SUPPLEMENTARY MATERIAL

Methods and analysis

Details of recruiting AF patients

In order to facilitate recruitment of AF patients, a network of Cardiologists who run large cardiac arrhythmia clinics has been established in collaborating health centers (Nicosia General Hospital, University Hospital of Heraklion and Soroka Research Clinical Center) at each of the three countries. Relations have also been established with the Clinical and Nursing staff of the Clinics and Patients' Associations and the details of the project have been explained to them. Screening of the AF patients at each site started in Summer 2018. The medical/symptom and medication history and downloads from patients' pacemakers or ICDs are obtained and examined in order to assess whether the candidate for enrolment fulfils the eligibility criteria. The age itself has not been used as a limiting factor for the participation in the study, but the inability to understand and use study tools (smartphones, software applications), due to age, intellectual disability, etc. Also, patients on terminal illness, bed-bound patients and/or patients with impaired physical mobility are excluded from the study, due to the limited outdoor exposure. The patients' recruitment has been facilitated by the medical staff of cardiology clinics, who are aware of the medical history (e.g. permanent AF, other reversible causes of AF), the comorbidities (e.g. visual impairment, hearing impairment), the lifestyle habits (e.g. active smoking, regular change of household) and the readiness of each patient to participate in the study and comply with the basic requirements.

Patients are able to ask questions for clarification of all aspects of the program. Eligible AF patients are then invited to participate in the MEDEA program after they give written informed consent. An independent researcher provides the sequential number and the assignment group at the baseline clinical visit, who is responsible also for the participants' training on the use of devices after recruitment. Due to the nature of the study, the participants couldn't be blinded to the assignment group.

Several old types of pacemakers implanted to AF patients do not store more than 16 arrhythmia episodes. Thus, for the performance of the AF panel study we rely mainly on patients with implanted ICD's or modern pacemakers such as Advisa (Advisa DR MRI™ and Advisa SR MRI™, Medtronic, United States) and Adapta (Adapta DRTM and Adapta SRTM, Medtronic, United States). These pacemakers save all fast rate episodes, regardless of the time interval between interrogations of the device.

Details on wearable devices

One of the main and earliest challenges of the project was the memory capacity and energy efficiency of the device, as this may affect the credibility of the collected data. In order to overcome this issue, we evaluated several commercially available smart watch devices and we chose the LEMFO-LM25 smartwatch equipped with the EMPBRACETM software (Embrace Tech LTD, Cyprus). This smartwatch does not require manual synchronization with another

device but acts as a stand-alone device that is able to upload data automatically when it gets in contact with the WI-FI network at the participant's house.

Details of implementation of the intervention

When predefined algorithms of PM_{10} levels are fulfilled, MEDEA air pollution scientists at each study site, promptly communicate alerts for the appearance of DDS through the e-platform to the participants in the intervention legs of the study, but not to the participants in the control group. To this effect, emails, smartphone applications and text messaging are used to disseminate the specific exposure reduction recommendations in text and animated videos. The participants are familiarised at recruitment with the respective intervention recommendations through animated videos and take home hard-cover flyers printed in a user-friendly layout, to encourage compliance to the intervention.

In participants who are randomized to the combined outdoor and indoor intervention, we also arrange at recruitment to visit their houses within the same week and install air-cleaning devices. Instructions on the use of air cleaners are provided to patients on site. During the home visit, we also assess the placement, and thus functionality of the air cleaner, in a room of the house where the participant spends most of the time (typically between bedroom and sitting room). Reminders are taped on the air cleaners advising to keep them functioning continuously, throughout the six-month study period. Monthly clean-ups of the HEPA filters of the air cleaner are performed by the research staff, as recommended by the manufacturer.

Study organisation & coordination

DATA ACCESS, OWNERSHIP OF RESULTS, DATA TRANSFER AND PUBLICATION AGREEMENTS

A consortium agreement signed by all participating centers sets the obligations for data access, ownership of results, data transfer and publication agreements.

RESPONSIBILITIES AND COMMITTEES

Coordinating center: Apart from the coordination of the study, the coordinating center is responsible for the acquisition of rights for tools usage.

Data management team: The team consists of researchers form the three centers aiming to ensure data collection, data cleaning and the appropriate preparation of the study dataset.

Steering Committee: The Steering Committee scrutinizes the quality of the project performance, acts as a supervisory body to ensure that the work described in individual actions is carried out and is responsible for troubleshooting. The members of the steering committee include the Project Coordinator, Project Manager, and the Leaders of all other project partners (Soroca Clinical Research Center, University of Crete, Cyprus University of Technology, E.n.A. Consulting, Department of Labor Inspection, Cyprus Broadcasting Corporation, Cyprus Department of Meteorology).

External Advisory Committee: The external advisory committee is responsible to counsel the project and to help transform our results to policies. It consists of 33 members from relevant regulatory authorities and interested stakeholders from all participating sites (Cyprus, Greece, Israel).

A data monitoring committee was not needed for this study, because the participants are adults, the behavioural intervention has very low chance of producing harm, and the duration of the follow-up period for each participant is short (6 months).

PARTICIPANT CONFIDENTIALITY

Administrative safeguards:

Data are completely anonymized and encrypted prior to sending to the central database. The full record of AF participants with names, addresses, and other personal information are kept by the principal investigator (PY) at the Medical School of the University of Cyprus and only authorized personnel will have access to this data (LIFE MEDEA+ project scientist PK). All collected data will be analyzed and discussed between program partners only by using codes (a participant identification number (Participant ID, PID) to ensure that the anonymity of the participants is fully preserved and to maintain confidentiality.

Technical safeguards:

Electronic access to patient data requires a user name and password that is only held by authorized personnel. All computer entry and networking programs are done using PIDs only. In addition, the Microsoft Azure storage platform used for the purpose of data storage and backup, is Health Insurance Portability and Accountability Act (HIPAA) compliant that establishes requirements for the use, disclosure, and safeguarding of individually identifiable health information.

The University of Cyprus has a policy that requires computer users not to leave computers unattended and not to exchange entry codes between them. Still, it is worth mentioning that after a few hours of non-use, the computer automatically turns off and locks again, requiring the use of the input code again. In the event that a computer containing personal data is no longer used, the University of Cyprus ensures that the data will either be transferred or destroyed.

Physical safeguards:

The Medical School of the University of Cyprus is housed at the Shakolas Educational Center, a safe building on Nicosia-Limassol Old Road, in Aglantzia, Nicosia. The building is protected internally and with the supervision of the surrounding area, on a daily basis with a 24-hour security guard. The guard checks all incoming people in the building. Data that may be in print will be kept in a closet in the office of the Project Coordinator so that no unauthorized person has access to them. All records will be kept in a locked file cabinet.