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A self-management support intervention for patients with atrial fibrillation: a randomized controlled pilot trial

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Abstract

Background: Atrial fibrillation (AF) is the most common arrhythmia worldwide. Despite effective treatment, it is characterized by frequent recurrences. Optimal therapeutic management of AF requires active participation and self-management from patients. Two major components of self-management are self-monitoring and sign-and-symptom management. Pulse self-palpation (PSP) is a method of self-monitoring; however, not all AF patients are capable of successfully performing PSP. Due to a lack of interventions on this topic, a nurse-led intervention for patients with AF (PSPAF intervention) was developed to foster self-monitoring and to enhance self-management through PSP. The purpose of this pilot study was to test the acceptability, feasibility, and potential effects of this intervention on the capability of patients' PSP and sign-and-symptom management. Moreover, we aimed at gathering data on the feasibility of applied research methods to aid in the design of future studies.

Methods: The pilot trial involved 20 adult patients with AF, randomized to an intervention or usual care group. At baseline and during a home visit 3–5 weeks later, we collected data using questionnaires, checklists, field notes, a mobile ECG device, and a diary. Acceptability and feasibility measures were validated through predefined cut-off points. Effect size estimates were expressed as relative risks (RR) and the number needed to treat (NNT).

Results: The PSPAF intervention seemed feasible, but only partly acceptable. There were limitations in terms of potential effectiveness, suitability, addressing participants' willingness to implement its content in daily life, and adherence. Estimations of effect sizes suggest a large effect of the intervention on patients' PSP capability (RR = 6.0; 95% CI = [0.83, 43.3]; NNT = 2.4), but almost no effect on sign-and-symptom management (RR = 1.5; 95% CI = [0.7, 3.1]; NNT = 4.0). The feasibility of applied research methods showed minor limitations on recruitment and participant burden.

Conclusions: Despite some limitations, the intervention seemed to be applicable and promising. Taking into account the suggestions and amendments we have made, we recommend conducting a full-scale trial to examine the efficacy of the PSPAF intervention.

Trial registration: This pilot study was registered in the German Clinical Trials Register at September 4, 2017 (Main ID: [DRKS00012808](https://www.clinicaltrialsregister.de/ct2/show/study/DRKS00012808)).

Keywords: Atrial fibrillation, Pulse palpation, Pulse self-palpation, Self-management, Self-monitoring, Symptom management, Nurse-led intervention, Pilot trial

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Background

Atrial fibrillation (AF) is the most common arrhythmia worldwide [1, 2] with an estimated 33.5 million people suffering from this illness [3]. The incidence and prevalence of AF increase, especially in the older population [3]. AF is a chronic condition associated with an increased risk of mortality [4], morbidity [5], as well as cognitive decline and dementia [6]. It is one of the major causes of stroke [5], impairs patients' quality of life [7], and can cause depression [8] in affected patients. In addition, AF increases the economic burden of health care systems [9] due to increased absences from work, lower productivity [10], and higher utilization of health care services [9, 11–13].

The primary goals of AF management include stroke prevention, as well as heart rate and/or rhythm control [5]. The treatment of AF is complex [14] and challenging to manage in practice [15]. Furthermore, AF is characterized by frequent recurrences [16] with rates ranging from 22 to 83%, depending on therapy, time, and study [17–22]. In order to achieve optimal therapeutic management of AF and minimize the risk of complications, active patient participation is essential [23], as well as emphasizing the importance of patients' self-management [24].

For the purpose of this study, we defined self-management as an "individual's ability, in conjunction with family, community and the appropriate health care professionals, to successfully manage the symptoms, treatment, physical, psychosocial, cultural and spiritual consequences and inherent lifestyle changes required for living with a long-term chronic disease" ([24], p. 1145). Effective self-management of chronic conditions encompasses cognitive decisions to maintain physiologic stability as well as the recognition and response to symptoms [25]. In addition, self-management is associated with positive outcomes for patients and health care systems [25–29]. According to Richard and Shea [25], the concept of self-management is seen as an illness-related process embedded in the more broader concept of self-care. This, in turn, is associated with promoting and maintaining health.

Incorporated in the domain of self-management are the concepts of self-monitoring and symptom management. Self-monitoring is defined as the "awareness of symptoms or bodily sensations that is enhanced through periodic measurements, recordings and observations to provide information for improved self-management" ([30], p.343). For chronically ill patients, the recognition of symptoms marks the beginning of the decision-making process to which actions need to follow. Symptom management, when performed by patients, is seen as an element of self-monitoring and self-management [25]. Its aim is the delay and prevention of negative

outcomes [31]. Besides symptoms as a subjective experience [31], signs are objective indications of a disease [32] and are considered to be important for recognizing problems [31]. The effective management of signs and symptoms is a process that starts with detection and interpretation, then leads to the selection of a strategy, and ends with an evaluation of the chosen strategy [33]. The manifestation and awareness of AF symptoms (such as lethargy, palpitations, dyspnea, chest tightness, sleeping difficulties, and psychosocial distress [5]) can vary greatly from symptom-free to a massive impairment of daily life [34–36]. AF recurrences can frequently be asymptomatic, and while patient reported symptoms are considered to be an inaccurate estimation [37], an irregular pulse, regarded as a clinical manifestation of or sign for AF, can be a measurable indicator of the disease or recurrence [38, 39] that can be detected through pulse palpation. In current guidelines, pulse palpation is only recommended to health care providers as a method for screening individuals above the age of 65 [5] or as an assessment method for patients with specific symptoms [40]. Patient involvement in terms of pulse self-palpation (PSP) has not yet been explicitly considered in any guidelines.

PSP means feeling one's own pulse wave with fingertips without the help of technical devices to determine the rate, rhythm, and quality of the pulse [41]. PSP is a simple, ubiquitous, non-invasive [42], cheap [43], useful, and safe [44] method to identify an irregular pulse. In studies, pulse palpation to assess heart rhythm has shown a sensitivity of 76%, a specificity of 86% when performed by the general population [45], and a rate-dependent accuracy of 82–92% when performed by the elderly [46]. A PSP by stroke patients unveiled a small number of false-positive measurements and achieved a sensitivity of 54% and a specificity of 96% [42].

Unfortunately, a limited number of AF-patients know that AF can be detected by regular pulse palpation [47], and even fewer are capable of performing PSP or in fact do so [23, 48]. In order to fill this gap and to promote patient involvement, it is recommended to educate patients with AF about PSP [49, 50].

Studies comprising PSP interventions focused on screening for AF and only included participants without AF [38, 42, 44, 45, 51, 52], but showed improvements in technique and capability of PSP, with rates ranging from 69 [44] up to 100% [52] in the intervention groups. These results suggest that inexperienced individuals can successfully learn PSP without negative outcomes. Interventions especially designed for AF patients focusing on self-management could not be identified in the published literature. For this reason, the "Pulse Self-Palpation for patients with Atrial Fibrillation (PSPAF)" intervention has been developed to foster self-

monitoring and sign-and-symptom management, and thus to enhance self-management.

Aims

The aim of this pilot trial was to test the PSPAF intervention and to gather data towards designing a future trial to test the efficacy of the intervention. Specific aims were (1) to assess the acceptability and feasibility of the intervention, (2) to assess the feasibility of research methods and the perceived burden of study participation, and (3) to estimate a potential effect of the intervention on the capability to perform PSP, and on sign-and-symptom management.

Methods

Reporting on this pilot trial was guided by the recommendations of the CONSORT statement extension to randomized pilot and feasibility trials [53] (Reporting checklist: see Additional file 1).

Design and setting

This single-center, single-blind randomized controlled pilot trial was conducted on a ward with a focus on heart rhythm diseases at an academic tertiary medical heart center in Germany.

Participants, recruitment, and randomization

A sample of $N = 20$ participants ($n = 10$ per group) was targeted. This sample size was based on suggestions in the literature [54–56]. No formal sample size calculation was conducted.

Patients were included if they (1) were hospitalized, (2) had a diagnosis of paroxysmal or persistent AF, (3) were at least 35 years of age, (4) lived within 30 min by car from the health care center, and (5) were able to read, write, and understand German. Patients with (1) a cognitive (e.g., dementia) or (2) a physical impairment of both hands (e.g., peripheral polyneuropathy), (3) a third-degree heart block or condition after AV nodal ablation and an implanted pacemaker, (4) a life expectancy of less than 2 months according to the physician, or (5) individuals who had already taken part in any comparable education program, were excluded.

Screening of potential participants via electronic health records was carried out by the study coordinator. Eligible participants were informed about the trial both verbally and by written information. Patients who provided informed consent were randomized to either the intervention group (IG) or the usual care group (UCG) via sealed, opaque, and consecutively numbered envelopes containing paper cards with the group allocation. Group allocation was randomized by means of a computer-generated blocked randomization procedure with possible block sizes of 2, 4, 6, or 8 that were also

randomly specified [57]. The confidential preparation and arrangement of envelopes was undertaken by a person not involved in any stages of this trial.

Intervention

The nurse-led PSPAF intervention is a behavioral intervention at an individual level for one or two recipients, which can be referred to as “complex” due to several interacting components [58]. The intervention was developed by a group of experienced nurses and advisory cardiologists following the principles of action research [59] and was based on the four sources of evidence [60]: (1) empirical evidence, (2) clinical experience (involving nurses, physicians, and other health experts), (3) contextual factors, and (4) patient preferences (field testing), resulting in the creation of an intervention manual. Formal guidance of intervention development was retrieved from the work of Sidani and Braden [61].

The PSPAF intervention consisted of five consecutive components whose contents were presented orally in a face-to-face session by a trained registered nurse (study coordinator) using interactive teaching methods and written materials. Four main topics were addressed: (1) background information on the disease, pulse, and pulse measurement; (2) learning the technique of PSP; (3) determining heart rate and heart rhythm; and (4) interpretation of values and possible actions. To illustrate the mechanisms of the intervention, its active ingredients were classified as intervention functions [62] with a set of corresponding behavioral change techniques [63]. A detailed description of the PSPAF intervention is provided in Table 1.

Variables and measurement

Variables and corresponding instruments are listed in detail in Table 2. All instruments were developed specifically for this study, based on literature or expert opinion. Therefore, no external evidence exists on their validity and reliability. In a cognitive pretest with nine individuals (three AF patients, five healthy individuals, one cardiac nurse), written study information, questionnaires, and the pulse diary were tested for clarity, readability, and comprehensibility using verbal probing and think-aloud interviews [64]. Vague or ambiguous items and formulations were revised. Regarding applicability and usability, field-note forms and checklists were explained to study assistants and discussed in advance with one assistant. The checklist assessing the capability of performing PSP and the vignettes assessing sign-and-symptom management were discussed with two expert nurses and one physician to gauge the accuracy of measuring the respective concepts.

Table 1 Consecutive components and content of the PSPAF intervention with corresponding intervention functions and behavioral change techniques

Components	Function	BCT	Content in PSPAF
1) Information	Education	Information about health consequences	Oral information about the pulse as a clinical sign, physiological and pathophysiological values, and the significance of measurement of one's own pulse in terms of AF
2) Technique of a PSP	Education	Instruction on how to perform a behavior	Explanation of the procedure of a PSP
	Training	Demonstration of the behavior	Demonstration and joint exercise of the procedure of a PSP
3) Determination of heart rate and heart rhythm	Training	Instruction on how to perform a behavior	Elucidations and examples on how to determine heart rate and heart rhythm
	Training	Demonstration of the behavior	Demonstration and joint completion of how to determine heart rate and heart rhythm
4) Interpretation, action, and motivation	Training	Instruction on how to perform a behavior	Explanations on the interpretation of values
	Enablement	Action planning	Explanations of what actions to take with different heart rates and rhythm constellations
	Training	Behavioral practice/rehearsal	Stand-alone repetition of a complete PSP procedure (technique, determination of heart rate and heart rhythm, interpretation of values)
	Training	Habit formation	Prompt to perform a PSP at least twice a day: in the morning after breakfast and in the evening after dinner
	Training	Behavioral practice/rehearsal	Emphasis on and motivation to practice PSP more than two times/day in the first days after intervention
5) Delivery of supplementary material	Enablement	Verbal persuasion about capability	Verbal positive reinforcement of participants PSP capability
	Education	Information about health consequences	A fact sheet containing key information, illustrations, and explanation of the PSP process, with recommendations regarding sign and symptom management in the form of an algorithm displayed in a flowchart
	Education	Self-monitoring of behavior	Provision and explanation of a pulse diary where the values of heart rate and heart rhythm can be noted

BCT behavioral change techniques, PSP pulse self-palpation, PSPAF pulse self-palpation for patients with atrial fibrillation-intervention

Participant characteristics

Various socio-demographic and clinical characteristics were assessed via a self-reported questionnaire (Q1).

Intervention acceptability

Acceptability was operationalized into five attributes [61]: (1) appropriateness, (2) perceived effectiveness, (3) perceived disadvantages of the intervention, (4) suitability, (5) willingness, and (6) adherence. Attributes 1 to 5 were measured through a self-reported questionnaire consisting of two parts (Q2.A.I and II) containing 11 items in total and that were framed based on the suggestions of Francisco and Butterfoss [65]. Adherence to PSP was measured based on the number of entries in a pulse diary (D1) relative to the individual period between the date of intervention and the home visit. This was calculated as the number of entries presented divided by the number of possible entries. A participant was considered to be adherent to PSP if $\geq 80\%$ of the possible entries in the pulse diary were filled out.

Intervention feasibility

Feasibility was operationalized into three components [61]: (1) context/resources (i.e., the existence of enough suitable rooms for delivering the intervention), (2) fidelity of intervention implementation (i.e., clarity, comprehensiveness, and logical sequencing of the information given to patients), and (3) time needed for delivering the intervention. Context/resources were determined through field notes (F2). In order to assess the fidelity of intervention implementation and time for interventions, every session was audiotaped. Recordings were then rated by the principle investigator.

Research method feasibility

Feasibility of research methods was determined with regard to three domains according to Thabane et al. [66]: (1) process, (2) resources, and (3) management. The domain process was comprised of the recruitment and data collection processes. It was assessed through field notes (F1) and a checklist (C0). Additionally, data were collected on attrition. The extent of treatment

Table 2 Description of outcome variables, instruments, and cut-off points

Outcome variable	Label of instrument	Description of instrument Type of instrument Sub-concept/-variable Items/scales/assessment	Time of measurement; group	Scale calculation/cut-off points
Demographic and clinical characteristics of participants	Q1	<p><i>Self-reported questionnaire</i></p> <p>Demographic data (4 items)</p> <ul style="list-style-type: none"> Age (in years) Sex Housing situation (living alone; with another person) Highest educational qualification <p>Clinical characteristics (4 items)</p> <ul style="list-style-type: none"> Years of diagnosis of AF (in years) Experience in pulse self-palpation (yes, no) Presence of an electronic device for pulse measurement at home (yes, no) Regular implementation of pulse self-measurement at home (no, yes [multiple times a day; once per day; not daily, but multiple times per week; not every week, but multiple times per month; not every month, but multiple times per year]) 	T ₁ ; IG and UCG	
Acceptability of intervention	Q2.A1	<p><i>Self-reported questionnaire</i></p> <p>Assessment of appropriateness of the intervention (7 items)</p> <ul style="list-style-type: none"> Usefulness of intervention (5-point Likert-scale, very useful–not useful) Importance of learning PSP when suffering arrhythmias (5-point Likert-scale, very important–not important) Liking of intervention (5-point Likert-scale, very much–not at all) Would participants recommend the intervention to others (yes, no) Appraisal of duration of intervention (too short, accurate, too long) Appraisal of difficulty level of intervention (5-point Likert-scale, very easy–very difficult) Appraisal of comprehensibility of content of intervention (5-point Likert-scale, very easy to understand–very difficult to understand) 	T ₁ (directly after intervention); IG	<p>The PSPAF intervention was considered acceptable to intervention participants when:</p> <ul style="list-style-type: none"> ≥ 75% will rate the intervention partly to very reasonable ≥ 75% will rate the intervention partly to very important ≥ 75% will like the intervention partly to very much ≥ 75% will eventually or definitively recommend the intervention to others ≥ 75% will rate the duration of the intervention as accurate ≥ 75% will rate the difficulty level of the intervention partly to very easy ≥ 75% will rate the comprehensibility of the intervention as partly to very high ≥ 75% will rate the intervention partly to very helpful ≥ 90% did not experience any negative consequences related to the intervention ≥ 75% will rate implementation of the content of the intervention in daily life partly to very easy ≥ 75% will rate the likelihood of continuing a daily PSP twice a day as likely to very likely ≥ 75% will be considered adherent to PSP (> 80% of possible entries are filled out)
	Q2.A11	<p><i>Self-reported questionnaire</i></p> <p>Assessment of perceived effectiveness (1 item)</p> <ul style="list-style-type: none"> Extent of how helpful the intervention was concerning dealing with AF in everyday life (5-point Likert-scale, very helpful–not helpful) <p>Assessment of perceived disadvantages (1 item)</p> <ul style="list-style-type: none"> Negative consequences of intervention (yes, no, do not know) <p>Assessment of perceived suitability (1 item)</p> <ul style="list-style-type: none"> Difficulty level of implementation of the content of the intervention in everyday life (5-point Likert-scale, very easy–very difficult) <p>Assessment of willingness of implementation (1 item)</p> <ul style="list-style-type: none"> Likelihood of continuing a PSP twice a day (5-point Likert-scale, very likely–very unlikely) 	T ₂ ; IG	
	D1	<p><i>Pulse diary</i></p> <p>Assessment of adherence to PSP</p> <p>Booklet consisting of a table with 35 lines and 10 columns. Each line represents a day and has two fields for indications of time of day, heart rate and regularity or irregularity of the measured pulse, respectively. A total of 70 pulse measurements could be recorded. An additional field was implemented for any specifics or further measurements.</p>	T ₁ –T ₂ ; IG	
Feasibility of the intervention	F2	<p><i>Field note form</i></p> <p>Boxes assessing date, location, the existence of enough suitable rooms for delivering the intervention, and the presence of relatives during the delivery of the intervention</p>	T ₁ (directly after intervention); IG	<p>The PSPAF intervention was considered feasible when:</p> <ul style="list-style-type: none"> The intervention can be delivered within 30 min,

Table 2 Description of outcome variables, instruments, and cut-off points (Continued)

Outcome variable	Label of instrument	Description of instrument Type of instrument Sub-concept/-variable Items/scales/assessment	Time of measurement; group	Scale calculation/cut-off points
Feasibility of research methods	Audio recording	<p><i>Audio recordings of intervention sessions</i></p> <p>Fidelity of intervention implementation (3 items)</p> <ul style="list-style-type: none"> ▪ Rating of clarity, distinctness, and comprehensiveness of language, and verbalizations of interventionist (each item, 4-point rating scale; not at all (0 points)–completely (3 points); single weighting) ▪ Rating whether the whole content and all components have been delivered as listed in the intervention manual (4-point rating scale, not at all (0 points)–completely (3 points), threefold weighting) ▪ Rating whether the whole content and all components have been delivered in the correct order as listed in the intervention manual (4-point rating scale, not at all (0 points)–completely (3 points), threefold weighting) <p>Time needed for delivering the intervention</p> <ul style="list-style-type: none"> ▪ Assessed by the length of audio recordings (minutes, seconds) 	T ₁ ; IG	<ul style="list-style-type: none"> – Fidelity to the intervention protocol will maintain at 85% – Appropriate and enough room will exist in ≥ 85% of sessions
	F1	<p><i>Field note form</i> (set up for every screening session)</p> <p>Process of recruitment (7 criteria)</p> <ul style="list-style-type: none"> ▪ Date ▪ Location ▪ Amount of screened individuals ▪ Amount of eligible individuals ▪ Amount of excluded individuals ▪ Amount of included individuals <p>Reasons for refusal</p> <ul style="list-style-type: none"> ▪ Free text (indication was voluntary) 	Stage of screening; Study coordinator	<p>Research methods was considered feasible when:</p> <ul style="list-style-type: none"> – Recruitment of the target number of participants ($n = 20$) was accomplished within 4 months of beginning the study – ≥ 80% of intervention participants attended the follow-up session (home visit) – Attrition will be ≤ 15% – ≥ 80% of data sets were completed – Treatment contamination occurred in ≤ 15% – ≥ 90% of participants perceived no or low burden of study participation
	C0	<p><i>Checklist</i></p> <p>Process of recruitment and documentation of eligibility criteria</p> <p>Assessment of occurrence of each in- and exclusion criterion for every screened individual</p>	Stage of screening; Study coordinator	
Burden of study participation	F3	<p><i>Field note form</i></p> <p>Resources and management (5 criteria)</p> <ul style="list-style-type: none"> ▪ Date ▪ Number of homes visits (on that day) ▪ Amount of driven kilometers (on that day) ▪ Amount of time (minutes) required for home visits and travel routes (on that day) ▪ Specifics (free text) 	T ₂ ; IG and UCG study assistant	
	Q2.C	<p><i>Self-reported questionnaire</i></p> <p>Assessment of treatment contamination (3 items)</p> <ul style="list-style-type: none"> ▪ Participation in a training to learn PSP 3–4 weeks since inclusion in study (yes, no, do not know) ▪ Reading or watching media reports containing a training to learn PSP 3–4 weeks since inclusion in study (yes, no, do not know) ▪ Advice or training to learn PSP through family physician 3–4 weeks since inclusion in study (yes, no, do not know) 	T ₂ ; UCG	
	Q2.B	<p><i>Self-reported questionnaire</i></p> <p>Burden of study participation (1 item)</p> <ul style="list-style-type: none"> ▪ Grading the statement “I felt burdened by participating in this study.” (5-point Likert- 	T ₂ ; IG and UCG	

Table 2 Description of outcome variables, instruments, and cut-off points (Continued)

Outcome variable	Label of instrument	Description of instrument Type of instrument Sub-concept/-variable Items/scales/assessment	Time of measurement; group	Scale calculation/cut-off points
Capability of PSP	C1	<p>scale, totally agree–totally disagree, translated into very high–no burden)</p> <p>Subscale: if burden was perceived → specification of kind of burden (3 items): psychological and/or physiological and/or financial burden</p> <p><i>Checklist</i> (for structured observation by study assistant)</p> <p>Structure (2 items)</p> <ul style="list-style-type: none"> ▪ PSP in rest (correct, wrong) ▪ Use of a clock with second hand (correct, wrong) <p>Process (5 items)</p> <ul style="list-style-type: none"> ▪ Location of measurement (correct, wrong) ▪ Technique of measurement (correct, wrong) ▪ Duration of the measurement (correct, wrong) ▪ Stating determined value of the heart rate (no, yes [value in bpm]) ▪ Stating determined value of the heart rhythm (no, yes [rhythmic, arrhythmic]) <p>Outcome (2 items)</p> <ul style="list-style-type: none"> ▪ Comparison of heart rate determined by the participant and heart rate determined by mobile ECG device (bpm) [verification of the value after consultation with a physician] (correct, wrong—heart rate was considered correct if heart rate measured by participants was ± 8 bpm in comparison to the ECG) ▪ Comparison of heart rhythm determined by the participant and heart rhythm determined by mobile ECG device [ECG evaluation by a physician, rhythmic/arrhythmic] (correct, wrong—heart rhythm was considered correct if the measurement of participants was equal to the evaluation of a physician) 	T ₂ ; IG and UCG	A participant is seen as capable of PSP if all 9 components are correct or fulfilled, respectively.
Sign and symptom management	V1-3/Vs1-3	<p><i>Mobile ECG device</i> ME 90; Beurer GmbH, Ulm</p> <p><i>Vignettes</i> (in written form) V1—physiologic values, V2—mild pathologic values, V3—severe pathologic values</p> <p>Sign and symptom management was rated “correct” or “wrong” by a study assistant by means of a standard solution for each vignette (Vs1-3).</p>	T ₂ ; IG and UCG	Participants were considered being able to manage signs and symptoms if they solved the vignette correctly.

AF atrial fibrillation; ECG electrocardiogram; IG intervention group; UCG usual care group; C0, Q1, Q2, F1, F2, C1, V1-3, Vs1-3 = assessment instruments; PSPAF pulse self-palpitation for patients with atrial fibrillation-intervention; PSP pulse self-palpitation; T₁, T₂ = time points

contamination [67] was assessed through a self-reported questionnaire (Q2.C). Resources and management domains were assessed by collecting data on the time spent for recruitment and on the field notes made by study assistants during home visits (F3).

Burden of study participation

Perceived burden of study participation was operationalized into the domains of psychological, physiological, and financial burden [68] and was assessed through a self-reported questionnaire (Q2.B).

Capability and sign-and-symptom management

Capability of performing PSP was operationalized into nine components, where all had to be fulfilled in order to rate a PSP as correctly performed. These components referred to the three dimensions of quality, i.e., structure, process, and outcome [69]. Capability was measured through a checklist (C1) and a mobile ECG device (ME 90; Beurer GmbH, Ulm).

Sign-and-symptom management was operationalized as the ability to correctly evaluate and respond to signs and/or symptoms of AF and was assessed using vignettes. Vignettes “comprise stimuli that selectively portray elements of reality to which research participants are invited to respond” (p. 918) and can appear in different forms [70]. They represent a practical, ethical, and cost-effective method to generate data [71] and can be used to assess perceptions, attitudes, and behaviors [70], and were used in the context of self-care decision-making [72]. For the purpose of this study, three different vignettes (V1–3) in written form were developed by the principle investigator and the study coordinator taking into account the recommendations of Hughes and Huby [73]. Each vignette briefly described a situation that contained a statement to heart rate and partly to symptoms in different severity levels (V1—physiologic values, V2—mild pathologic values, V3—severe pathologic values) and concluded with the question how participants would behave in this situation. Only one vignette at a time was presented to the participants for processing. The simultaneous processing of all three vignettes by all participants would have made it possible to compare them and thus facilitate their solution.

Vignettes were allocated during the randomization process under the proviso of an equal distribution in each group. In each group, V1 and V3 existed three times and V2 existed four times in a random sequence. Participants were considered capable of managing signs and symptoms if they correctly solved the vignette relative to a standard solution (Vs1–3).

Procedures and data collection

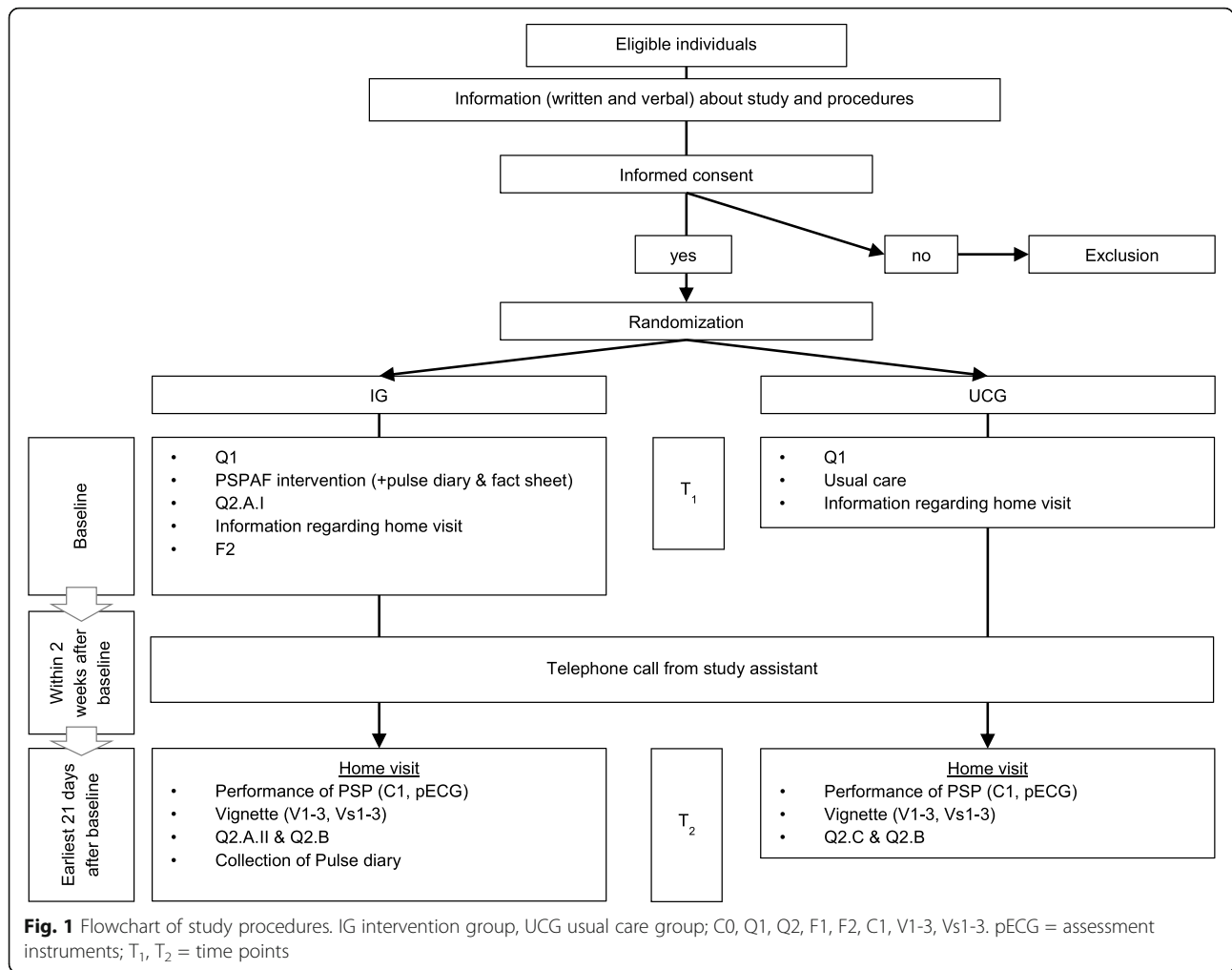
Recruitment and follow-up took place between September 2017 and March 2018. After consent and randomization, baseline data were collected for all study participants (data collection point 1 = T₁). Hereafter, participants in the IG received the PSPAF intervention and the pulse diary. After the session, participants in the IG filled out questionnaire Q2.A.I. Additional field notes (F2) were recorded by the study coordinator following each session. Participants in the UCG received care as usual, i.e., no education on pulse self-palpation.

In the first 2 weeks after enrollment, all participants received a phone call from a study assistant to schedule an appointment for a home visit (data collection point 2 = T₂) within a period of 3–5 weeks after the intervention. Prior to the home visit, questionnaires addressing the acceptability of the intervention and the burden of study participation (IG) or on treatment contamination and the burden of study participation (UCG) were mailed to participants. A study assistant blinded to group allocation performed all home visits. During these visits, participants of both groups were asked to perform a PSP and their capability was assessed followed by an ECG recording using the mobile device. The assigned vignette was then presented to participants and they were asked to tell which action they would take in the depicted situation. The answer given was then rated by the study assistant with respect to the standard solution (Vs1–3). Finally, pulse diaries (only IG) and questionnaires were collected. After every home visit, the study assistant filled out a field note form (F3). A flowchart of the study procedures is provided in Fig. 1.

Data analysis

Data were entered by the study coordinator. An independent study assistant randomly selected 50% of datasets and screened them for data entry accuracy prior to analysis. Potential entry errors were counted and corrected. A rate of entry errors greater than 10% would have had resulted in a complete revision and review of all data sets. The data were analyzed according to the intention-to-treat principle using IBM SPSS Statistics for Windows, version 22 (IBM Corp., Armonk, N.Y., USA) and Microsoft Excel 2013 (Microsoft, Redmond, Washington, USA).

Frequencies and percentages were calculated for all variables as appropriate. Means and standard deviations (SD) were calculated for normally distributed data. Medians (Mdn) and interquartile ranges (IQR) were calculated for non-normally distributed data. Validation of the acceptability and feasibility of the intervention, as well as of the feasibility of research methods was ascertained by predefined cut-off points (Table 2). Effect size estimates were calculated for capability and sign-and-



symptom management and expressed as relative risks (RR) with 95% confidence intervals (CI) and as number needed to treat (NNT). In case of a value of zero in any cell of the contingency tables, we added plus one to every cell to allow for RR calculation. Missing values were descriptively summarized and their pattern was analyzed using Little’s Missing Completely at Random test. Cases with missing data were pairwise deleted in the respective statistical analysis.

Results

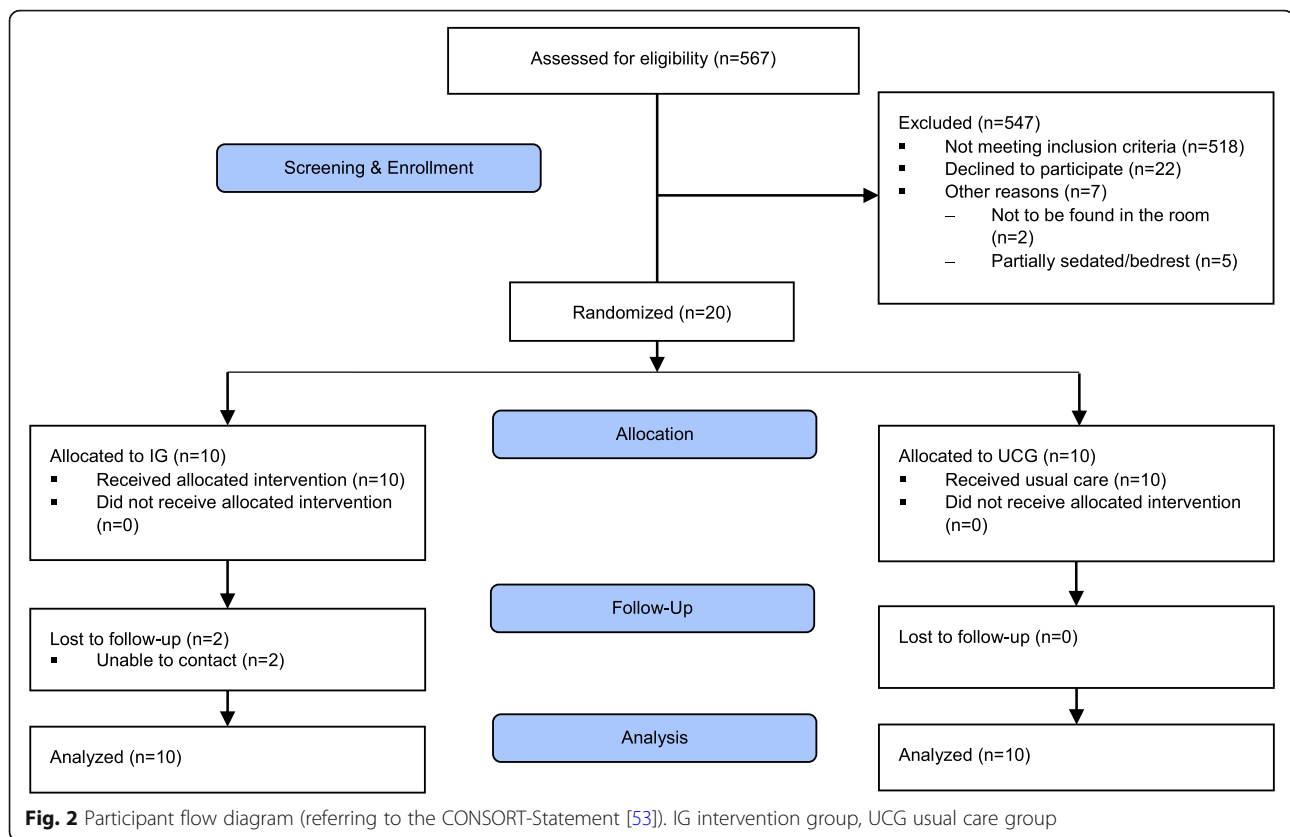
Sample

For this study, a consecutive sampling approach was used. Figure 2 shows participant flow throughout the trial in a diagram according to the CONSORT statement extension to randomized pilot and feasibility trials [53]. Details on screening and recruitment are described later in the “Feasibility of research methods” section. The sample consisted of 20 individuals (70% male) with a mean age of 68.1 years (SD = 10.3; range = 43–84). Time since the diagnosis of AF ranged from 0.04 to 24 years

(Mdn = 2.6; IQR = 0.2–8.8). Thirteen participants (65%) were living with another person in the same household. Sixteen participants (80%) held either a primary or a secondary school degree. Eight participants (40%) stated having experiences with PSP and 16 (80%) possessed an electronic device for pulse measurement. Six participants (30%) measured their pulse once or multiple times a day, whereas a quarter of participants (n = 5) had never measured their pulse at home (Table 3).

Acceptability of the intervention

Immediately after the intervention (T₁), participants of the IG (n = 10) rated it as follows: very useful (50%), rather useful (40%), or partly useful (10%) and also very important (80%) or rather important (20%). The intervention was rather liked (30%) or very much liked (60%) and all participants of the IG stated they would recommend it to others. The intervention was rated as having an accurate duration (100%), an easy level of difficulty (90%), and as easy to comprehend (100%).



At T₂, five participants (71.4%) of the IG ($n = 7$) perceived the intervention as being helpful or very helpful in dealing with AF in everyday life. No participant perceived negative consequences in relation to the intervention. However, one participant (14.3%) did not know whether a negative consequence was perceived or not. For 57.1% of the IG, the intervention was very easy to implement into daily life. One participant (14.3%) perceived it as partly easy/difficult, whereas two participants (28.6%) had great difficulties with the implementation into daily life. The self-reported probability of continuing a daily PSP twice a day was likely or very likely for 71.4% of the IG. All negative ratings on T₂ were made by the same individuals.

Eight pulse diaries (80%) of the participants could be collected. The median time between intervention and home visit to observe the adherence to PSP was 26 days (IQR = 25.5–32.0; range = 19–54). Four participants (50%) filled out 87–100% of possible diary entries and were therefore considered to be adherent to PSP. Four participants (50%) were considered to be non-adherent because only 0–47% of possible diary entries were completed (Fig. 3). Seven out of the 12 preliminary cut-off points to validate acceptability of the intervention were reached (Table 4).

Feasibility of the intervention

No relative was present during any of the intervention sessions. The median duration of the interventions was 17:41 min (IQR = 15:40–19:19; range = 11:07–24:42). The median rate of the fidelity of intervention implementation was 92.6% (IQR = 85.2–96.3; range = 70.4–100). In eight of the intervention sessions, minor comprehension limitations were observed due to the use of technical terms by the interventionist. In two sessions, the cut-off rate (85%) was not reached due to comprehension problems in combination with minor deviations in content. All preliminary cut-off points to validate the feasibility of the intervention were reached (Table 5).

Feasibility of research methods

Recruitment process

Recruitment of participants was accomplished on 16 dates, with a respective minimum interval of 7 days between dates. In order to reach the target number of participants, the recruitment phase lasted 134 days, exactly 12 days longer than the cut-off period of 4 months.

A total of 567 electronic health records or individuals were screened and assessed for eligibility. Of these, 525 individuals (93%) were ineligible to participate in the trial. Of 42 eligible patients, 20 consented to become participants, representing a recruitment rate of 50% (Fig. 1). The

Table 3 Demographic and clinical characteristics of study groups

	IG (n = 10)	UCG (n = 10)
Mean age in years (SD, range)	65.8 (11.2, 43.0–78.0)	70.3 (9.3, 55.0–84.0)
Median number of years with diagnosis of AF (IQR, range)	0.9 (0.1–8.5, 0.04–20.0)	4.0 (0.8–10.0, 0.06–24.0)
Sex	n (%)	
Female	2 (20%)	4 (40%)
Male	8 (80%)	6 (60%)
Housing situation		
Living alone	5 (50%)	2 (20%)
Living together with another person	5 (50%)	8 (80%)
Highest educational qualification		
None	0 (0%)	0 (0%)
Primary/main school	4 (40%)	4 (40%)
Secondary school	4 (40%)	4 (40%)
Polytechnic school	0 (0%)	0 (0%)
High school	1 (10%)	2 (20%)
University	1 (10%)	0 (0%)
Existing experience in PSP		
Yes	3 (30%)	5 (50%)
No	7 (70%)	5 (50%)
Presence of an electronic device for pulse measurement at home		
Yes	7 (70%)	9 (90%)
No	3 (30%)	1 (10%)
Regular implementation of pulse self-measurement at home		
No	3 (30%)	2 (20%)
Multiple times a day	0 (0%)	1 (10%)
Once per day	3 (30%)	2 (20%)
Not daily, but multiple times per week	3 (30%)	1 (10%)
Not every week, but multiple times per month	1 (10%)	2 (20%)
Not every month, but multiple times per year	0 (0%)	2 (20%)

IG intervention group, IQR interquartile range, PSP pulse self-palpation, SD standard deviation, UCG usual care group

main reasons for refusal were (1) concerns that participation would be too burdensome, (2) no interest or doubts about the meaningfulness of the intervention, or (3) organizational reasons (i.e., immediate discharge or transfer).

Eligibility criteria

The three most common inapplicable inclusion criteria were “living within a 30 min car ride to the participating health care center” (449 times, 79.2%), “diagnosis of

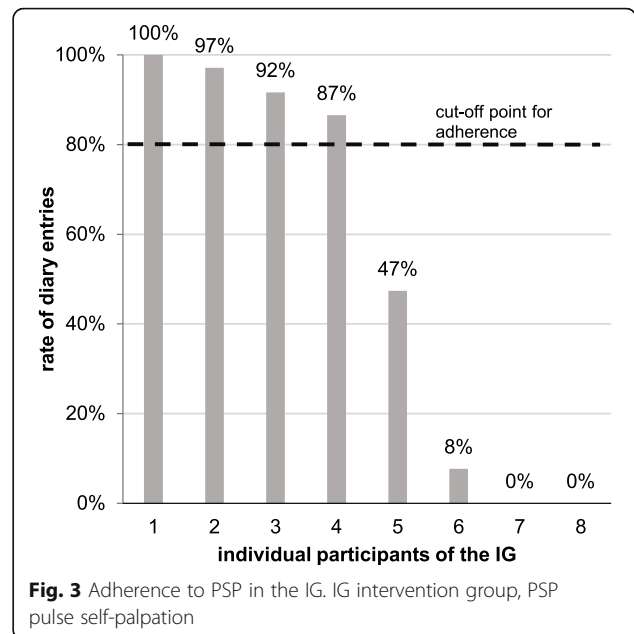


Fig. 3 Adherence to PSP in the IG. IG intervention group, PSP pulse self-palpation

paroxysmal or persistent AF” (279 times, 49.2%), and “being able to read, write and understand German” (66 times, 11.6%). Moreover, 174 individuals (30.7%) were excluded due to living outside the predefined geographical area. The most commonly occurring exclusion criteria were “physical impairment of both hands” (22 times, 3.9%) and “cognitive impairment” (19 times, 3.4%). Additionally, 19 patients (3.4%) were excluded because of reasons not described in the exclusion criteria. These reasons could be summarized in two categories: (1) patient is sedated or on bedrest and/or (2) patient could not be found in his/her room.

Follow-up and missing data

Overall, 18 participants (90%) attended the home visit at T₂. Two participants of the IG were unavailable for scheduling a home visit, representing an attrition rate of 10%. Another participant from the IG did not complete the questionnaires on T₂, but took part in the home visit. During a visit to a UCG participant, no ECG could be recorded due to technical difficulties. Complete data sets were available for 16 participants (80%) (IG, 7/70%; UCG, 9/90%). Ultimately, there were no missing data for T₁, and at T₂, the rate of missing data ranged from 10 to 30%. There was no consistent pattern for missing data.

Treatment contamination

Treatment contamination could not be observed. During the study period, no participant of the UCG (n = 10) took part in a PSP training, read or watched any media containing elements of PSP training, or received advice and/or training from a general practitioner to learn PSP.

Table 4 Acceptability of the PSPAF intervention and cut-off points

Preliminary cut-off points	Threshold (%)	Observed values (%)	Cut-off point reached?
The PSPAF intervention was considered acceptable when participants...			
1. Rated the intervention partly to very useful	≥ 75	100	Yes
2. Rated the intervention partly to very important	≥ 75	100	Yes
3. Liked the intervention partly to very much	≥ 75	100	Yes
4. Will eventually or definitively recommend the intervention to others	≥ 75	100	Yes
5. Rated the duration of the intervention as accurate	≥ 75	100	Yes
6. Rated the difficulty level of the intervention partly to very easy	≥ 75	100	Yes
7. Rated the comprehensibility of the intervention as partly to very high	≥ 75	100	Yes
8. Rated the intervention partly to very helpful concerning dealing with AF in everyday life	≥ 75	71.4	No
9. Did not experience any negative consequences related to the intervention	≥ 90	85.7	No
10. Rated implementation of the content of the intervention in daily life partly to very easy	≥ 75	71.4	No
11. Rated the likelihood of continuing a daily PSP twice a day as rather likely to very likely	≥ 75	71.4	No
12. Were considered adherent to PSP (> 80% of possible entries were filled out)	≥ 75	50.0	No

PSP pulse self-palpation, PSPAF pulse self-palpation for patients with atrial fibrillation intervention

Resources and management

During recruitment, the study coordinator had a time exposure of 3–5 h per date of recruitment. Study assistants accomplished 18 home visits. In total, study assistants covered 416 km (Mdn = 35; IQR = 16.3–70.5; range = 1–83) and had an overall time exposure of 1205 min (Mdn = 110; IQR = 90–148; range = 40–180) for the home visits.

Burden of study participation

Overall, 15 out of 17 participants (88.2%) experienced low or no burden throughout study participation. In the UCG (*n* = 10), no (70%) or a low burden was perceived. In the IG (*n* = 7), one participant experienced a very high burden (psychological and physiological) and another participant reported a partly (psychological) burden. No participant reported a perceived financial burden. Four out of the six preliminary cut-off points to

Table 5 Feasibility of the PSPAF intervention and cut-off points

Preliminary cut-off points to validate the feasibility of the intervention	Threshold	Observed values	Cut-off point reached?
1. Maximum timeframe for delivering the intervention	30 min	17:41 ^{a,b} (max = 24:42 ^b)	Yes
2. Rate of fidelity to the intervention protocol	≥ 85%	92.6% ^a	Yes
3. Rate of intervention sessions with appropriate and enough room	≥ 85%	100.0%	Yes

max maximum, PSPAF pulse self-palpation for patients with atrial fibrillation-intervention

^aMedian

^bMinutes:seconds

validate the feasibility of research methods were reached at T₂ (Table 6).

Capability

IG and UCG differed in terms of the capability of PSP. Four participants (50%) of the IG (*n* = 8) and no participant of the UCG (*n* = 10) were considered capable of performing PSP. This resulted in a RR of 6.0 (95% CI = [0.8, 43.3]) and a NNT of 2.4. When comparing individual components of a PSP, the highest RR values were observed for the reporting of the determined value of the heart rhythm, and in determining heart rate and rhythm. The lowest RR values were observed for performing a PSP in the rest state and in reporting the determined value of the heart rate (Table 7).

Table 6 Feasibility of research methods and cut-off points

Preliminary cut-off points to validate the feasibility of research methods	Threshold	Observed values	Cut-off point reached?
Recruitment of the target number of participants (<i>n</i> = 20) within 4 months of study initiation (= 122 days)	122 days	134 days	No
Attendance of intervention participants in follow-up sessions (home visits)	≥ 80%	90.0%	Yes
Attrition rate	≤ 15%	10.0%	Yes
Rate of complete data sets	≥ 80%	85.0% ^a	Yes
Rate of treatment contamination	≤ 15%	0.0%	Yes
Rate of participants having perceived no or low burden of study participation	≥ 90%	88.2%	No

IG intervention group, UCG usual care group

^aIG, 8/80% and UCG, 9/90%

Table 7 Group comparison regarding capability of PSP

Components of PSP	Rating	IG (<i>n</i> = 8) <i>n</i> (%)	UCG (<i>n</i> = 10) <i>n</i> (%)	RR (95% CI)
1) PSP in rest	Correct	5 (62.5)	4 (40.0)	1.6 (0.6–3.9)
	Wrong	3 (37.5)	6 (60.0)	
2) Use of a clock with second hand	Correct	6 (75.0)	3 (30.0)	2.5 (0.9–6.9)
	Wrong	2 (25.0)	7 (70.0)	
3) Location of measurement	Correct	6 (75.0)	4 (40.0)	1.8 (0.8–4.4)
	Wrong	2 (25.0)	6 (60.0)	
4) Technique of measurement	Correct	6 (75.0)	2 (20.0)	3.8 (1.0–13.8)
	Wrong	2 (25.0)	8 (80.0)	
5) Duration of the measurement	Correct	6 (75.0)	2 (20.0)	3.8 (1.0–13.8)
	Wrong	2 (25.0)	8 (80.0)	
6) Reporting determined value of the heart rate	Yes	5 (62.5)	4 (40.0)	1.6 (0.6–3.9)
	No	3 (37.5)	6 (60.0)	
7) Reporting determined value of the heart rhythm	Yes	4 (50.0)	0 (0.0)	6.0 (0.8–43.3)
	No	4 (50.0)	10 (100.0)	
8) Determined heart rate ^a	Correct	5 (62.5)	1 (11.1)	5.6 (0.8–38.5)
	Wrong	3 (37.5)	8 (88.9)	
9) Determined heart rhythm ^a	Correct	4 (50.0)	0 (0.0)	5.5 (0.8–39.4)
	Wrong	4 (50.0)	9 (100.0)	
Overall PSP performance	Correct	4 (50.0)	0 (0.0)	6.0 (0.8–43.3)
	Wrong	4 (50.0)	10 (100.0)	

IG intervention group, PSP pulse self-palpation, RR relative risk, UCG usual care group

^aOnly nine cases were analyzed in UCG because of missing values due to technical problems with the mobile ECG

Sign-and-symptom management

Six participants (75%) of the IG (*n* = 8) and five of the UCG (*n* = 10) solved the vignettes correctly, resulting in a RR of 1.5 (95% CI = [0.7, 3.1]) and a NNT of 4.0. Vignette V1 was solved correctly by all four participants (IG: *n* = 1; UCG: *n* = 3) and V3 was solved correctly by 83.3% (IG: *n* = 3; UCG: *n* = 2) of the participants (*n* = 6). Vignette V2 was answered incorrectly by 75.0% (IG: *n* = 2; UCG: *n* = 4) of the participants (*n* = 8).

Discussion

In this pilot trial, the PSPAF intervention was tested with respect to acceptability and feasibility. Moreover, the feasibility of research methods and the burden of study participation were assessed in combination with the calculation of effect size estimates of PSP capability and sign-and-symptom management. In summary, the PSPAF intervention seemed to be feasible, but only partly acceptable. The feasibility of applied research methods highlighted some limitations. While estimations of effect sizes seemed to correlate to an effect of the intervention on the capability of performing PSP, the effect on sign-and-symptom management remains unclear.

Acceptability and feasibility of the PSPAF intervention

The PSPAF intervention did not reach preliminary cut-off points at T₂; therefore, it could only be considered to be partially acceptable. The intervention seemed appropriate and comprehensible and had no negative consequences for participants. Yet it showed limitations in its potential effectiveness, suitability, and in addressing participants' willingness of implementing its content into daily life. The latter of which was also reflected in the rate of adherence to PSP. Two individuals experienced difficulties with including the intervention into daily life, resulting in zero pulse diary entries. The lack of one-third of the data at T₂ on this outcome further hinders a final judgment.

Overall, adherence to PSP was heterogenous, and two different groups could be observed. One group was adherent and the other was non-adherent to PSP. This differs from another pilot study [52] where 94% of participants filled out more than 88% of possible diary entries. Reasons for the lower rate in this study remain unclear as corresponding data were not collected. We hypothesize that self-efficacy (as a moderator and mediator of all elements of self-management [25]) and motivation (as an essential element of healthy behavior [74]) differed in participants, ultimately affecting their adherence. In addition, AF is associated with depression [8],

which in turn could have negatively affected adherence to self-monitoring [75]. Another possibility is a lower perceived level of disease controllability, thus affecting the willingness for regular self-monitoring [76]. Ideally, the intervention should encompass these aspects.

The PSPAF intervention could be considered feasible. It was completed within a short period of time, underlying its practicability in health care settings. However, this is based solely on one pilot study in one local setting. The fidelity of intervention implementation was high. Nevertheless, minor limitations were observed despite the interventionist being a co-developer of the intervention with prior advanced knowledge of its mechanisms and content.

Feasibility of research methods

Applied research methods could not be considered feasible because of a longer-lasting recruitment phase and an increased rate of burden throughout study participation.

The transgression of the originally defined recruitment phase was lower than 10% and might therefore be considered to be reasonable. The prolongation of the recruitment phase was due to delays in recruitment: numerous holidays during the recruitment phase and a large number of ineligible patients further highlight recruitment as one of the most common challenges in randomized controlled trials [77]. Interestingly, other studies with similar interventions showed lower recruitment rates (15–33%) [44, 51, 52]. In our trial, one-third of eligible individuals had to be excluded due to living outside the predefined geographical area suggesting the criterion to be too restrictive. However, given the constraints of this pilot study, including limited financial and personnel resources, this could not have been altered. Additionally, only half of eligible participants consented to study participation. The assessment of reasons for refusing participation aided in understanding why potential participants declined [78]. These reasons taken together, suggest that the potential disadvantages of participation outweighed the benefits when deciding to participate [79]. Furthermore, besides the supposition of a potential burden, some eligible individuals were concerned about the meaningfulness of the intervention. Similar to the assumption of Koller et al. [80], the latter could be partially attributed to the fact that clinical nursing research in Germany, especially at the study site, is still quite novel. Patients are not familiar with this branch of science and could have been reluctant to participate. Adaptations and improvements of recruitment strategies could perhaps change presuppositions of potential participants towards perceiving studies to be more beneficial, which could enhance recruitment rates [77, 79, 81].

Two participants of the IG experienced a notable psychological and physiological burden throughout study participation. A comparable pilot study found a low rate of participant burden [52]. However, the burden was not specified as it was in our study and the participants obtained monetary incentives for several data collection points, potentially altering their experience. Due to the subjective nature of perceiving burden [68] and since we did not further investigate detailed reasons for these kinds of burden, we can only speculate about potential reasons.

In addition, the possible influence of the intervention must be considered. Although no participant experienced negative consequences from the intervention, there could have been an effect on their perceptions. In the literature, the following possible reasons are mentioned: proactive involvement with AF in terms of self-management was distressing [82], and too much time and cognitive efforts were required [64]. It must also be considered that the two participants of the IG who were lost to follow up did not continue participation because of burden. Although definitive reasons for the burden of study participation remain unknown, there are indications for potential burden that need to be monitored in a future trial.

Effect size estimates

The probability of being capable of PSP was six times greater in the IG compared to the UCG. The RR suggests a large effect of the PSPAF intervention [83] concerning the capability of carrying out PSP that is considered to be clinically significant [84]. However, the broad confidence interval reveals the inaccuracy of this value and by including the value 1, there is a risk of no effect at all. This also applies to the individual components of a PSP. The small NNT [85] indicates that on average, two patients would have had to receive the PSPAF intervention (instead of usual care) for at least one additional patient to be capable of performing PSP. We might therefore assume, albeit with caution, that the intervention could have improved this capability, which is consistent with the findings of other studies with similar interventions [38, 44, 45].

With respect to sign-and symptom-management, group differences were smaller. The probability of correctly solving the vignette was 50% greater in the IG compared to the UCG. The RR suggests almost no effect of the PSPAF intervention concerning sign-and-symptom management knowledge [83], but it could also be considered to be clinically significant [84]. Furthermore, the confidence interval includes the value 1, which in turn implies no effect. The NNT indicates that on average, four patients would have had to receive the PSPAF intervention (instead of usual care) for at least

one additional patient to show correct knowledge about sign-and-symptom management. Although this ratio seems to be acceptable [85], the effect of the intervention seems questionable. Other studies have investigated a similar outcome and observed greater effects but our findings are hardly comparable due to differences in operationalization [52] and/or methodology [38].

Limitations

The present study has several limitations. Consecutive sampling and restrictive eligibility criteria reduced the external validity of our results [86]. Furthermore, the small sample size, which might be reasonable for a pilot study [87], undermines statistical conclusion validity [88]. Missing data and the practice of pairwise deletion further contribute to this fact. In our study, it mostly affected the determination and accuracy of effect sizes, which in any case tend to be larger in pilot trials than in a definitive trial [88]. Although pilot trials do not provide meaningful effect sizes [89], it is possible to investigate the potential mechanisms of efficacy for a new intervention [87]. Therefore, only an estimation of effect sizes has been intended in our study but the results must be regarded as preliminary and interpreted with caution.

Another limitation is the exclusive use of newly developed instruments for data collection without having information regarding the psychometric properties based on systematic analysis. Although the instruments may be considered to be face valid [90], and verbal probing as well as think-aloud interviews can strengthen content validity and the reliability of instruments [64], they cannot be considered to be fully valid or reliable. This results in the potential of imprecise measurements, which ultimately have implications on statistical conclusion validity [91]. Above all, drawing inferences from diary entries about adherence remains uncertain as evidence indicates that some patients do not use diaries despite recommendations [92]. The same is true for the use of vignettes as indicators of sign-and-symptom management. Despite their advantages in examining judgments and decisions [93], their accuracy is unknown and questionable [88] and, thus, may have biased the results.

Lastly, it cannot be confirmed that the blinding of study assistants was always maintained. Study participants may have imparted their group appointment to the assistant and/or assistants may have drawn conclusions due to improperly packed documents collected at T₂. These circumstances may have led to reduced objectivity of study assistants' judgements [94], and possibly resulted in incorrect ratings.

Implications

Based on the results of this study, we formulate the following suggestions and recommendations regarding the

PSPAF intervention with a possible progression to a future definitive trial.

The intervention could be enhanced with encouraging elements to improve the motivation and adherence of participants. Using elements of motivational interviewing [74, 95], stressing the advantages of the intervention and the diary [92] and encouraging an increased involvement of relatives [75] could be conceivable. Furthermore, the use of telephone calls shortly after the intervention should be considered as a means to identify and address difficulties of participants and facilitating implementation and adherence [75].

In order to allow for a larger sample, the inclusion criterion limiting the geographical area should be adjusted. Recruitment should be performed at different centers, and recruitment strategies optimized through adaptation of the written study information and personnel training. At last, the relocation of the follow-up assessment to a central location in combination with incentives for participants should be considered in order to decrease the number of or complete avoidance of home visits.

Participant burden should be monitored. The aforementioned telephone call would offer the possibility to identify and reduce patient burden. This topic will be best addressed in a future qualitative sub-study to explore the specific burden of study participants.

The instruments assessing the main study outcomes (capability, sign-and-symptom management, adherence) must be evaluated for their validity and reliability, so as to ensure precise measurements and valid statistical calculations. The fidelity of intervention implementation has to be ensured through careful training of interventionists [96] and should optimally be monitored continuously by two experts (rater, interrater), in order to warrant a high level of objective ratings and a good quality of intervention implementation.

Procedures to support study blinding have to be strictly observed in order to reduce the risk of bias. Data collectors require careful briefing on this topic and study participants need to be urged to not communicate information regarding group appointment and/or received intervention.

Further investigations should also include an analysis of correlations between demographic and clinical characteristics and outcomes, which could identify possible determinants for outcome measures, as observed in other studies [42, 44].

Conclusions

Results of the present pilot trial contribute to a better understanding of the PSPAF intervention, afford a first impression of its possible effects, and provide information for planning a follow-up study. At large, the intervention appears to be promising and applicable and

could be optimized with a few adjustments. Due to methodological restraints, the true effects of the intervention remain vague and need to be further examined in a fully powered trial. We recommend conducting a full-scale trial with respect to the suggestions and amendments mentioned above in an effort to ensure the benefit and efficacy of the PSPAF intervention. For planning and conducting such a trial, investigators can use the results obtained in this pilot trial.

Supplementary information

Supplementary information accompanies this paper at <https://doi.org/10.1186/s40814-020-00624-y>.

Additional file 1. CONSORT extension for Pilot and Feasibility Trials Checklist for the PSPAF Pilot Trial.

Abbreviations

AF: Atrial fibrillation; BCT: Behavioral change techniques; C0: Checklist to assess the feasibility of research methods; C1: Checklist to assess the capability of PSP; CI: Confidence interval; D1: Pulse diary (assessment of adherence to PSP); ECG: Electrocardiogram; F1: Field note form to assess the feasibility of research methods; F2: Field note form to assess the feasibility of the intervention; F3: Field note form to assess the feasibility of research methods; IG: Intervention group; IQR: Interquartile range; max: Maximum; Mdn: Median; NNT: Number needed to treat; PSP: Pulse self-palpation; PSPAF intervention: Pulse self-palpation for patients with atrial fibrillation intervention; Q1: Self-reported questionnaire to assess demographic and clinical characteristics of participants; Q2.A.I: Self-reported questionnaire to assess the acceptability of intervention at T₁; Q2.A.II: Self-reported questionnaire to assess the acceptability of intervention at T₂; Q2.B: Self-reported questionnaire to assess the burden of study participation; Q2.C: Self-reported questionnaire to assess the feasibility of research methods; RR: Relative risk; SD: Standard deviation; T₁: Data collection point 1; T₂: Data collection point 2; UCG: Usual care group; V1-3: Vignettes to assess sign and symptom management; Vs1-3: Standard solutions for vignettes V1-3

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Authors' contributions

SJ designed the pilot trial, developed assessment instruments, performed as interventionist, coordinated the study assistants, performed statistical analysis, and wrote the manuscript. SK supported the development of assessment instruments and rated the audio recordings of the intervention sessions. LL and SK supervised this trial and supported the preparation of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This pilot trial followed the conditions of the Declaration of Helsinki [97] and the ethical principles of beneficence, respect for persons, and justice as described in the Belmont Report [98]. All participants received essential information in oral and written forms and needed to provide written consent to participate. Participation was voluntary and could have been stopped anytime and without stating any reason. Furthermore, patient-related data were pseudonymized by using IDs and stored in a locked

cabinet and password-protected database. Study personnel with partial access to data signed a non-disclosure agreement.

Approval for this pilot trial was obtained from the Ethics Committee at the University of Freiburg (registration number: 407/17). The study was registered after ethical approval at the German Clinical Trials Register (Main ID: DRKS00012808) [99], a primary study register approved by the World Health Organization.

Consent for publication

Not applicable

Competing interests

All authors declare no competing interests.

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