abilities

In total, 1073 patients (87.2%) completed the SCQ at baseline and 12 or 18 months (757 ITT education patients and 316 SC patients). It should be stressed that the answers to this questionnaire reflect the self-perceived status of the patients. *Figure 2* shows a discrepancy in

Table 2 Correct scores per question of the Jessa Atrial fibrillation Knowledge Questionnaire for patients with at least three education moments for the education group vs. at the single completion of the Jessa Atrial fibrillation Knowledge Questionnaire for the standard care group

General AF knowledge	Total ($n = 1106$)	In-person ($n = 311$)	Online ($n = 308$)	App ($n = 174$)	SC ($n = 313$)	*P*-value
(1) AF is a heart condition with an irregular and often faster heartbeat	86.8 ± 28.9	87.4 ± 21.4	86.2 ± 30.3	89.6 ± 24.3	85.3 ± 35.5	**<0.001**
(2) AF is not always associated with symptoms	48.1 ± 40.1	56.9 ± 31.4	52.0 ± 37.9	49.5 ± 36.7	34.8 ± 47.7	**<0.001**
(3) AF can be monitored by taking the pulse at regular timepoints	63.0 ± 39.6	69.0 ± 30.0	65.5 ± 36.3	65.4 ± 36.3	53.4 ± 50.0	0.476
(4) AF can cause blood clots with an increased risk for stroke	81.7 ± 34.0	87.0 ± 22.6	83.4 ± 34.5	82.8 ± 30.9	74.1 ± 43.9	0.793
(5) Medication cannot prevent AF permanently; ageing increases the risk for relapse	49.0 ± 40.3	55.2 ± 32.7	54.0 ± 37.1	52.9 ± 37.7	35.8 ± 48.0	**<0.001**
(6) AF patients do not need to go to the general practitioner or emergency room every time they feel AF	70.7 ± 38.3	77.1 ± 26.7	75.8 ± 34.1	70.7 ± 36.0	59.4 ± 49.2	0.140
(7) Being overweight has an impact on AF	72.2 ± 37.8	80.1 ± 20.7	78.3 ± 33.6	83.3 ± 29.1	52.4 ± 50.0	**<0.001**
(8) Blood thinners are frequently prescribed for AF patients to prevent the formation of blood clots in the hearts, which can lead to stroke	90.3 ± 26.0	93.1 ± 15.3	91.8 ± 23.9	91.6 ± 23.4	85.3 ± 35.5	0.165
General anticoagulant knowledge	**Total ($n = 992$)**	**In-person ($n = 291$)**	**Online ($n = 273$)**	**App ($n = 160$)**	**SC ($n = 268$)**	***P*-value**
(9) Blood thinners should always be taken even if the patient does not feel AF	95.4 ± 18.1	96.5 ± 10.7	96.7 ± 14.6	95.7 ± 16.8	92.5 ± 26.3	0.065
(10) The occurrence of bleedings or prolong bleeding after an injury are side effects of blood thinners	85.3 ± 30.1	88.1 ± 20.5	85.8 ± 29.5	89.0 ± 23.2	79.5 ± 40.5	0.216
(11) AF patients on OAC treatment may use pain medication based on paracetamol	80.7 ± 33.5	87.0 ± 20.0	84.9 ± 28.0	83.7 ± 29.3	67.9 ± 46.8	0.530
(12) Patients should contact the doctor or specialist if they regularly suffer from (minor) nosebleeds but continue taking their blood thinner	88.3 ± 28.1	90.2 ± 18.0	93.1 ± 22.6	90.7 ± 24.2	79.9 ± 40.5	**<0.001**
(13) When a patient has to undergo surgery, he or she discusses this with the doctor	87.9 ± 27.2	89.0 ± 19.4	91.5 ± 23.2	84.8 ± 28.6	85.1 ± 35.7	**<0.001**
VKA knowledge	**Total ($n = 91$)**	**In-person ($n = 30$)**	**Online ($n = 22$)**	**App ($n = 15$)**	**SC ($n = 24$)**	***P*-value**
(14) The blood thinning must be checked at least once a month	93.4 ± 17.7	94.3 ± 10.0	90.4 ± 25.3	92.3 ± 11.3	95.8 ± 20.4	0.140
(15) When forgotten to take the blood thinner, the blood thinner can still be taken (immediately or at the next intake)	59.4 ± 39.0	70.7 ± 20.4	67.4 ± 39.7	60.3 ± 36.5	37.5 ± 49.5	0.159
(16) The international normalized ratio value is a measure of how thick or thin the blood is	80.8 ± 35.1	86.9 ± 25.2	82.6 ± 35.8	88.4 ± 19.1	66.7 ± 48.2	0.757
NOAC knowledge	**Total ($n = 919$)**	**In-person ($n = 269$)**	**Online ($n = 257$)**	**App ($n = 149$)**	**SC ($n = 244$)**	***P*-value**
(17) It is important to take the blood thinner daily at the same time	94.5 ± 19.3	95.9 ± 12.2	92.9 ± 22.4	95.7 ± 14.2	93.9 ± 24.1	**0.020**
(18) When forgotten to take the blood thinner, the blood thinner should still be taken if the time until the forgotten dose is smaller as the time until the next dose	65.3 ± 39.8	76.5 ± 23.9	70.6 ± 36.1	74.2 ± 35.2	41.8 ± 49.4	**<0.001**
(19) With the blood thinner comes a card that should be shown to the doctor or specialist	42.8 ± 38.2	46.7 ± 31.5	50.4 ± 35.8	37.9 ± 32.8	30.3 ± 46.1	**<0.001**

Bold text: $P < 0.05$.

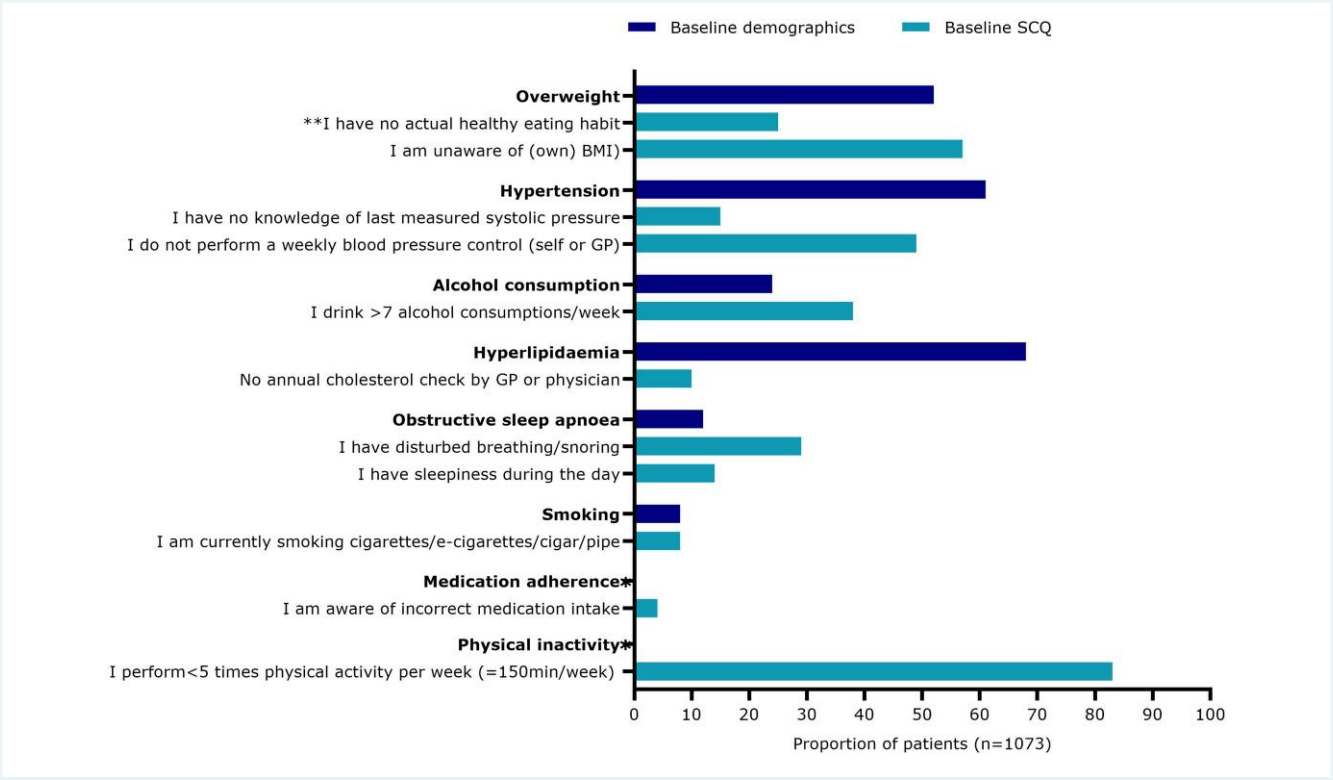


Figure 2 Difference in presence of risk factor between baseline demographics (objective results based on medical record) and baseline results of Self-Care Questionnaire (subjective assessment by the patient). *Parameters not mentioned in medical record. **No actual healthy eating habit (i.e. no limited salt intake, not enough fresh vegetables and fruit, fish, lean meat, etc.).

the number of self-perceived or controlled RF (based on answers to the baseline SCQ) compared with the baseline demographics (objective results assessed by the study team from the medical record). While overweight, hyperlipidaemia, and hypertension were under-estimated by patients, interestingly, alcohol consumption and sleep-disordered breathing were under-estimated in the medical record. In addition, there was no systematic assessment of physical (in)activity and correct medication intake in the clinical files.

Comparing baseline and end-of-study for specific questions, differences were seen between the ITT education groups and the SC group (see Supplementary material online, *Table S1*). For 6 of the 11 questions of the SCQ (i.e. questions on knowledge of BMI and eating healthy food, i.e. no limited salt intake, not enough fresh vegetables and fruit, fish, lean meat, etc., snoring and sleepiness, drinking >7 alcohol consumption a week, or having blood pressure control once weekly), a significant improvement in patient awareness over time was seen in the education groups but not in the SC group. When evaluating the interaction between intervention (i.e. education ITT or SC) and time (*Figure 3*), the odds for 'no weekly blood pressure control' [odds ratio (OR) 0.66 (0.46–0.94); $P = 0.023$] and 'no knowledge of systolic blood pressure control' [OR: 0.45 (0.25–0.84); $P = 0.012$] were significantly lower in the education group. Such effect was also clear for 'disturbed breathing or snoring' [OR: 0.34 (0.12–0.95); $P = 0.04$].

As shown in *Figure 2*, no data for correctness of medication intake and physical (in)activity were available in the medical files of the patients. Only a small fraction of the patients considered themselves as not taking their medication correctly as prescribed (education: 4.6% vs. SC: 2.8%) at baseline, and no significant improvement was seen neither with education ($P = 0.57$). In contrast, insufficient physical activity (i.e. ≤150 min of exercise per week) is the most frequent RF, which also proves to be most difficult to address [OR: 1.15 (0.79–1.68); $P = 0.48$]. Less than 20% of the patients met the guideline recommendations on physical activity after 12–18 months (i.e. 30 min of moderate-intensity physical activity or 15 min of vigorous intensity at least 5×/week, or a combination of both)[16] (*Figure 4*). Forty per cent to 50% of the patients were even not performing 90 min of physical activity per week.

Discussion

This article provides important tertiary outcome data for the AF-EduCare RCT on integrated care with a focus on education and patient empowerment for an unselected population of patients with AF. The AF-EduCare study was unable to demonstrate the beneficial effects of intense, repetitive, and targeted patient education on the primary outcome of unplanned cardiovascular events during medium-term follow-up. However, >85% of the patients completed all study visits until 18 (or 12) months, stressing the feasibility of an intensive educationally based follow-up. Patients in the intervention groups had a significantly increased knowledge level compared with SC, which was retained over time. Differences were manifested at baseline in RF self-awareness of patients. Targeted education partly improved RF awareness in the education group (vs. no change in the SC patients), but augmenting physical activity and smoking cessation proved hard to tackle by the educational intervention.

Targeted education improves knowledge level, but not all education is equal

As shown by our baseline results, other studies also concluded that AF patients still have important knowledge gaps concerning their

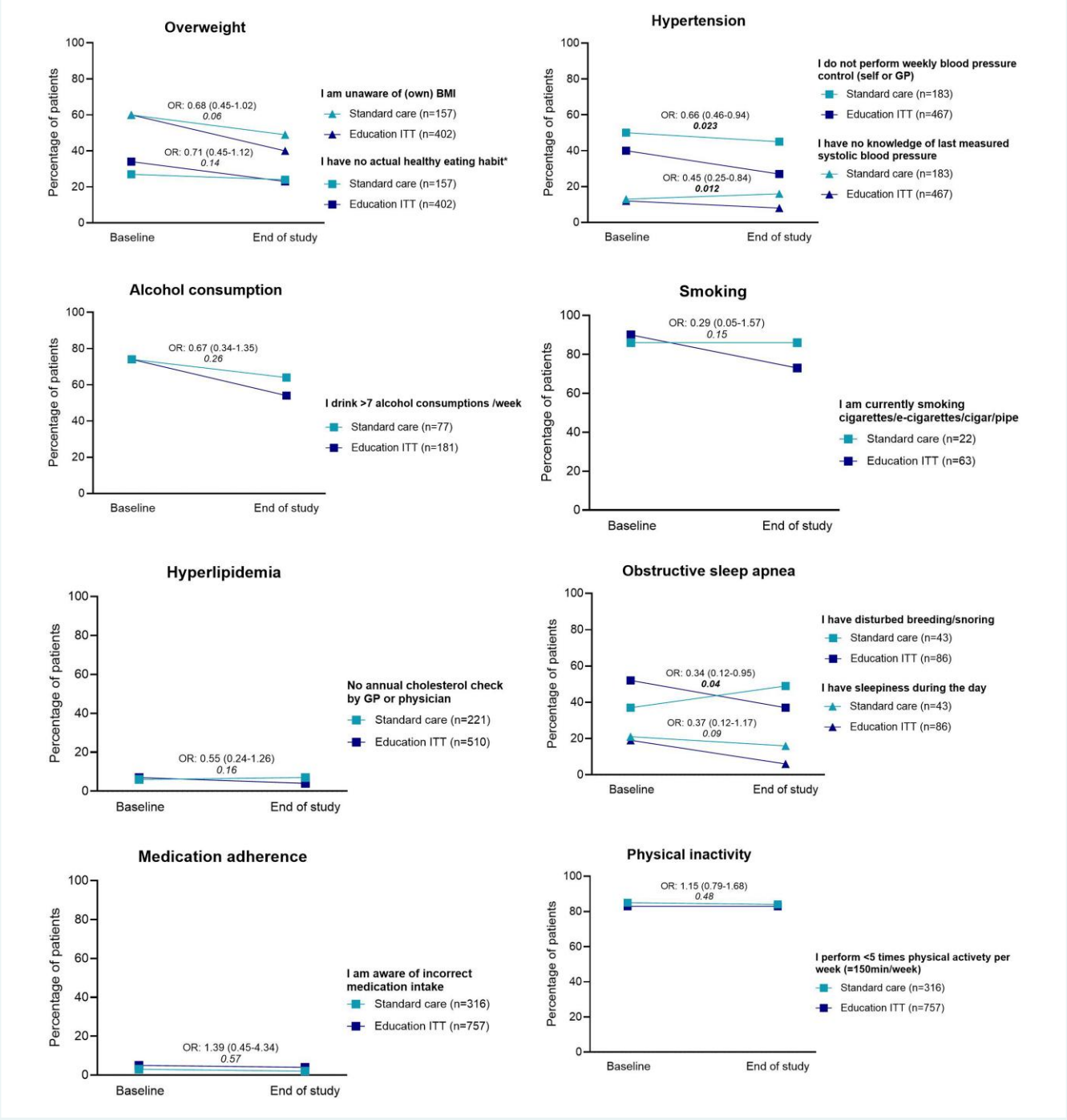


Figure 3 Variation of patients indicating to have a risk factor over time based on the Self-Care Questionnaire for all patients (concerning medication and physical activity) or for those with a risk factor present from the medical evaluation at baseline as determined by the study team. The effect of the interaction of time and group for each question of the Self-Care Questionnaire. General estimating equation was used with an odds ratio (and 95% confidence intervals) shown. *P*-values are in italics and in bold if $P < 0.05$. *No actual healthy eating habit (i.e. no limited salt intake, not enough fresh vegetables and fruit, fish, lean meat, etc.). ITT, intention-to-treat.

arrhythmia and its management.[10–12,17,18] Therefore, the most recent AF guidelines recommend that more comprehensive patient education is needed.[2] A recent qualitative study by Ferguson *et al.*[19] also revealed that patients consider education necessary and that patient-tailored education methods should be explored. In this context, the JAKQ was developed by our research group and has proven to be a good tool for providing targeted education and maintaining a high knowledge level.[10–12] We confirmed in this larger trial a significant increase over time by each of the three interventional approaches in this study. All three education groups retained their knowledge despite longer breaks between repeat educational sessions. A nurse-led AF chronic care programme with reinforced in-person education by Hendriks *et al.*[3] also

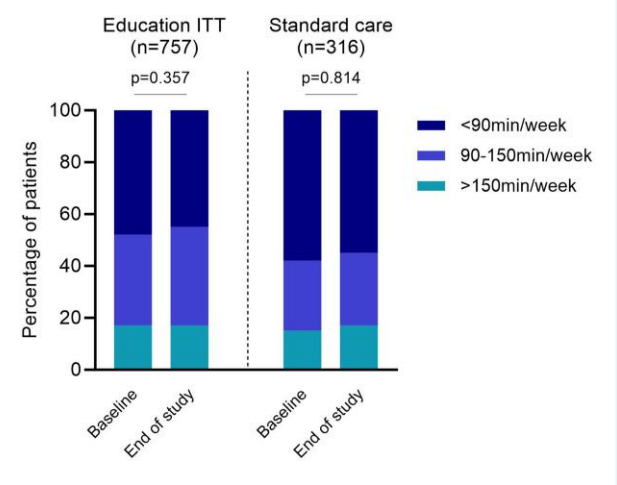


Figure 4 Categories of physical activity at baseline and end of study (18 or 12 months for App intention-to-treat group) with 30 min moderate intensity equals 15 min vigorous intensity.

showed a significant increase in knowledge after 1 year. In contrast to our study, the time to educate patients in this nurse-led AF chronic care programme was 30 min. In our study, it took <8 min per session (i.e. 4.8 min to complete the questionnaire and 3.1 min to educate patients) to provide these targeted sessions.

The in-person and online OT groups scored significantly higher than the app OT group, both when evaluated at 12 or 18 months, despite the same knowledge at baseline and a similar remote follow-up schedule. Interestingly, the time spent to complete the questionnaire and to receive targeted education was significantly lower in the app group. It seems that the app patients, working on their smartphones, are less 'actively' engaged than the other two groups, in which patients had to actively turn on their laptop or come to the hospital to complete the questionnaires and receive education. Research shows that patients' behaviour depends on self-motivation and self-determinedness (i.e. initiating an activity because it is interesting and satisfying).[20] In addition, different theories (e.g. stages of change theory and health belief model) show that it is important in which mindset the patient is: e.g. aware of and acknowledge the problem, motivated or not to change, and ready to make a plan and/or take actions.[21–23] This certainly deserves further study since it requires rethinking the paradigm that easier access (on a smartphone) would lead to better (or at least similar) outcome results.

The patient vs. practitioner perspective on risk factor management

In addition to anticoagulation therapy and symptom control, there is increasing international focus on addressing RFs in patients with AF, i.e. the C in the ABC pathway.[2,24] A subset of these RFs are considered modifiable, such as hypertension, obesity, diabetes mellitus, alcohol consumption, obstructive sleep apnoea, sedentary lifestyle, and tobacco use.[25,26] More than 90% of AF patients have at least one RF on top of AF, and AF patients over 65 years of age often have as many as five comorbidities.[27,28] With the proven beneficial effects of RF management on AF burden,[29–31] the American Heart Association already in 2020 and in 2023 endorsed the need for good RF management and the development of patient-focused, multi-disciplinary AF programmes.[32,33] A recent European survey in 339 healthcare providers revealed the difficulties of addressing RFs.[34] According to 67% of the respondents, at least 40% of AF patients need referral to a specialist to tackle comorbidities. Lack of integrated care models and lack of time were among the top four barriers for referring to specialist services.

We showed that patients have different subjective perceptions of RFs compared with the objective assessment by the study team, and this was true in both directions. This calls for another methodology to assess RF and their control, combining patient and objective information at different time points besides baseline, which was not yet done in the current study as it was not within its scope. This is currently being investigated in two large European trials, EHRA-PATHS and AFFIRMO.[35,36] For almost all questions related to the different RF, an improvement in awareness over time was seen in the education groups. However, further research is needed on how to tackle the RFs in a structured manner, as education alone will not be enough to tackle these RFs. Conversely, medication adherence and physical (in)activity, two important RFs, are currently under-reported in the medical files. On the positive side, previously published results from this AF-EduCare/AF-EduApp study showed that therapy adherence to OAC was very high in the included population (i.e. >90%), in accordance with the self-awareness in only a small percentage of patients that they did not take their medication correctly.[37] Low physical activity (i.e. <150 min) seems to be the most difficult RF to tackle. The number of patients doing too little physical activity (83.3% at baseline) is much higher than in the EORP-AF registry in which 39.3% of the patients had no regular exercise.[38] Despite educational motivation, it proved almost unfeasible to achieve the 5×/week mild or vigorous activity level as set forward by the ESC preventive guidelines.[16] Even performing 90 min of physical activity per week (i.e. 3×/week mild or vigorous activity a week) was not feasible for 40–50% of the patients in this study. Previous research in an overweight AF population ($n = 143$) showed that of the 109 patients who attempted to reduce weight, 49.5% combined dieting and more physical exercises, and only 5.5% were only more physical active to reduce weight. Most patients (40.6%) preferred a home-based programme and only 17.3% a telerehabilitation programme to help them increase physical activity.[39] Further research is needed to investigate how to motivate patients to increase their physical activity and how to objectively track their physical activity.

Limitations

Due to methodological constraints, the app study had a shorter planned follow-up of 12 months. Therefore, in all ITT analyses, the app group was compared with 18 months of follow-up of the other study groups. Nevertheless, when comparing the 12 month data points where available, the findings gave the same result (not shown). Despite efforts to include all AF patients in this trial, 33% of eligible AF patients could not be included or refused to participate, although there were hardly any exclusion criteria.[14] Inclusion bias, with more motivated patients who participated, is therefore likely, as was confirmed by our findings when comparing also those that were eligible for online or app intervention, but did not qualify due to impossibility to adhere to the intervention (i.e. not-online and no-app groups). Our ITT vs. OT analyses made it possible to assess in how far some populations may be more at risk and need to motivate the healthcare community to develop means to also address such patients. Patients of the SC groups did not receive the JAKQ at baseline compared with patients of the education groups who received the JAKQ at different timepoints. This could have created bias by patients improving their knowledge due to repeated learning. However, it was a deliberate choice not to give SC patients the JAKQ because giving the questionnaire would start to trigger patients to search for information which could have affected the results of the SC groups.

Conclusions

Patients in the education groups had increased awareness of various RF and improved their AF knowledge. Additionally, the results show that a structured educational follow-up, in-person, online, or via an app, is feasible, with >85% of patients still engaged after 12 or 18 months. Overall, users of the app performed less than the other education groups, presumably due to more distraction and hence less patient involvement. Additional efforts are required to make education and patient commitment to self-care even more appealing in order to further improve AF and RF management. The results of the primary endpoint of the AF-EduCare study also show that clinically guided treatment, one-on-one interaction with a physician or other healthcare provider, and quick medical actionability might be more significant predictors of success than only patient empowerment and education alone.[40]

Supplementary material

Supplementary material is available at *European Journal of Cardiovascular Nursing* online.

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Conflict of interest: H.H. did receive personal lecture and consultancy fees from Bayer, Biotronik, Bristol Myers Squibb, Daiichi Sankyo, Milestone Pharmaceuticals, Pfizer-BMS, Centrix India, C.T.I. Germany, European Society of Cardiology, Medscape, and Springer Healthcare Ltd. He received unconditional research grants through the University of Antwerp and/or the University of Hasselt from Abbott, Bayer, Biosense-Webster, Boston-Scientific, Daicchi Sankyo, Fibricheck/Qompium, Medtronic, and BMS-Pfizer alliance, all outside the scope of this work.

Data availability

The raw data supporting the conclusions of this article will be made available by the authors upon request.

Ethical approval

This clinical study was approved by the leading Ethics Committee of UZA/UA and took into account the advice of the local ethics committees.

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