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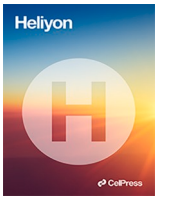

Protocol

Effect of visual presentation of atherosclerotic carotid plaque on adherence to secondary preventive therapy using mHealth technologies (*PreventiPlaque* app): Study protocol for a randomized controlled trial

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A R T I C L E I N F O

Keywords:
Cardiovascular diseases
Telemedicine
mHealth
Patient adherence

A B S T R A C T

Background: Cardiovascular disease is the major cause of death worldwide. Although knowledge regarding diagnosing and treating cardiovascular disease has increased dramatically, secondary prevention remains insufficiently implemented due to failure among affected individuals to adhere to guideline recommendations. This has continued to lead to high morbidity and mortality rates. Involving patients in their healthcare and facilitating their active roles in their chronic disease management is an opportunity to meet the needs of the increasing number of cardiovascular patients. However, simple recall of advice regarding a more preventive lifestyle does not affect sustainable behavioral lifestyle changes. We investigate the effect of plaque visualization combined with low-threshold daily lifestyle tasks using the smartphone app *PreventiPlaque* to evaluate change in cardiovascular risk profile.

Methods: and study design: This randomized, controlled clinical trial includes 240 participants with ultrasound evidence of atherosclerotic plaque in one or both carotid arteries, defined as focal thickening of the vessel wall measuring 50% more than the regular vessel wall. A criterion for participation is access to a smartphone suitable for app usage. The participants are randomly assigned to an intervention or a control group. While both groups receive the standard of care, the intervention group has additional access to the *PreventiPlaque* app during the 12-month follow-up. The app includes daily tasks that promote a healthier lifestyle in the areas of smoking cessation, medication adherence, physical activity, and diet. The impact of plaque visualization and app use on the change in cardiovascular risk profile is assessed by SCORE2. Feasibility and effectiveness of the *PreventiPlaque* app are evaluated using standardized and validated measures for patient feedback.

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Ethics and dissemination: This clinical trial is approved by the ethics committee of the University of Duisburg-Essen (Germany). Study results will be disseminated at conferences and in peer-reviewed journals. Information regarding the PreventiPlaque app is available via print media, social media channels, and on the authors' websites.

1. Introduction background

The burden of atherosclerotic cardiovascular disease is high, as it is the most common cause of death and morbidity worldwide [1, 2]. The number of related premature deaths, in particular, should be stressed as it leads to the deaths each year of more than 1.4 million people in Europe before they reach the age of 75 [3]. Coronary artery disease, peripheral artery disease, and cerebrovascular disease are the most common presentations of atherosclerotic disease and cause life-threatening complications such as myocardial infarction, acute limb ischemia, and stroke [1]. Since therapeutic interventions for these acute, life-threatening events are continually improving with medical progress and leading to increased survival rates, secondary prevention has taken on greater significance. According to current guidelines, the treatment of cardiovascular risk factors targets arterial hypertension, hypercholesteremia, diabetes mellitus, smoking cessation, and the promotion of a healthy diet combined with regular physical activity [4]. Although these lifestyle changes, taken together, represent an important cornerstone in the conservative treatment of atherosclerotic diseases to avoid further progression, they continue to be insufficiently conducted and rarely lead to sustainable behavioral lifestyle changes. One reason might be the shortage of medical resources in ambulatory care in contrast to the large number of those affected by cardiovascular diseases [5]. Another reason might be the simple, unidirectional, verbal communication between practitioners and patients; this is frequently characterized as brief and general rather than being a recommendation tailored to the specific patient in regard to behavioral lifestyle changes that have the potential to decrease his or her risks for cardiovascular events and increase health [6,7]. Technologies referred to as mHealth provide opportunities to overcome the challenge of a lack of infrastructure for the growing number of patients in need. Furthermore, personalized digital interventions have demonstrated their potential to improve adherence to therapy by increasing feelings of self-efficacy and involving patients in their chronic disease management. We designed *PreventiPlaque* aiming for a patient-centered approach; personalized pictorial information is added to visualize disease stage and combined with low-threshold, daily in-app lifestyle tasks that promote active involvement. Engagement and active involvement that create feelings of self-efficacy have already proven to be a crucial precondition for long-term behavior changes [8–10]. The aim of the present study is to evaluate whether the demonstration of one's atherosclerotic plaque has an impact on health-promoting lifestyle changes in patients with known atherosclerotic disease.

2. Methods

The aim of this clinical trial is to evaluate the effect of visual presentation of atherosclerotic carotid plaque on patients' adherence to secondary prevention strategies. We test the hypothesis that using the *PreventiPlaque* app for plaque visualization leads to an overall improvement of treatment adherence and, subsequently, to improvement in participants' cardiovascular risk profiles. Established cardiovascular risk calculators are used to assess participants' cardiovascular risk profiles and changes to these during the follow-up period. The results of participants using the *PreventiPlaque* app will be compared to a control group without app access but receiving standard care.

The *PreventiPlaque* study aims to answer the following research questions.

1. Does atherosclerotic plaque visualization using digital intervention treatment affect adherence as assessed by improvement of the participant's overall cardiovascular risk profile?
2. What effect does the app have on the target group, and what changes, if any, are seen in participants' cardiovascular risk profiles?
3. What strategies can be implemented to make the app feasible for everyday use?

To address the research questions, established cardiovascular risk calculators will be used to assess participants' cardiovascular risk profiles with a focus on changes between baseline and 12-month follow-up. Participants will also be invited to rate the *PreventiPlaque* app using well-validated instruments and to self-report their medication and physical therapy adherence. Additionally, backend data in terms of frequency and duration of app use will be analyzed, and barriers leading to the cessation of use will be identified.

Primary outcome. The primary outcome is the change in cardiovascular risk profile as measured by the SCORE2 (Systematic Coronary Risk Evaluation) risk calculator [11]. The score comprises age in years, blood cholesterol levels, systolic blood pressure, non-HDL cholesterol levels, sex, and nicotine use. The change will be assessed by comparing the calculated risk at baseline and at 12-month follow-up.

Secondary outcome. Regarding the secondary outcome measures, changes in the Life's Simple 7 score will be evaluated at baseline and follow-up visits [12]. Changes in clinical parameters will also be assessed; LDL cholesterol levels were measured at baseline and at each follow-up visit, in addition to changes in body weight and blood pressure. Moreover, patients will be required to report their self-assessed physical activity and medication adherence at each visit. Changes in nicotine dependency will be evaluated using the Fagerstrom Test for Nicotine Dependence in active smokers [13]. During the study period, satisfaction with outpatient care will be assessed using the questionnaire Satisfaction in Outpatient Care [14].

At the last follow-up visit, participants will evaluate the *PreventiPlaque* app using the mobile Application Rating Scale: user version (uMars) questionnaire [15]. Table 1 provides an aggregated overview of the assessed outcomes and timeline.

The *PreventiPlaque* trial is a two-armed randomized, open-label, single-center clinical trial. During a 4-month period, 240 participants will be recruited. The recruitment process, baseline examinations, and follow-up visits will take place at the University Clinic of Essen, West German Heart and Vascular Center, Department of Cardiology and Vascular Medicine. The trial is registered at ClinicalTrials.gov and can be found at ClinicalTrials.gov with the identifier NCT05096637. This study is approved by the local ethics committee of the University of Duisburg-Essen (20-9157-BO).

Participants will be randomly assigned to an intervention group and a control group. The follow-up period is 12 months and includes the baseline examination and four follow-up visits after 3, 6, and 9 months as well as the last follow-up examination at 12 months (Fig. 1). The informed consent of all participants will be collected prior to the examination visits. Both groups will receive the best medical treatment according to current guidelines, including a 5-min standardized verbal briefing on secondary prevention [4]. Afterward, the intervention group will be given access to the *PreventiPlaque* app; this includes access to the previously recorded ultrasound images of the carotid artery. The control group will receive the same medical treatment but without access to the *PreventiPlaque* app. The CONSORT diagram shows the enrollment of subjects, their allocation to treatment, disposition status and how they are analyzed in the trial (Fig. 2).

In regard to inclusion criteria, adults ages 18–79 years with a life expectancy of more than one year are eligible to participate in this study. In addition, ultrasound evidence of atherosclerotic plaque in one or both carotid arteries is necessary. The presence of carotid plaque is defined as a focal thickening of the vessel wall measuring 50% more than the regular vessel wall or regional outlined carotid intima-media thickness (CIMT) bulging more than 1.5 mm into the lumen of the vessel [16]. Other criteria for inclusion are to own a smartphone and to be able to correctly use smartphone applications. Finally, the motivation and commitment to comply with the study protocol as well as written, informed consent are required. Defined exclusion criteria are congestive heart failure with New York Heart Association (NYHA) III–IV symptoms, severe valve disease, no knowledge of the German language, or being unwilling to use the app or submit to diagnostic procedures and attend follow-up visits. Table 2 summarizes the inclusion and exclusion criteria.

At the first medical visit, patients willing to participate in the *PreventiPlaque* trial receive a medical briefing and attend baseline examinations after they have provided written consent. The standardized medical briefing and education is led by psychologists and medical doctors. During the medical briefing, the importance of secondary prevention in cardiovascular disease is explained in a standardized manner with a duration of 5 min. In the course of this briefing, participants receive guideline-coherent recommendations regarding physical activity, and the importance of smoking cessation is pointed out if the participants are active smokers. Afterward, patients also undergo an ultrasound of their carotid arteries. They are asked about their smoking status and, stratified according to smoking status, participants are randomly assigned to the intervention or to the control group.

In the course of the randomization, patients are allocated to the intervention or control group using a random number generator. Since use of the PreventiPlaque app is possible only according to group assignment, there is no blinding of the study participants. However, the study personnel will be blinded during the baseline as well as the follow-up visits.

During baseline visits, the study procedure is explained, and informed consent is obtained from each participant. After informed consent is given, clinical examinations are performed. In addition to the ultrasound of their carotid arteries mentioned above, participants also undergo blood work, including the measurement of low-density lipoprotein, high-density lipoprotein, triglycerides, and HbA1c. Patients are encouraged to self-assess their physical activity level and adherence to their medication regimen in a personal interview with study personnel. Physical activity levels will be self-assessed by the study participants stating their number of "active days per week" as well as exercise duration and choosing between light exercise and exercise of a higher intensity. Patients who are active smokers are also interviewed regarding their nicotine use. Medical history and demographic data are documented for study purposes. In addition, participants assigned to the intervention group receive a short explanation of the installment process and use of the *PreventiPlaque* app.

The study includes a total follow-up period of 12 months. During the initial meeting, four additional visits are scheduled after 3, 6, 9, and 12 months. At these visits, participants will undergo the previously performed clinical examinations again, including the carotid artery ultrasound to update the app representation. Changes in medical history, medication, and, for active smokers, nicotine use since the baseline visit will be documented. Patients will reassess their physical activity and its development during the previous months. At the final follow-up visit after 12 months, an additional questionnaire and interview will be conducted. Using this questionnaire, the *PreventiPlaque* app will be rated, and the results used for further patient-centered app development.

Table 1
Baseline and follow up examinations.

	Baseline	3-, 6-, 9-Month Follow-Up	12-Month Follow-Up
Ultrasound	Carotid artery ultrasound	Carotid artery ultrasound	Carotid artery ultrasound
Clinical parameters	Blood work including LDL-Cholesterol, HDL-Cholesterol, HbA1c	Blood work including LDL-Cholesterol, HDL-Cholesterol, HbA1c	Blood work including LDL-Cholesterol, HDL-Cholesterol, HbA1c
Self-Assessment	Physical activity Adherence to medication Nicotine abstinence	Physical activity Adherence to medication Nicotine abstinence	Physical activity Adherence to medication Nicotine abstinence
Scores	SCORE2, LifeSimple7	SCORE2, LifeSimple7	SCORE2, LifeSimple7
Other	Written approval to participate, consent discussion		uMARS questionnaire (intervention group)

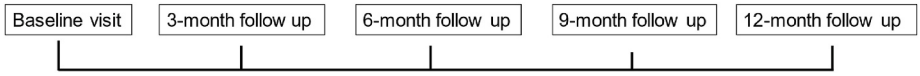


Fig. 1. Timeline of the PreventiPlaque-trial.

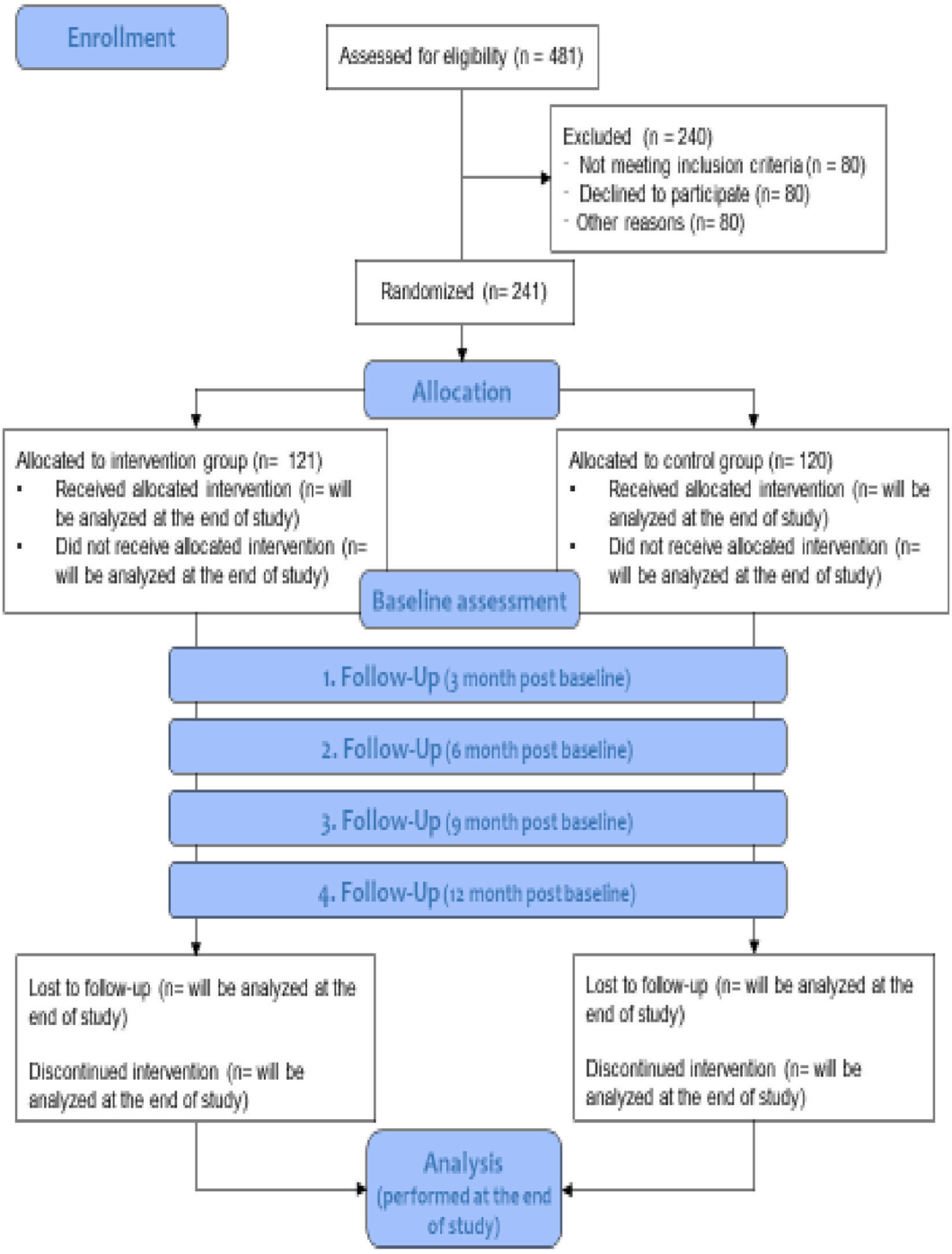


Fig. 2. CONSORT flow chart.

Table 2
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Ultrasound evidence of atherosclerotic plaque in one or both carotid arteries	No evidence of atherosclerotic cardiovascular disease
Smartphone suitable for the use of the Preventi Plaque app	Unwillingness to use the app and/or no suitable Smartphone available
Presumed life expectancy of more than one year	Severe co-morbidities • Congestive heart failure with NYHA (New York Heart Association) III-IV symptoms • Severe valve disease
Willing to comply with the protocol and provide written informed consent	Unwillingness to undergo diagnostic procedures and attend to follow-up visits No knowledge of the German language

The study aims to measure the effects of the visual atherosclerotic plaque presentation using mHealth technologies on participants' treatment adherence as well as on their overall cardiovascular risk profile. The intended power is 0,95 (*t*-test; type of power analysis: a priori; effect size d: 0,5; alpha error probability: 0,05; group 1 sample size: 105; group 2 sample size: 105). To allow for dropouts and missing data, estimated at 15%, a total of 240 participants will be recruited.

2.1. The PreventiPlaque app

Home screen. The main goal of the *PreventiPlaque* app is to improve the user's adherence to the therapeutic regimen by enabling the user to visualize his or her carotid plaque. Therefore, the primary component of the home screen is an ultrasound image of carotid atherosclerotic plaque. By clicking on the image, participants can see their own most-recent ultrasound images including highlighting of their carotid plaque burden. The lower part of the home screen depicts a weekly overview of completed low-threshold daily tasks and, by clicking, leads the user to the different task subcategories (Figs. 3 and 4).

Daily tasks. Participants, independent of smoking status, can record their daily progress in each of three or four health categories.

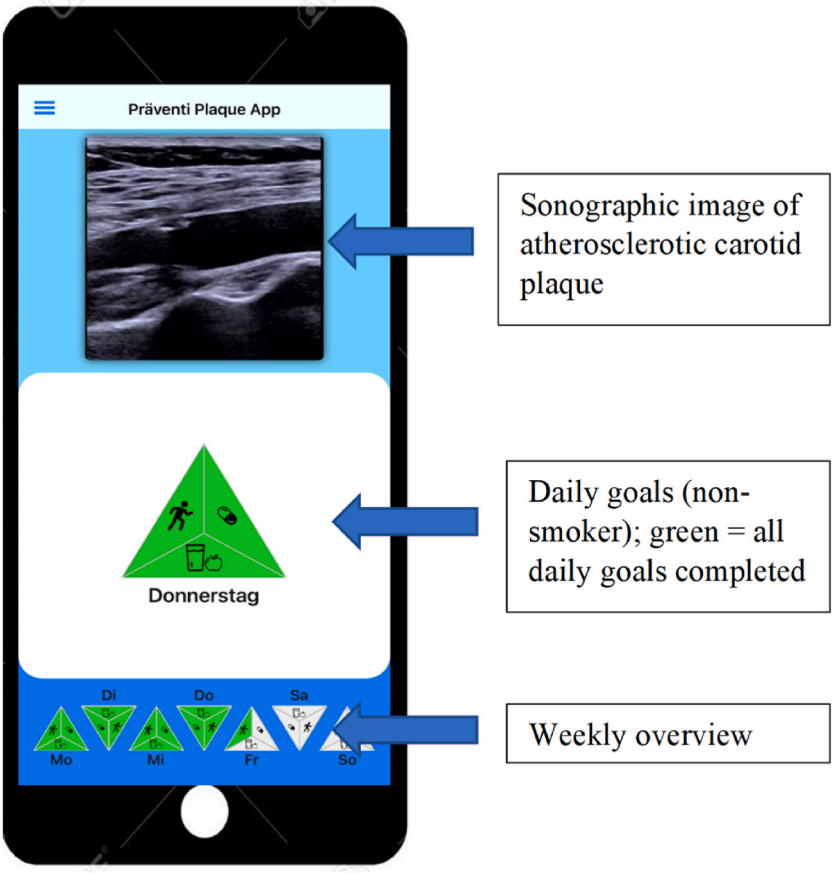


Fig. 3. PreventiPlaque-app home screen (non-smoker).

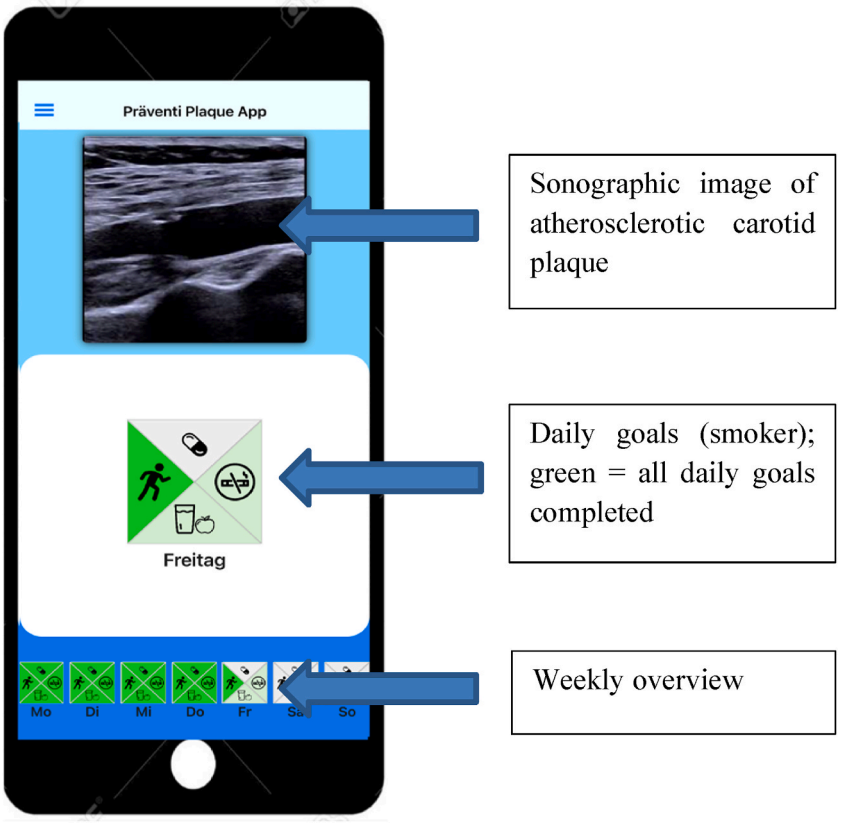


Fig. 4. PreventiPlaque-app home screen (smoker).

These include physical activity, water intake, medication adherence, and number of cigarettes smoked in the case of active smoking. They are presented as chains of seven triangles (non-smokers) or 7 squares (smokers) per week. Completing all daily tasks in each health category causes the triangle or square to change to green. Completing part but not all of the daily tasks cause the shape to turn yellow. Not completing any of the daily tasks results in a red color. The health categories include the following daily subtasks.

- *Physical activity.* Participants can record the duration and type of physical activity themselves. They can choose between activities with different intensities. To choose an intensity, participants will review examples of different kinds and intensities of physical activities, such as walking (light activity), cycling (moderate activity), or playing tennis (high intensity). To reach the daily goal, 20 min of physical activity is needed (Fig. 5).
- *Drinking.* Daily water intake is recorded and aligned with a previously defined water intake at the start of the study. The segment of the triangle/square turns green when the target quantity is reached or missed by less than 10% (Fig. 6).
- *Medication adherence.* This category records whether the participant has taken the prescribed medication on the current day. Clicking the "yes" button indicates the successful completion of the task (Fig. 5).
- *Smoking.* This category is displayed only for active smokers. This task is completed by smoking fewer than the recorded number of cigarettes smoked on the previous day (Figs. 4 and 5).

2.2. Current gap in research

Current guidelines paint a clear picture of how to prevent the progression of atherosclerotic cardiovascular disease by lowering the patient's cardiovascular risk profile. Although there are evidence-based measures regarding primary and, especially, secondary prevention of cardiovascular disease, they often fail due to a lack of guidelines and medication adherence [6,17,18]. This emphasizes the importance of developing methods to improve patients' treatment adherence by raising their disease awareness. The simple communication of one's cardiovascular risk profile or status within a certain risk score range, as consistently done in ambulatory care, is in a number of ways not sufficiently specific for patients and regularly misses the goal of helping them attain sustainable lifestyle changes [19,20]. The sole verbal transmission of non-personalized cardiovascular risk information seldom leads to rational behavioral modification [7,21]. In fact, research has shown that the two main aspects of patient-centered care in order to improve treatment adherence and the feeling of self-efficacy are patient involvement and maximum personalization of information [9,22,23].

Influencing patients' health behaviors by providing information in the form of pictorial images of their current disease status or risk

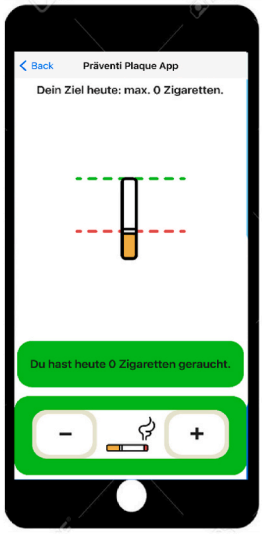
Daily goal: 20 minutes of physical activity

You moved 0 minutes today

10 minutes of physical activity

Did you take your medication?

Yes/No



Your goal today: smoking 0 cigarettes

You smoked 0 cigarettes today

Fig. 5. Daily goals in the PreventiPlaque-app.

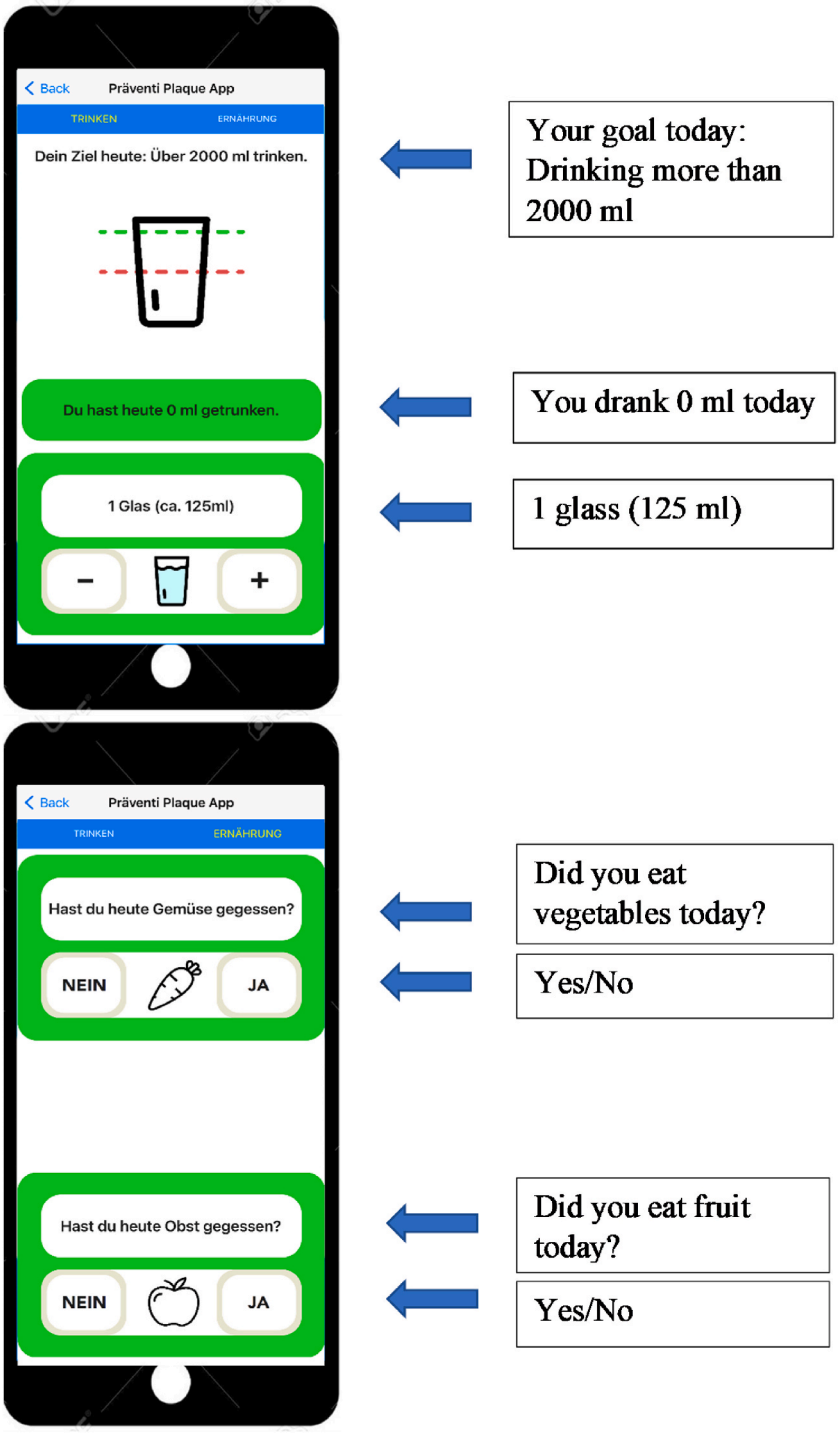


Fig. 6. Daily goals (diet and water intake).

of disease progression has been an ongoing aim in clinical research. It has been shown to have the potential for positive behavioral changes by increasing patients' motivation [24,25]. Moreover, it appears to be more effective for improving treatment adherence than other methods of personalized risk feedback [19,24]. Applying this innovative concept of visualizing atherosclerotic plaque to the secondary prevention of atherosclerotic cardiovascular disease can raise patients' awareness more effectively than verbal patient education alone. The pictorial presentation of subclinical atherosclerosis has been shown to improve patients' motivation to follow secondary preventive measures [25–27]. However, results of the contributory effect of visually based information regarding silent

atherosclerosis on prevention and therapeutic adherence are inconsistent. The screening of atherosclerotic carotid plaque, in particular, has been proven to have a positive impact on therapy adherence in type 2 diabetes mellitus as well as in hypertension [28,29]. In contrast, the positive effect of pictorial presentation of atherosclerotic plaque in regard to the aim of smoking cessation has shown mixed results [30,31]. Most studies implement plaque presentation by visualizing sonographic or angiographic images during hospital visits [24,32], but in order to account for a sustainable behavior change, a long-lasting image exposure with a frequent reminder option is necessary. Therefore, within the *PreventiPlaque* app, we combined the in-app pictorial plaque presentation with low-threshold daily tasks. The daily tasks, with minor gamification aspects like color-coding weekly accomplishments, were developed mainly to achieve frequent viewing of the user's carotid atherosclerotic lesion [33]. In this context, mHealth technologies offer significant opportunities to expand the sustainable effects of visualized and personalized risk communication to ambulatory care [34]. The *PreventiPlaque* app, as the first of its kind, points out new ways to personalize and digitalize risk communication in outpatient aftercare.

Ethics approval and consent to participate

This study was approved by the local ethics committee of the University of Duisburg-Essen (20-9157-BO). Written informed consent will be collected from each participant prior to any study procedures, and each participant will receive contact information.

Author contribution statement

Alexander Bäuerle - Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.
Alina Dönmez - Analyzed and interpreted the data; Wrote the paper.
Amir Mahabadi: Analyzed and interpreted the data, Wrote the paper.
Christos Rammos: Contributed reagents, materials, analysis tools or data; Wrote the paper.
Greta Ullrich: Conceived and designed the experiments; Performed the experiments, Wrote the paper.
Julia Lortz: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.
Katrin Paldán: Contributed reagents, materials, analysis tools or data; Wrote the paper.
Lenka Schnaubert: Performed the experiments; Wrote the paper.
Ramtin Knuschke: Performed the experiments; Wrote the paper.
Tienush Rassaf: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of interest's statement

The authors declare no competing interests.

Acknowledgements

Acknowledgements will be noted following the completion of the study.

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