



University of Southern Denmark

**Development of an online psychological intervention to prevent depression in patients with atrial fibrillation
lessons learned in a user-centered design study**

Helmark, Charlotte; Ahm, Robert; Brandes, Axel; Skovbakke, Søren J; Nielsen, Jens Cosedis; Frostholm, Lisbeth; Taylor, Rod S; Pedersen, Susanne S

Published in:
Pilot and Feasibility Studies

DOI:
[10.1186/s40814-024-01586-1](https://doi.org/10.1186/s40814-024-01586-1)

Publication date:
2025

Document version:
Final published version

Document license:
CC BY-NC-ND

Citation for published version (APA):

Helmark, C., Ahm, R., Brandes, A., Skovbakke, S. J., Nielsen, J. C., Frostholm, L., Taylor, R. S., & Pedersen, S. S. (2025). Development of an online psychological intervention to prevent depression in patients with atrial fibrillation: lessons learned in a user-centered design study. *Pilot and Feasibility Studies*, 11, Article 2. <https://doi.org/10.1186/s40814-024-01586-1>

Go to publication entry in University of Southern Denmark's Research Portal

Terms of use

This work is brought to you by the University of Southern Denmark.
Unless otherwise specified it has been shared according to the terms for self-archiving.
If no other license is stated, these terms apply:

- You may download this work for personal use only.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying this open access version

If you believe that this document breaches copyright please contact us providing details and we will investigate your claim.
Please direct all enquiries to puresupport@bib.sdu.dk

RESEARCH

Open Access



Development of an online psychological intervention to prevent depression in patients with atrial fibrillation: lessons learned in a user-centered design study

Charlotte Helmark^{1,2*} , Robert Ahm², Axel Brandes³, Søren J. Skovbakke², Jens Cosedis Nielsen⁴, Lisbeth Frostholm⁵, Rod S. Taylor^{2,6} and Susanne S. Pedersen^{2,7}

Abstract

Background Approximately 30% of patients with atrial fibrillation suffer from depression. Depression in patients with atrial fibrillation is associated with poor health outcomes, reduced health-related quality of life, and elevated societal costs. Preventing depression in this population may therefore lead to better health outcomes for the individual patient and reduced burden on society. Online psychological interventions are innovative and evidence-based modes of healthcare delivery. The objective was—through a user-centered design—to develop a personalized online psychological intervention aiming at preventing depression in patients with atrial fibrillation.

Methods Guided by the Intervention Mapping framework for the development of complex interventions, we used a qualitative design and conducted a series of collaborative workshops with patients ($n=8$) with atrial fibrillation.

Results Through intensive collaboration, we developed the HOPE-AF intervention targeting nine risk factors for depression that were meaningful to patients. It contains four basic modules that give effective tools to handle daily psychological struggles. Furthermore, patients will receive personal risk factors modules. The evidence-based psychological methodology was applied to all modules. Primary lessons learned were (1) engaging patients from the start to ensure the intervention becomes meaningful; (2) using positive phrasing in all patient-related materials to promote motivation; (3) incorporating patients' choice of preference where possible to personalize the intervention.

Conclusion Based on a user-centered design, the HOPE-AF intervention aiming to prevent depression in patients with AF, was developed. It was confirmed that it is crucial to engage end-users in the development of complex interventions to accommodate their needs and preferences. The Hope-AF intervention will now be tested in a feasibility study.

Keywords Atrial fibrillation, Depression, EHealth, Patient engagement, Prevention, User-centered design

*Correspondence:
Charlotte Helmark
kche@regionsjaelland.dk
Full list of author information is available at the end of the article



© The Author(s) 2025. **Open Access** This article is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License, which permits any non-commercial use, sharing, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if you modified the licensed material. You do not have permission under this licence to share adapted material derived from this article or parts of it. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by-nc-nd/4.0/>.

Key messages regarding feasibility

- A new online psychological intervention aiming at preventing depression in patients with atrial fibrillation has been developed. Its acceptability will now be tested in a feasibility study.
- Engaging the target population in the development phase has been crucial to meeting patients' individual needs and preferences, and may optimize motivation and adherence to the intervention.
- The lessons learned in this study have contributed to the design of a personalized online psychological intervention that appears attractive and manageable to the target population.

Background

Atrial fibrillation (AF) is the most common cardiac arrhythmia with an increasing incidence and a global prevalence of approximately 3% in adults [1]. AF is currently considered a global public health crisis, which can be attributed to the aging of the population [1]. Patients with AF frequently experience severe and disabling physical symptoms, such as palpitations, dyspnea, and fatigue, but also psychological challenges, such as anxiety and depression, and impaired health-related quality of life (HRQoL) [2]. Patients with AF tend to continuously focus on the body's signals, which may lead to difficulties accepting the disease. This is often paired with psychological reactions, such as excessive worry and anxiety, increasing withdrawal from social activities, with the risk of depression [3]. The prevalence of depression and anxiety in patients with AF ranges from 28 to 38%, with women being at greater risk of developing depression as compared to men [3]. Generally, depression in cardiac patients is associated with poorer HRQoL, greater risk of cardiovascular events [4], and increased costs [5], calling for the development of evidence-based preventive treatment interventions.

Evidence-based interventions for the treatment of depression in cardiac patients include psychotropic medication, exercise-based cardiac rehabilitation, and psychological interventions [6–9], including online cognitive behavioral therapy [10, 11]. Prevention of depression in contrast to treatment, focuses on mitigating severe health risks for cardiac patients, which may not only reduce societal costs [5] but also help patients develop competencies that ensure better health-related quality of life for the individual patient. In addition, the prevention of depression may enhance adherence to AF treatment including living a healthy lifestyle, delaying the progression of AF, reducing complications, and improving quality of life [12–14]. Thus, the delivery of

effective preventive interventions is important on both patient and societal levels.

Previous studies show that preventive psychological interventions such as psychoeducation and cognitive behavioral therapy can reduce the risk of depression by 21–22% in the general population and in at-risk populations, respectively [15, 16]. Reported risk factors for depression in patients with AF are for instance excessive worry and loneliness [3]. To our knowledge, there are no studies investigating whether prevention of depression is feasible in patients with AF and lead to better outcomes. A recent Cochrane systematic review concludes that research in psychological interventions for patients with AF is warranted due to lack of evidence [17], meaning this subpopulation of cardiac patients is relevant to explore.

Digital health solutions are on the rise and have the potential to improve the treatment course due to a high degree of flexibility and autonomy for the individual patient and to reduce the need for staff at a time when a severe shortage of health care professionals is expected [18]. Delivery of online psychological interventions via a European Union General Data Protection Regulation (GDPR) secure web platform is an innovative model of care. It enables patients to access the intervention at any time of their convenience from any place, as long as they have access to the internet, which may increase the integration in patients' lives and thus, adherence to AF treatment [19, 20].

Online psychological interventions are complex due to the high number of components and large variation in the delivered components [21]. When designing and evaluating new and complex interventions the framework from the Medical Research Council in the United Kingdom recommends starting with engaging the key stakeholders in the development of the intervention, in terms of the target population and those who are professionally affected by the intervention [21]. This is in alignment with recommendations from the European Society of Cardiology, as patients are experts in living with their cardiac condition [22]. Failing to adopt a user-centered approach when designing online psychological interventions for somatic patients may result in low treatment adherence and a lack of efficacy of the intervention [23]. Hence, applying a user-centered approach to the development of an intervention increases the chance of efficacy and later successful implementation [21].

The purpose of this user-centered study is to develop an online psychological intervention to prevent depression in patients with AF, by means of identifying and targeting risk factors for depression in each individual patient, using a precision-medicine approach.

Methods

This study is based on a qualitative design, guided by the Intervention Mapping (IM) framework [24] and conducted through a series of workshops with key stakeholders. The study is reported in alignment with the GRIPP2-SF reporting guideline [25].

The development of a preventive online psychological intervention is the first phase of the HOPE-AF project and will be followed by a feasibility study (phase II) and a randomized controlled trial (RCT) (phase III). This approach is consistent with the Medical Research Council framework for developing and evaluating complex interventions [21].

The Intervention Mapping framework

IM is a planning approach building on theory and evidence to develop complex health interventions [24]. As the development of complex psychological interventions is sparsely and heterogeneously described, replicating and identifying key factors is difficult [26]. Thus, IM was chosen to support the development process and improve the reporting of the study as suggested in the literature [27, 28]. IM contains six iterative steps with the possibility to go back and forth between steps. These six steps are briefly illustrated in Fig. 1 as used in this study. The current article focuses on step 4 in IM—the development of the intervention.

Data collection

As preparatory work for the development of the HOPE-AF intervention, an exploratory literature search for risk factors for depression was performed to support the needs analysis in step 1, a Logic Model was created in step 2 (a graphic illustration of the relationship between a program's resources, activities, and its expected effects), and the evidence-based psychological methods chosen in step 3 (Fig. 1).

To ensure a user-centered intervention in step 4, collaborative workshops with patients diagnosed with AF were planned and conducted (Table 1). Data collection included audio recording and extensive notes. The workshops took place from February to June 2023 with 3–4 weeks between workshops. Each workshop lasted 3 h. Further expert and stakeholder opinions were collected to determine barriers and facilitators for successful future implementation [29].

Setting

Building on expert knowledge and results of the previous IM steps, a series of five workshops were planned and conducted. Overall, the interactive workshops were facilitated by the first author. The workshops contained

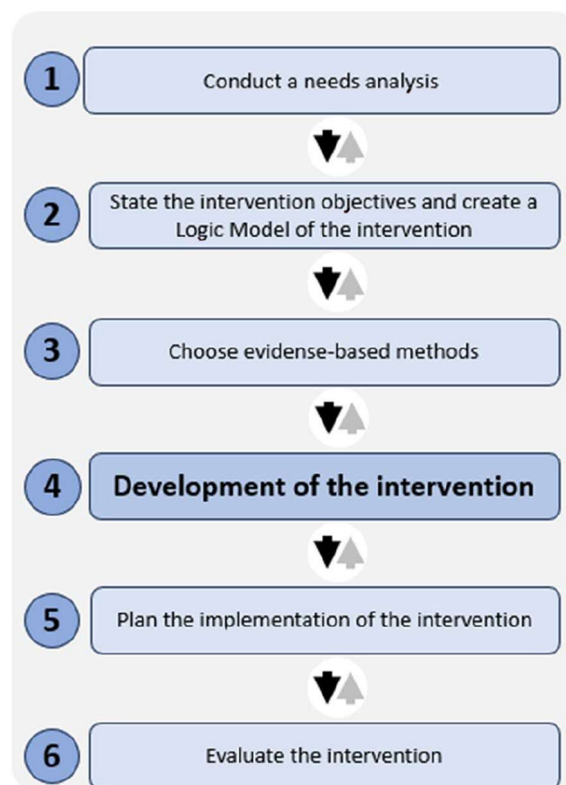


Fig. 1 The six steps in Intervention Mapping as used in this study

a mix of presentations, discussions, reflections, and tests of materials and contents. Prior to each workshop patients were asked to do some homework, e.g., reading intervention materials, testing questionnaires, and reflecting on potential barriers and facilitators for patients participating in the intervention. The homework was sent by email 1 week prior to each workshop with a description of the tasks, and/or handed out on paper when feasible. The patients could contact the team by email or phone in case needed. These five workshops took place at the University of Southern Denmark.

Despite efforts to recruit more men for the workshop, we failed at first. To ensure that the intervention did not lack important issues from men's perspective, we conducted an extra workshop. These patients were thoroughly prepared for the workshop via telephone and had beforehand read the results of the first five workshops. This workshop was mainly used for getting feedback on the adjustments made to the intervention and discussing barriers and facilitators for participating in the intervention from men's perspective. This workshop was conducted at Zealand University Hospital.

All workshops started out with an informal lunch, enabling small talk among patients and the research

Table 1 Overview of workshops

Workshop (participants)	Agenda	Short description	Homework prior to the workshop
Number 1 Four women	Welcome Pitch of the HOPE-AF study Online psychological interventions HOPE-AF logo Feedback on homework Q&A	<i>Introduction to the process</i> <i>Presentation of all participants</i> <i>Practicalities/confidentiality</i> <i>Presentation of the research project</i> <i>The purpose of engaging patients with AF in the development of the intervention</i> <i>Showcasing how modules may look online</i> <i>Engaging patients in the design of a logo</i> <i>Discussion of structure, language, figures, and extent of a test module on rumination</i> <i>Open discussion and reflections</i>	Reading through a basic module with a focus on text, readability, and understanding of assignments (11 pages including figures and assignments)
Number 2 Four women	Risk factors for depression Participation Key questionnaires Use of language and terminology Q&A	<i>Presentation and discussion of risk factors</i> <i>Discussion of barriers and facilitators for participation in this preventive intervention</i> <i>Presentation and discussion of questionnaires for primary outcome (HADS) and selected risk factors</i> <i>Feedback on adjusted text</i> <i>Open discussion and reflections</i>	Reading selected questionnaires for perceived relevance (HADS/CAQ/eHeals/PSS) Evaluating the adjusted module from workshop 1 with respect to adjusted text
Number 3 Four women	Participant information Missing features/content Types of assignments Remaining questionnaires Q&A	<i>Feedback on participant information</i> <i>Reflections on potential lacking content</i> <i>Feedback on various types of assignments</i> <i>Presentation of remaining questionnaires</i> <i>Open discussion and reflections</i>	Reading a flyer with "Participant information" with focus on barriers and facilitators for recruiting patients (Four short pages including figures/a folded A4 format) Reading the official "Participant information" with all rights and legislation (Four pages)
Number 4 Four women	Adjusted intervention Time consumption Yoga AF Q&A	<i>Discussion of adjusted intervention</i> <i>Discussion and reflections on patient-related time consumption in the intervention</i> <i>Presentation of test versions of yoga videos</i> <i>Q&A about AF (facilitated by cardiologist)</i> <i>Open discussion and reflections</i>	No reading material, but patients were asked to reflect on barriers and facilitators for patient engagement and adherence to the intervention
Number 5 Four women	HOPE-AF logo HOPE-AF intervention Recruitment Baseline questionnaire Wrapping up and next steps	<i>Presentation of the developed logo</i> <i>Discussion of the adjusted intervention</i> <i>Discussion of barriers and facilitators for recruitment</i> <i>Discussion of introductory text to the baseline questionnaire</i> <i>Information about next steps and the possibility to follow the process</i>	Reading through the introduction text to the baseline questionnaire with a focus on clarity of purpose with the questionnaires (Half page) Reading through an adjusted module with a focus on readability and understanding of assignments (Nine pages)
<i>Four men with AF in an extra workshop</i>			
Number 6 Four men	Welcome Pitch of the HOPE-AF study Men with AF Participant information Participation and recruitment Time consumption Q&A	<i>Introduction and purpose of the workshop</i> <i>Presentation of all participants</i> <i>Practicalities/confidentiality</i> <i>Presentation of the newly-adjusted HOPE-AF intervention</i> <i>Purpose of engaging men with AF</i> <i>Feedback on participant information</i> <i>Barriers and facilitators from men's perspective</i> <i>Discussion and reflections on patient-related time consumption in the intervention</i> <i>Open discussion</i>	Reading a flyer with "Participant information" with a focus on barriers and facilitators for recruiting patients (Four short pages including figures—a folded A4) Reading through the first basic module with a focus on readability and understanding of assignments (Nine pages)

team. Patients were asked to be respectful of each other's opinions and privacy, encouraged to contribute with their honest opinions, and asked any questions they had. All participants from the research team took

turns presenting and facilitating points for discussions. For all workshops, 10–15 min were set aside at the end to facilitate free discussions and to explore whether patients had aspects related to the intervention that had been overlooked.

Table 2 Patient characteristics (n = 8)

Variable	Total	Women	Men
Sex, n (%)	8 (100)	4 (50)	4 (50)
Age in years: mean (range)	70 (48–78)	67 (48–76)	72 (67–78)
Years with AF: mean (range)	9 (3–20)	7 (4–12)	11 (3–20)
Educational level. Bachelor or above, n (%)	5 (63)	3 (75)	2 (50)

Participants

Patients diagnosed with AF (paroxysmal or persistent) are the main end-users of the intervention and to gain variation in patient perspectives, we strived to include patients of different ages, sex, and education (Table 2).

Six patients (4 women and 2 men) were recruited from a course for patients with AF at the Danish Knowledge Centre for Rehabilitation and Palliative Care (REHPA); however, the men withdrew their consent due to severe comorbidity and lack of time, respectively.

Hence, from the Department of Cardiology, Zealand University Hospital, and via the Danish Heart Foundation, we recruited four men with AF to attend one “men-only” workshop.

Other key stakeholders participating in the workshops were two psychologists, a cardiac nurse, and a cardiologist. A designated student assistant participated in all workshops, handling practicalities, and taking extensive notes.

Ethics

Permission to conduct this study was obtained from the Danish Data Protection Agency through the Region of Southern Denmark (21–62,093). Ethical approval was obtained from the Regional Committees on Health Research Ethics for Southern Denmark (S-20230078). The study complies with the Helsinki Declaration and all patients provided written informed consent. Participation was voluntary and the participants did not receive payment but were reimbursed for the costs of transportation and received free catering.

Results

Maintaining an informal tone throughout the process of all workshops helped to promote a sense of cohesiveness in the group and increased engagement. Everybody contributed with spontaneous comments, questions, and reflections. Everybody also listened respectfully to individual experiences and opinions and frequently used humor. Patients had a wide spectrum of experiences and perspectives related to all facets of the intervention (e.g., wording used, exercises, and drawings).

The following results are presented as key components of the development of the HOPE-AF intervention.

Design of intervention

All patients were very satisfied by the fact that the intervention will be targeting patients with AF, as they felt that this subgroup of patients was neglected as compared to other cardiac subgroups. One patient expressed the following: “The doctors just tell me that it (AF) won’t kill me, but I still get symptoms, worry a lot and become insecure (woman, 76 years)”. This perceived relevance was the main reason for choosing to participate in the workshops.

The original idea of the intervention was to screen patients for five major risk factors for depression in cardiac patients (depressive symptoms, rumination, negative cognitive style, recent stressful event, and social isolation) and offer a psychological intervention that would target those risk factors where patients had a positive screen, using a precision medicine approach. However, after discussing and reflecting on various aspects of the risk factors, it was clear that this did not make sense to patients, and something was lacking:

“I’m not sure I get the risk factors, they are not that relatable (woman, 73 years)”

Using a collaborative approach, we adjusted and expanded the number of risk factors to nine (rumination, anxiety, low self-esteem, sleep disorders, loneliness, social isolation, stress, physical inactivity, and anhedonia). The patients were pleased by this new selection and found it meaningful.

After several discussions among all participants—both patients and the research team—the final structure for the intervention was agreed upon (Fig. 2). This structure balances variations in patients’ motivation for preventive treatment and the range of risk factors experienced by the patients.

Using a comprehensive baseline questionnaire, patients will be screened for the nine risk factors, using both validated questionnaires and purpose-designed questions. The intervention will begin with a diagnostic interview with the assigned therapist—a psychologist trained in delivering the intervention and a treatment manual will be available to ensure fidelity of the intervention delivery. After the interview, the therapist will present the patient with the results of the baseline questionnaire and the risk factors for depression identified. In a dialogue between the patient and the therapist, a decision will be made with respect to which modules will be part of the intervention for each individual patient.

All included patients—regardless of risk factors—will receive four basic modules, each designed to take 1 week

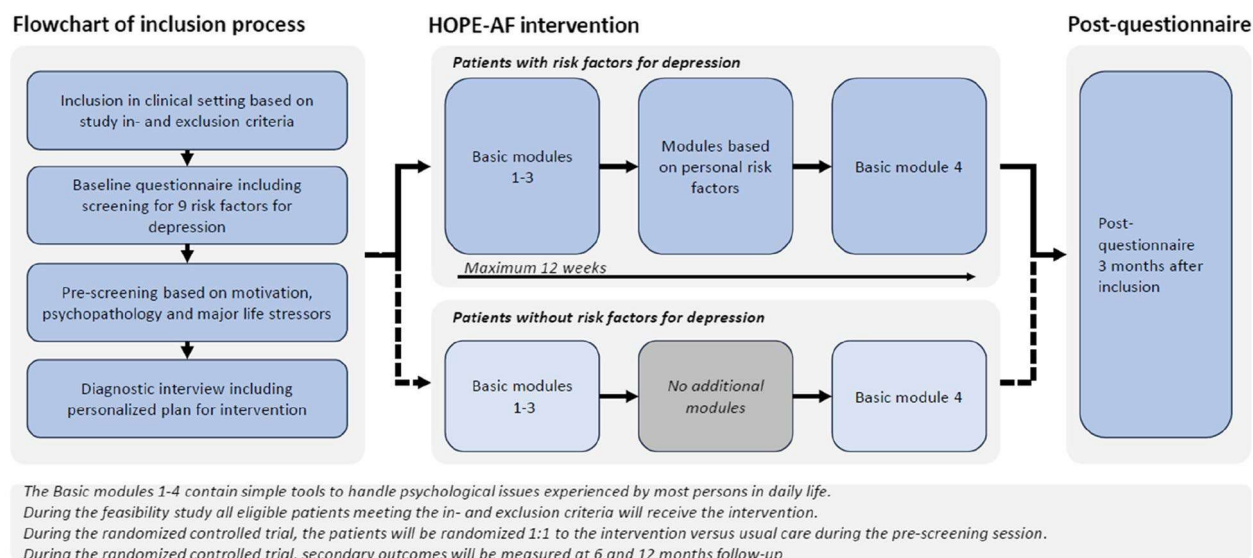


Fig. 2 The HOPE-AF intervention

to complete, adding to a total of 4 weeks. On top of the four basic modules, the patients will be assigned modules tailored to their individual risk factors. If a patient is not motivated to work with a specific risk factor, the module will not be administered. Patients will discuss with their therapist in which order the risk factor-specific modules should be completed to enhance engagement and obtain the greatest benefit of the intervention. Most modules are scheduled to take 1 week, but a few are scheduled to take 2 weeks due to the amount of assignments in the module. The intervention will last a maximum of 12 weeks. Thus, if a patient screens positive on all risk factors, the intervention will still be limited to 12 weeks. This structure was decided to ensure that patients would not feel the full intervention was too overwhelming. Patients with no current risk factors for depression are only administered the four basic modules. The basic modules contain psychoeducation, like an introduction to the cognitive diamond, and training in basic CBT techniques. Thus, the basic modules serve both as a prerequisite for risk factor-specific modules for patients with risk factors and as a self-contained preventive treatment for patients without risk factors.

Patients had different preferences with respect to whether contact with the psychologist during the intervention should be by phone or video. One patient said:

“I would not be able to have video consultations as I don’t have a webcam on my computer (man, 73 years)”

However, all agreed that it should be up to the individual patient’s preference and possibilities.

It was meaningful to patients with an extensive pre- and post-questionnaire to measure changes in risk factors during the intervention. In addition, patients requested a measure of their psychological state after each module, hence a tool for this was included (CORE-10) [30].

Psychological methodology

Building on the choices of evidence-based psychological methodology in the IM step 3 (Fig. 1), we adjusted the methodology in the intervention to match the agreed risk factors (Table 3). The women had confidence in the chosen methodology and found the content meaningful but pointed strongly at adding yoga videos, which we included. The men likewise had confidence in the approach posed by the women and were positive towards yoga despite none having any experience. To accommodate patients’ individual levels of physical capacity these videos contain different levels at which yoga can be conducted.

The treatment modules in HOPE-AF were developed by the research team, drawing on their expertise in creating internet-based psychological interventions [31]. The modules specifically address the nine identified risk factors and incorporate techniques from evidence-based therapies, including cognitive behavioral therapy, acceptance and commitment therapy, and metacognitive therapy (Table 3). These therapies have been proven effective in treating depression, anxiety, and stress [32–34]. The remaining risk factors can be seen as early signs of depressive symptoms. Therefore, the therapies used in HOPE-AF are expected to be effective in addressing these risk factors.

Table 3 Overview of psychological methodology for each risk factor

Risk factor	Treatment modules	Psychological treatment	Examples of treatment components
Rumination	Worry less	MCT and CBT	Identification of trigger thoughts Restructuring of metacognitive beliefs Identification of activities that can replace rumination
Anxiety	Greater courage	CBT	Exposure-based exercises
Low self-esteem	Improve your self-esteem	CBT	Restructuring of self-critical thoughts Self-compassion visualization exercises
Sleep disorders	Good sleep	CBT	Behavioral sleep pattern changes Restructuring of unhelpful thoughts about sleep
Loneliness	Thriving in social relations	CBT with a focus on social skills	Restructuring of unhelpful interpretations of social situations Mentalization exercises
Social isolation	Greater social network	CBT with a focus on social skills	Behavioral changes regarding seeking social opportunities Restructuring of unhelpful beliefs about social situations
Stress	1) Less stress 2) Problem-solving 3) Renewed meaning	CBT and ACT	1) Psychoeducation about stressors, and tools to create balance between resources and demands 2) CBT-based problem-solving skills training 3) Restructuring of unhelpful views on self, and the world, and identification of own core values
Physical inactivity	Use your body	CBT combined with yoga	Restructuring of unhelpful thoughts and mental barriers to exercise Creation and evaluation of exercise plan Introductory yoga exercises
Anhedonia	Activate yourself to improve happiness and energy	CBT	Psychoeducation about different forms of activities including pleasant activities Gradual behavioral activation

Abbreviations: CBT Cognitive Behavioural Therapy, MCT metacognitive therapy, ACT acceptance and commitment therapy

Intervention materials

All patients recommended keeping text material short and limiting academic terminology. They liked illustrations to visualize features, such as exercises and descriptions, and also as a tool to split longer text paragraphs in order to reduce the perceived burden of each module:

“In the long text paragraphs my concentration just vanished, that was really annoying (woman, 71 years)”

Regarding the choice of logo, the participants had individual wishes with respect to colors and layout, indicating that this was more about personal preference than a specific format being attractive to this AF population. Throughout all workshops, patients clearly indicated they preferred materials to be more positively phrased, like focusing on what to gain instead of what to avoid by rephrasing “handle sleep disorders” to “achieve healthy sleep habits”. Disease-specific questionnaires were generally preferred as they were perceived as more relevant by the participants as compared to generic questionnaires, for instance, the Cardiac Anxiety Questionnaire (CAQ) [35] was better liked than the anxiety scale of the Hospital Anxiety and Depression Scale (HADS) [36].

Barriers and facilitators for participation

One key issue discussed in the workshops was how to get patients to engage in a preventive intervention. Patients

pinpointed the importance of how the psychological tools acquired from the intervention would be helpful with respect to dealing with other challenges in life:

“It would definitely be more appealing to me if I knew I could use it for other things I struggle with (man, 67 years)”

Most patients were willing to use 1–2 h per week on the intervention, but more than that was perceived as too burdensome. The possibility of splitting assignments into parts so patients did not need to finish a full module at one time was appealing and meant it would be easier to fit the intervention into daily life. The desired timing of inclusion was individual, with patients suggesting that patients could be offered the intervention at various points in their AF patient journey. Patients suggested that an “indicator for progress” on the intervention platform would be motivating, as it would enable them to monitor how far they were in each module. We did not identify differences in perceptions of barriers and facilitators across sex.

Taken together, patient perspectives called for adjustments to our original concept and contributed valuable ideas and reflections throughout the development process. We adopted the majority of the patients’ suggestions to enhance patient engagement, as they did not compromise the overall concept of the personalized preventive intervention.

Patients evaluated that participation in the development process was meaningful and they expressed that a positive dialogue during the workshops had encouraged their active participation and that “Such things (development of intervention) can only be done by involving the persons it is all about (woman, 48 years)”.

Discussion

We developed the HOPE-AF intervention through a user-centered design. Our findings showed that user involvement was crucial to make the intervention relevant and appealing to the target population, and the primary lessons learned were (1) to engage patients from the start of the development phase; (2) to use positive phrasing in all patient-related materials; and (3) incorporate patients' choice of preference where possible in the intervention.

After having developed a first version of the intervention patients challenged us, as they did not fully comprehend the risk factors that the preventive intervention would target, despite these being identified through a literature search in the conducted needs analysis in Step 1 (Fig. 1). Hence, an important lesson learned is to engage patients from start to identify their needs and thereby optimize the design of the intervention [28, 37], as done by others [38, 39]. By engaging patients earlier in the process, we may have had a better-matched intervention proposal from the beginning of the workshops.

The second lesson learned was the continuous request for positively phrased language. Patients pointed out that in order to attract them, the preventive intervention should use positive language and terms, and focus on improving their quality of life. Hence, we rewrote the intervention with a bigger emphasis on positively phrased language and a larger focus on general quality of life improvements. The use of more positive psychological terminology has also been advocated by others [40], including in a recent scientific statement from the American Heart Association that highlights factors such as optimism and happiness that are independently associated with positive cardiovascular outcomes [41].

Involving users and incorporating patient preferences in the development of eHealth interventions are recommended to improve integrative cardiac care [42]. To personalize the intervention and improve inclusion rates and adherence in this study, the third lesson learned was to incorporate possibilities for choice based on patient preference. Many suggestions for this were provided by the patients. One example was that patients would like to be able to choose whether contact with their therapist should be by phone or video. As mentioned previously, one patient did not have a webcam and would therefore be excluded for practical reasons if video was mandatory. One study found that not having a face on your therapist

was a relief for some patients [20], indicating that online interventions with no face-to-face interaction may be preferred for some patients. Thus, by adding this choice of preference we can offer the intervention to patients who may otherwise have been excluded or have declined participation. Another example was that the women were very keen to include yoga videos, and the men had no objections to this. However, it was previously found that men can have reservations about mindfulness exercises [19]. In case some patients have reservations about yoga, we decided to make yoga optional. As the user-centered design studies contain relatively few participants, sex differences in preferences may be purely coincidental, but as sex differences in recruitment to cardiac studies are established [43], it is important to consider how to optimize recruitment and adherence across potential sex differences.

This intervention was developed by involving the target population. As the involved participants were limited to eight, there may be unnoticed important factors with respect to e.g. age, sex, disease burden, or ethnicity. Future research should therefore seek to include more diversity in the population to optimize the generalizability of the results [42]. In the following HOPE-AF feasibility trial, we will recruit 30 either newly diagnosed or “experienced” AF patients to get better variation in the population. To ensure that we include a broad range of patient perspectives, we will interview the first round of patients who finalize the intervention in the feasibility study ($n=10$), so we can validate the lessons learned in this study and/or make relevant adjustments according to new findings. The aim of the feasibility trial will be to further optimize the intervention and recruitment procedures prior to evaluating the actual efficacy in a large-scale RCT.

Strengths and limitations

Strengths of this study include a wide range of patient perspectives that were generously shared and discussed in an informal tone, including the expression of difficult emotions. This allowed for plenty of feedback and fruitful discussions among all participants that improved the development of the intervention. Starting each workshop with an informal lunch may also have supported the high patient engagement [37], as this created a positive atmosphere. Limitations include that the process contained the development of the intervention, whereas the intervention may be perceived differently by patients once finalized on the intervention platform. Because we wanted to keep the burden for participating patients at a reasonable level, we did not get feedback on all the details of the intervention. In addition, a limitation is that 63% of the participants involved in

the current study hold at least a bachelor's degree. This could potentially affect the results, as patients with a lower level of education may have different suggestions and perspectives. Another potential limitation is that due to logistics, the workshops ended up being sex-separated, while having both men and women in the same workshops may have led to broader insights. Contrarily, the scenario may also have supported the willingness to speak freely as women's engagement is found to be influenced by the perceived safety of the environment [40].

Conclusions

Based on a user-centered design, the HOPE-AF intervention aiming to prevent depression in patients with AF, was developed. Engaging patients in the development of complex interventions was crucial to ensure that the intervention became meaningful for patients and acceptable in their everyday lives. Thus, user perspectives should be taken into account in future research as beliefs and ideas from health professionals may not always be in alignment with what patients actually wants. The developed HOPE-AF intervention will now be tested in a feasibility study, focusing on acceptability and limited efficacy [44].

Abbreviations

AF	Atrial fibrillation
HRQoL	Health-related quality of life
IM	Intervention Mapping
RCT	Randomized controlled trial
REHPA	Danish Knowledge Centre for Rehabilitation and Palliative Care

Acknowledgements

We would like to thank the Danish Heart Foundation and "Snedkermester Sophus Jacobsen og hustru Astrid Jacobsens Fond" for supporting this study financially with a grant to Susanne S. Pedersen. We would also like to thank REHPA, the Department of Cardiology ZUH, and the Danish Heart Foundation in Roskilde for helping with recruiting patients for this study. Finally, we would like to thank all the patients who participated in the workshops and helped us develop the HOPE-AF intervention.

Authors' contribution

CH, RA, and SSP conceptualized the design of the project and were responsible for data collection, interpretation of data, and analysis. CH and SJS were responsible for data management. AB, JCN, LF, and RT were supervised during the project. CH drafted the manuscript and all authors substantially revised it. All authors read and approved the final manuscript.

Funding

This study was supported by a grant from the Danish Heart Foundation (# 22-R156-A10239-22204).

Data availability

As participating patients have not given consent to data sharing we are not able to share our data.

Declarations

Ethics approval and consent to participate

Permission to conduct this study was obtained from the Danish Data Protection Agency through the Region of Southern Denmark (21–62093). Ethical approval was obtained from the Regional Committees on Health Research Ethics for Southern Denmark (S-20230078). The study complies with the Helsinki Declaration and all patients provided written informed consent prior to participation.

Consent for publication

Not applicable.

Competing interests

AB declares receiving grants to his institution from the Danish Heart Foundation, Theravance, Region Zealand, European Union Interreg 5A Programme, Independent Research Foundation Denmark, and Lecture honorarium from Bristol-Myers Squibb. RT declares receiving grants from NIHRR to research in cardiac rehabilitation. SSP declares receiving a grant from the Danish Heart Foundation for the conduction of the HOPE-AF study. The remaining authors have nothing to declare.

Author details

¹Department of Cardiology, Zealand University Hospital, Roskilde, Denmark. ²Department of Psychology, University of Southern Denmark, Odense, Denmark. ³Department of Cardiology, Department of Regional Health Research, University of Southern Denmark, Esbjerg-Hospital—University Hospital of Southern, Denmark. ⁴Department of Cardiology, Department of Clinical Medicine, Aarhus University Hospital, Aarhus University, Aarhus, Denmark. ⁵Department of Clinical Medicine, Aarhus University, Aarhus, Denmark. ⁶School of Health & Wellbeing, University of Glasgow, Glasgow, Scotland. ⁷Department of Cardiology, Odense University Hospital, Odense, Denmark.

Received: 28 August 2024 Accepted: 24 December 2024

Published online: 06 January 2025

References

- Kornej J, Börschel CS, Benjamin EJ, Schnabel RB. Epidemiology of Atrial Fibrillation in the 21st Century: Novel Methods and New Insights. *Circ Res*. 2020;127(1):4–20.
- Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J*. 2021;42(5):373–498.
- Patel D, Mc Conkey ND, Sohaney R, Mc Neil A, Jedrejczyk A, Armanijan L. A systematic review of depression and anxiety in patients with atrial fibrillation: the mind-heart link. *Cardiovasc Psychiatry Neurol*. 2013;2013:159850.
- Pogosova N, Saner H, Pedersen SS, Cupples ME, McGee H, Höfer S, et al. Psychosocial aspects in cardiac rehabilitation: from theory to practice. A position paper from the Cardiac Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation of the European Society of Cardiology. *Eur J Prev Cardiol*. 2015;22(10):1290–306.
- Szpakowski N, Qiu F, Masih S, Kurdyak P, Wijeyesundera HC. Economic impact of subsequent depression in patients with a new diagnosis of stable angina: a population-based study. *J Am Heart Assoc*. 2017;6:e006911.
- Vaccarino V, Badimon L, Bremner JD, Cenko E, Cubedo J, Dorobantu M, et al. Depression and coronary heart disease: 2018 ESC position paper of the working group of coronary pathophysiology and microcirculation developed under the auspices of the ESC Committee for Practice Guidelines. *Eur Heart J*. 2019.
- Wang L, Sun Y, Zhan J, Wu Z, Zhang P, Wen X, et al. Effects of exercise therapy on anxiety and depression in patients with coronary heart disease: a meta-analysis of a randomized controlled study. *Front Cardiovasc Med*. 2021;8:730155.

8. Richards SH, Anderson L, Jenkinson CE, Whalley B, Rees K, Davies P, et al. Psychological interventions for coronary heart disease. John Wiley and Sons Ltd; 2017.
9. Wells A, Reeves D, Capobianco L, Heal C, Davies L, Heagerty A, et al. Improving the effectiveness of psychological interventions for depression and anxiety in cardiac rehabilitation: pathway—a single-blind, parallel, randomized, controlled trial of group metacognitive therapy. *Circulation: Lippincott Williams & Wilkins Hagerstown, MD*. 2021. p. 23–33.
10. Schneider LH, Hadjistavropoulos HD, Dear BF, Titov N. Efficacy of internet-delivered cognitive behavioural therapy following an acute coronary event: a randomized controlled trial. *Int Inter*. 2020;21:100324-.
11. Johansson P, Westas M, Andersson G, Alehagen U, Broström A, Jaarsma T, et al. An internet-based cognitive behavioral therapy program adapted to patients with cardiovascular disease and depression: Randomized controlled trial. *MIR Ment Health*. 2019;6(10):e14648.
12. Ai Y, Xing Y, Yan L, Ma D, Gao A, Xu Q, et al. Atrial fibrillation and depression: a bibliometric analysis from 2001 to 2021. *Front Cardiovasc Med*. 2022;9:775329.
13. van Zoonen K, Buntrock C, Ebert DD, Smit F, Reynolds CF 3rd, Beekman AT, et al. Preventing the onset of major depressive disorder: a meta-analytic review of psychological interventions. *Int J Epidemiol*. 2014;43(2):318–29.
14. Särholm J, Skúladóttir H, Rück C, Axelsson E, Bonnett M, Bragesjö M, et al. Cognitive behavioral therapy improves quality of life in patients with symptomatic paroxysmal atrial fibrillation. *J Am Coll Cardiol*. 2023;82(1):46–56.
15. Cuijpers P, van Straten A, Smit F, Mihalopoulos C, Beekman A. Preventing the onset of depressive disorders: a meta-analytic review of psychological interventions. *Am J Psychiatry*. 2008;165(10):1272–80.
16. Cuijpers P, Muñoz RF, Clarke GN, Lewinsohn PM. Psychoeducational treatment and prevention of depression: the “Coping with Depression” course thirty years later. *Clin Psychol Rev*. 2009;29(5):449–58.
17. Ski CF, Taylor RS, McGuigan K, Long L, Lambert JD, Richards SH, et al. Psychological interventions for depression and anxiety in patients with coronary heart disease, heart failure or atrial fibrillation. *Cochrane Database Syst Rev*. 2024;4(4):Cd013508.
18. Frederix I, Caiani EG, Dendale P, Anker S, Bax J, Böhm A, et al. ESC e-cardiology working group position paper: overcoming challenges in digital health implementation in cardiovascular medicine. *Eur J Prev Cardiol: SAGE Publications Inc*. 2019;26(11):166–77.
19. Schmidt T, Kok R, Andersen CM, Skovbakke SJ, Ahm R, Will UK, et al. Development of an internet-delivered program and platform for the treatment of depression and anxiety in patients with ischemic heart disease in eMindYourHeart. *Inform Health Soc Care*. 2021;46(2):178–91.
20. Helmark C, Ahm R, Andersen CM, Skovbakke SJ, Kok R, Will UK, et al. Internet-based treatment of anxiety and depression in patients with ischemic heart disease attending cardiac rehabilitation: a feasibility study (eMindYourHeart). *Eur Heart J Dig Health*. 2021.
21. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:n2061.
22. Fitzsimons D. Patient engagement at the heart of all European Society of Cardiology activities. *Cardiovasc Res*. 2019;115(10):e99–101.
23. Norlund F, Wallin E, Olsson EMG, Wallert J, Burell G, von Essen L, et al. Internet-based cognitive behavioral therapy for symptoms of depression and anxiety among patients with a recent myocardial infarction: the u-care heart randomized Controlled trial. *Journal of Medical Internet Research*. 2018;20(3):e88.
24. Fernandez ME, Ten Hoor GA, van Lieshout S, Rodriguez SA, Beidas RS, Parcel G, et al. Implementation mapping: using intervention mapping to develop implementation strategies. *Front Public Health*. 2019;7:158.
25. Staniszewska S, Brett J, Simeri I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ*. 2017;358:3453.
26. van Agteren J, Iasiello M, Ali K, Fassnacht DB, Furber G, Woodyatt L, et al. Using the intervention mapping approach to develop a mental health intervention: a case study on improving the reporting standards for developing psychological interventions. *Front Psychol*. 2021;12:648678.
27. Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. *Health Res Policy Syst*. 2020;18(1):17.
28. Talevski J, Kulnik ST, Jessup RL, Falls R, Cvetanovska N, Beauchamp A. Use of co-design methodology in the development of cardiovascular disease secondary prevention interventions: a scoping review. *Health Expect*. 2023;26(1):16–29.
29. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10(1):1–13.
30. Barkham M, Bewick B, Mullin T, Gilbody S, Connell J, Cahill J, et al. The CORE-10: A short measure of psychological distress for routine use in the psychological therapies. *Couns Psychother Res*. 2013;13(1):3–13.
31. Pedersen SS, Andersen CM, Ahm R, Skovbakke SJ, Kok R, Helmark C, et al. Efficacy and cost-effectiveness of a therapist-assisted web-based intervention for depression and anxiety in patients with ischemic heart disease attending cardiac rehabilitation [eMindYourHeart trial]: a randomised controlled trial protocol. *BMC Cardiovascular Disorders: BioMed Central Ltd*; 2021. p. 20.
32. Hofmann SG, Asnaani A, Vonk IJ, Sawyer AT, Fang A. The efficacy of cognitive behavioral therapy: a review of meta-analyses. *Cognit Ther Res*. 2012;36(5):427–40.
33. Beygi Z, Tighband Jangali R, Derakhshan N, Alidadi M, Javanbakhsh F, Mahboobzadeh M. An overview of reviews on the effects of acceptance and commitment therapy (ACT) on depression and anxiety. *Iran J Psychiatry*. 2023;18(2):248–57.
34. Wells A, Reeves D, Heal C, Davies LM, Shields GE, Heagerty A, et al. Evaluating metacognitive therapy to improve treatment of anxiety and depression in cardiovascular disease: the NIHR Funded PATHWAY Research Programme. *Front Psychiatry*. 2022;13: 886407.
35. Eifert GH, Thompson RN, Zvolensky MJ, Edwards K, Frazer NL, Haddad JW, et al. The cardiac anxiety questionnaire: development and preliminary validity. *Behav Res Ther*. 2000;38(10):1039–53.
36. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta psychiatrica Scandinavica*. 1983;361–70.
37. Nesbitt K, Beleigoli A, Du H, Tirimacco R, Clark RA. User Experience (UX) Design as a co-design methodology: lessons learned during the development of a web-based portal for cardiac rehabilitation. *Eur J Cardiovasc Nurs*. 2022;21(2):178–83.
38. Greaves CJ, Wingham J, Deighan C, Doherty P, Elliott J, Armitage W, et al. Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. *Pilot and Feasibility Studies*. 2016;2(1):37.
39. van Mol M, Nijkamp M, Markham C, Ista E. Using an intervention mapping approach to develop a discharge protocol for intensive care patients. *BMC Health Serv Res*. 2017;17(1):837.
40. Ghisi GLM, Kin SMR, Price J, Beckie TM, Mamataz T, Naheed A, et al. Women-focused cardiovascular rehabilitation: an International Council of Cardiovascular Prevention and Rehabilitation Clinical Practice Guideline. *Can J Cardiol*. 2022;38(12):1786–98.
41. Levine GN, Cohen BE, Commodore-Mensah Y, Fleury J, Huffman JC, Khalid U, et al. Psychological health, well-being, and the mind-heart-body connection: a scientific statement from the American Heart Association. *Circulation*. 2021;143:E763–83.
42. Ski CF, Cartledge S, Foldager D, Thompson DR, Fredericks S, Ekman I, et al. Integrated care in cardiovascular disease: a statement of the Association of Cardiovascular Nursing and Allied Professions of the European Society of Cardiology. *Eur J Cardiovasc Nurs*. 2023;22(5):e39–46.
43. Cho L, Vest AR, O'Donoghue ML, Ogunniyi MO, Sarma AA, Denby KJ, et al. Increasing participation of women in cardiovascular trials: JACC Council Perspectives. *J Am Coll Cardiol*. 2021;78(7):737–51.
44. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. *Am J Prev Med*. 2009;36(5):452–7.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.