Evaluation of the Feasibility of a Gamified Lifestyle Change Intervention for Patients with Atrial Fibrillation Scheduled for Catheter Ablation: GAMES4CARE.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON57232

Source
ToetsingOnline

Brief title
GAMES4CARE

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medical Center
Source(s) of monetary or material Support: Ministerie van OC&W,The Dutch Heart Foundation (De Hartstichting)

Intervention

Keyword: Atrial Fibrillation, Behavior change, Gamified lifestyle intervenion, Lifestyle intervention

Outcome measures

Primary outcome

The primary endpoint of this study is adherence. Adherence is expressed as the

proportion of days the gamified mobile application was opened during the

3-month gamification intervention integrated with a recently developed platform

for continuous lifestyle monitoring (Care-On) in patients with atrial

fibrillation (AF) referred for catheter ablation.

Adherence=(Number of days the app was opened / Total intervention days (84)) x

100

Sufficient adherence is defined as an adherence of at least 70%.

Secondary outcome

The secondary endpoints are:

1) Lifestyle behavior change after 3 and 6 months (physical activity,

sedentary behavior, smoking, alcohol consumption, nutrition behavior and mental

stress) assessed by the percentage change from the baseline to the 3-month and 6-month mark post the baseline assessment. The correlation between adherence to the intervention and lifestyle behaviors will be compared for each of the lifestyle factors separately

2) AF symptoms assessed by the Atrial Fibrillation Severity Scale (AFSS)

3) Quality of life, the difference in quality-of-life assessments from baseline to the 3-month and 6-month time points after the start of the intervention aiming to capture any improvements attributed to adherence to the intervention

4) Usability will be measured using the System Usability Scale (SUS) score.

5) To measure the correlation of the self efficacy with adherence, the General Self*Efficacy Scale (GSES) will be used

Study description

Background summary

Lifestyle behaviors including physical activity, nutrition, sleep, smoking and management of mental stress are significant factors for the clinical course and overall treatment results of chronic cardiac diseases. Specifically, it has been shown that these lifestyle factors are strongly related to the disease burden and quality of life of patients with atrial fibrillation (AF). Moreover, cardiac rehabilitation was shown to improve lifestyle behavior and reduce arrhythmia recurrence. Despite this evidence structured lifestyle interventions and Cardiac Rehabilitation often fail to be implemented efficiently. The reasons behind that can be patient-related (i.e., transportation problems, working obligations, not appealing for specific subgroups) or/and

healthcare-related (i.e. low referral rates, limited facilities, and resources).

Obviously, there is a need for personalized lifestyle interventions for these patients which can be implemented easily, while avoiding burdening the healthcare system. The proposed solution in this study is a structured lifestyle intervention platform that will combine the holistic gamified lifestyle interventions of the Greenhabit app integrated with a recently developed continuous lifestyle monitoring system Care-On (digital platform with wearable sensor and dashboard) that was evaluated in a recent study on feasibility and adherence. Advantages of this novel intervention over traditional cardiac rehabilitation from a patient perspective are that it does not require hospital visits and that it may be more appealing than a traditional program as it is a personalized goal-driven gamified intervention and it can be done together with family or friends. From a hospital perspective, the proposed intervention requires lower resources and personnel deployment as it is a self-management intervention.

The hypothesis of this study is that a gamified lifestyle intervention, integrated with a continuous lifestyle monitoring platform, will result in high adherence rates over a 3-month period in patients with atrial fibrillation referred for catheter ablation. We aim to evaluate the practicality of implementing this intervention and its acceptance by the patients.

Study objective

The primary objective of this study is to evaluate the adherence to a 3-month gamification intervention integrated with a recently developed platform for continuous lifestyle monitoring (Care-On) in patients with AF referred for catheter ablation.

The secondary objectives are:

- To explore the relationship between adherence to the intervention and improvements in lifestyle behaviors (physical activity, sedentary behavior, smoking, alcohol consumption, nutritional behavior, and mental stress) at 3- and 6-months post-baseline

- To evaluate the AF symptom burden

- To evaluate the usability of the intervention

- To explore potential improvements in patients* quality of life as a result of the intervention

- To evaluate self-efficacy as a predictor of adherence to the gamified

lifestyle intervention

Study design

This is a single-centre, prospective interventional study

Intervention

The intervention consists of the Greenhabit application which is integrated with a recently developed lifestyle monitoring system that provide objective feedback on lifestyle change (CARE-ON). Greenhabit (GH) works on physical and mental health in small steps. It uses various behavior change models to help people make healthy choices and develop new habits. Also, it uses gamification, so the process to be more enjoyable.

Greenhabit consists of a 12-week journey, during which participants can open a treasure chest which contains messages, challenges or measurements on a daily basis. One of the daily measurements is the reflection of how their day was, and it consists of five elements (Exercise, Healthy diet, social environment, positive thinking, relaxation)

Patients will be instructed to wear the CardiacSense Watch 3 (CS3) as much as possible (at least 12 hours per day) from the moment that they will have access to the lifestyle monitoring system for a 3- month period. During this period the patient will also be asked to report their lifestyle data via a chatbot integrated in the lifestyle monitoring system with a max of a week per month of reporting. The amount of lifestyle data reporting will depend on the two main goals that they will select in the Greenhabit app.

The patient will have to interact daily with the Greenhabit (GH) app. The first step is the selection of two main goals. On a daily basis, participants can open a treasure chest which contains messages, challenges or measurements. After a treasure chest is opened, the patient has specific days to read the information, complete the challenge or the measurements.

There is a *travel journal* where the patient can reread what has learned.GH also provides a feature in which a patient can choose a *buddy* (friend, sister or partner) who is also following the programme with their own goals. Finally, there is an App community, and the patient can share photos of their adventure with people they have chosen.

The GH programme always starts on a Monday. The first Monday on the timeline some questions appear and they are the baseline measurement. The patient*s answers help the algorithm to personalize the information and challenges. These questions which are based on different validated questionnaires, are repeated every 28 days.

In the beginning, the patient needs to select two main goals that wants to work towards. In total GH is providing 11 goals to choose from:

1) To be meaningful
2) Recovery or rehabilitation
3) More relaxed
4) Healthier eating
5) More energy
6) More balance
7) Social contacts
8) More moving
9) Weight loss
10) Being more positive
11) More self-confidence

During the game, GH is providing micro-goals which lead to the main goals. The patient can choose their micro goals every Monday.

Based on the selection of the main goals at the GH the Chatbot of the lifestyle monitoring system will ask the patients to report their lifestyle data.

Study burden and risks

The lifestyle intervention is not associated with significant risks as it consists of general lifestyle advices supplemented with an exercise program consisting of low to moderate intensity aerobic and strength exercises. Exercises will be adjusted for patients with a low exercise capacity.

Participation in the intervention may be experienced as burdensome as patients will be asked to wear an activity tracker (at least 12 hours per day) throughout the 12-week period: this may be perceived as unpleasant and the watch may cause irritation to the skin of the wrist when worn for long periods of time. However, this is no more likely than wearing any other watch. Furthermore, data on nutritional intake, mental stress and sleep quality will be acquired via questionnaires and a chatbot connected to a patient monitoring system accessible via mobile phone, tablet and desktop. Nevertheless, patients participate on a voluntary basis and will be motivated to improve their lifestyle behaviour. The number of hospital visits required for the intervention (i.e. 3 times, at baseline, 3 months and 6 months) is substantially lower than in the regular cardiac rehabilitation program.

The wrist-worn device (CS3) has been tested and found to be biocompatible. There are no known adverse events related to the use of CS System 3; however, there are possible adverse events related to monitoring systems that involve sensor application on the skin. These include the following:

i) Edema, ii), Erythema, iii) Irritation, iv) Sensitization

Contacts

Public
Maxima Medical Center

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients referred for catheter ablation due to symptomatic AF.
- Age >= 18 years.
- Able to speak and read the Dutch language.
- Willing and able to provide informed consent.

Exclusion criteria

- No internet connection at home.
- Not in possession of a computer or tablet; and mobile phone.
- Not able or willing to wear activity tracker on a daily basis (for example due to work related obligations).
- Major planned (cardiac) surgery in the upcoming 3 months.
- Life expectancy < 1 year (e.g., severe renal disease, metastatic cancer).
- Physical impairments interfering with the lifestyle monitoring system, including not able to perform daily physical activities due to orthopedic or neurological disease, bed/chair ridden patients, visual impairments/blindness, sever cognitive disability.
- Presence of wounds, injuries or infectious diseases on the skin where the wrist-wearable device(s) will be placed.
- Other contra-indications for wearing the smartwatch (pregnant and breastfeeding women, people with pacemakers, or ICD0.
- Individuals deemed not mentally able to use the app.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Greenhabit
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87652.015.24