Santé-AF Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation

Feasibility study to inform a randomised controlled trial

Participant Information Sheet

Version 1.4 – Date 26 January 2021

We would like to invite you to take part in a research study

- To help you make an informed decision, we would like to ask you to read this document.
- Please do not hesitate to contact us to ask for further information at any time (contact details are on the final page).
- Please feel free to discuss any of this with your family and friends.

What is the purpose of this study?

Research shows that people living with atrial fibrillation (AF) feel they have a lower quality of life than people who do not have AF. People with AF also report that as their level of symptoms increases, their quality of life decreases.

We want to do a large trial to see if people with atrial fibrillation experience a change in their symptoms and/or their quality of life if they have acupuncture or nutritional therapy.

First, we need to do a smaller study to see if a large trial is possible. You are being invited to take part in this smaller study.

Contents

Extra information

You do not have to read this, but it may provide helpful information

Why have I been invited?

You have been invited to participate in this study because your medical care team at your GP surgery have identified from your medical records that you have been diagnosed with atrial fibrillation, at least six months but less than five years ago, and that you are at least 45 years old (but under 70). Your AF care team have also checked your records to make sure that you have been offered all the appropriate medical care for your AF, and that you are not classified as clinically vulnerable in relation to COVID-19, before you were contacted about this study.

At this stage, we do not know if you are fully eligible to take part. To take part, you will need to meet the eligiblity conditions set out below (please see **How will I know if I am eligible to take part?** below). We will check and let you know if you are eligible to take part.

How will I know if I am eligible to take part?

To take part in this study, you need to meet the following conditions:

- You must be aware of your AF when it happens, and it should happen at least once a week (even if you are taking AF medication or have had any hospital treatments for your AF). This may mean that you feel unusually breathless, or have palpitations, fatigue, dizziness or fainting, or have chest discomfort;
- You must be willing to have either acupuncture or nutritional therapy alongside your usual care (your medications or other NHS treatments for AF);
- You must be willing to do two assessments: one at the start of the study, and one after about three months. Please note that, due to COVID-19, all study assessments will be carried out online. You will be guided to carry out the assessments, which involve taking some measurements and filling in some forms. Please see **What will happen at the online assessments?** on page 4, and the separate section **A Guide to Online Assessments** on pages 16-19 for more information about assessments;
- If you are randomly allocated to the Acupuncture group, you must be willing to travel to your acupuncture appointments (weekly over an 8–10 week period). We will pay you £5 per appointment to help meet your travel costs;
- If you are randomly allocated to the Nutritional Therapy group, you must be willing to attend nutritional therapy appointments (approximately once a month for 3 appointments). These will be carried out online to minimise the risk of COVID-19. You will be guided through the process of attending appointments online;
- You must be willing and able to use your own mobile phone and email address to receive and respond to text messages, phonecalls and emails about the study;
- You must have a computer, tablet or smartphone with Microsoft Teams OR be happy to use the study iPad (with guidance from the researchers) to do online assessments. Please see the section **A Guide to Online Assessments** on page 16-19 for more information about this;
- You must have a home broadband connection in a quiet, private room where you can do the online study assessments, twice in a 10-12 week period;

- You must be able to speak and write English well enough to talk with your acupuncturist or nutritional therapist without help from anyone else, and to complete the questionnaires we will give you without help from anyone else. This is because the study does not have the resources to fund translators or interpreters;
- You must be able to give your informed consent without help from anyone else.

You will NOT be able to take part in the study if you:

- Have a condition that might make it inadvisable for you to take part – such as advanced kidney disease, a blood clotting disorder, an eating disorder, any terminal or life-limiting illness, or any condition that means you should not do suitable moderate exercise;
- Have any of the following fitted: a pacemaker, an implanted defibrillator, a neurostimulator or any other type of active implantable device;
- Are regularly using a TENS machine or receiving any regular diathermy, diagnostic or therapeutic ultrasound, radiation therapy, electrosurgery or x-rays;
- If your AF is related to your heart valves ("valvular AF"), or if it is officially diagnosed as "permanent", which means that it happens all the time;
- Are pregnant or trying to conceive;
- Are shielding, or classified as either clinically vulnerable or clinically extremely vulnerable to COVID-19, according to NHS advice; or if you are living with or bubbled with anyone in any of these categories;
- Are taking part in any other medical research that might affect the results of this study, or which might affect your safety if you enter this study in addition.

If I am eligible, what will happen next?

Using the details you gave us on the Permission to Approach form, we will telephone you in the next few days to ask whether you have any questions about the study. When we have answered those (or if you don't have any questions), then if you would like to take part in the study you should sign and return to us one copy of the Consent Form in the envelope provided.

When we receive your signed Consent Form, we will telephone you again – this time to ask some questions to check that you are fully eligible to take part (the "screening phonecall"). We will then invite you to attend a first online assessment (a "baseline assessment"). Please see **What will happen at the online assessments?** (page 4) for information about the assessments and what we will ask you to do.

If this second phonecall reveals that you are NOT eligible to take part, we will send you a letter to let you know this. We will securely store the information you have given us so that we can show why you are not eligible to take part. In the study write-up, we will report anonymously all the reasons that people were not eligible. You will not be publicly identifiable in any way. We will securely destroy this information after 10 years.

We have put more details about the progress of the study in the **Study Roadmap**, on page 20-21 of this information booklet. Please read this for more information about how the study will progress, what we will ask you to do, and when we will ask you to do it.

What will happen at the online assessments?

We will ask you to do two assessments. One will be at the start of the study, and the second will be about three months after the start of the study. Both assessments will be identical, although the questionnaire will be slightly different at each assessment.

To minimise the risk of COVID-19, we will carry out all assessments online. The researcher will stay online with you throughout the assessment. Please read the section **A Guide to Online Assessments** on page 16-19 for more information about online assessments.

In each online assessment, we will ask you to:

- **Record details of your current medications.** If you prefer, you can simply show your medication bottles and boxes to the camera. The researcher will write down the names and dosages.
- **Take away an AF symptom diary sheet to complete over the next 7 days.** We will give you an AF symptom diary sheet, so you can write down your AF symptoms over the following 7 days. We will give you a stamped envelope to return this in the post.
- **Tell us your height.**
- **Fill in a questionnaire** about your health, your personal information, your AF, your ways of taking care of yourself, and your quality of life.
- **Interview you about your experience of having AF and your experience of taking part in the study.** If you have told us you are willing to be interviewed about these things, we will also carry out your interview at this appointment. The interview should last no longer than 40 minutes, in addition to the 40 minutes of other activities above. Please note that we cannot interview everyone who is willing, due to time constraints.
- **Measure your weight, your waistline, your hip circumference and your blood pressure.** We will provide equipment for you to use, and we will guide you through the process of taking these measurements. You can turn the camera off for these sections, if you prefer.
- **Fit a CardioSTAT® heart monitor** to your chest, with guidance (if you have been randomly selected to wear one). Please see **What is the CardioSTAT® heart monitor?** on page 7 more information. If you have been selected to wear a CardioSTAT®, we will deliver it to you, and we will guide you to fit this during your online assessment.

When we have gathered all the data from your second assessment, we will give you a £10 retail voucher as thanks for your time. Please see **Will it cost me money to take part in the study?** on page 8 for more information about what we will pay you and how we will pay it.

After the first online assessment, what happens next?

After we have collected all your baseline data, and you have returned your AF diary sheet (and CardioSTAT® if you are selected to wear one), we will enrol you in the study. This means you will be randomly placed into one of three study groups: Acupuncture, Nutritional Therapy or Usual Care. The researchers have no control over which group you are placed in.

We will write to you, to let you know which group you have been placed in. If you have been placed in the Acupuncture or Nutritional Therapy groups, we will send you details of the acupuncturist or nutritional therapist who will be working with you, and we will ask you to contact them to make your first appointment at your own convenience. If you have been placed in the Usual Care group, you will simply continue with your usual treatment for AF as given by your GP or your cardiologist.

Please feel free to call us at any time to ask any questions you may have regarding this study. You can find contact details at the end of this Information Sheet.

There are three private acupuncturists and three private nutritional therapists working on the Santé-AF study. You may be assigned to receive treatment from any of these practitioners. If you are unhappy with the choice of practitioner assigned to you, please let us know **before your first appointment**, because we may be able to change this – but we can only do this before your first appointment, so it is important to get in touch with us straight away. You do not have to give any reasons for wanting to change your assigned practitioner, and the practitioner will not be told of your decision to change.

Whatever group you have been placed in, we will send you two text messages to ask how satisfied you are with your allocated treatment, and whether you expect your AF to improve, stay the same, or get worse during the study.

What are the three groups in the study?

The three groups in the study are:

- Group A: Acupuncture + Usual Care
- Group B: Nutritional Therapy + Usual Care
- Group C: Usual Care.

Everyone taking part in the study will continue with usual care (their existing NHS treatment for AF) no matter what group they are placed into. People placed into the Acupuncture or Nutritional Therapy groups will receive acupuncture or nutritional therapy *as well as* their existing NHS treatment. **It is very important to continue with your usual care while you are in the study.**

See **What are acupuncture, nutritional therapy, and usual care?** on page 6 for details of each kind of treatment in the study, and what they involve.

You are asked to continue with your usual care for AF (in addition to having acupuncture or nutritional therapy appointments if you are allocated to one of these groups). **It is very important that you do not make changes to your usual care (except any changes made by your NHS care team).**

Please note that while we will monitor changes in your AF as part of the study, we will do this for research purposes rather than for the purposes of your medical care. This means that data may not be analysed promptly. **It is very important that if you become aware of any changes in your health that are of concern to you, you must get in touch with your care team straight away.**

What are acupuncture, nutritional therapy, and usual care?

Group A: Acupuncture

If you are randomly placed into the Acupuncture group, you will have up to eight weekly sessions of acupuncture with a traditional acupuncturist while continuing with your usual treatments or medications for AF. Your acupuncturist will ask detailed questions about your health (not just your AF) and make a diagnosis according to the principles of Chinese medicine. They will insert small needles at acupoints to restore balance to your system. They may also use other treatments such as acupressure massage, burning a Chinese herb called moxa close to the skin, electro-acupuncture using a low electrical current, or seeds/tacks on ear pressure points. They will also offer you advice on self-care areas such as diet, exercise and relaxation.

A first appointment may take up to 1.5 hours, and every following appointment will take about an hour.

Group B: Nutritional Therapy

If you are randomly placed into the Nutritional Therapy group, you will have up to three online consultations with a nutritional therapist while continuing with your usual treatments or medications for AF. Your nutritional therapist will ask detailed questions about your health (not just your AF) and about your diet. They will analyse this information and write a dietary plan specifically designed for you. They may also offer you advice on self-care areas such as exercise and relaxation.

They will send this dietary plan to you and you will be able to discuss it with them at your second appointment. At a third appointment, they will check how you are getting on and make any adjustments to the plan that you need.

A first appointment may take up to 1.5 hours, and every following appointment will take about an hour.

Group C: Usual Care

If you are randomly placed into the Usual Care group, you will continue with your existing NHS treatments or medications for AF. These include:

- **medications** including anticoagulation and/or anti-arrhythmic drugs or drugs to control your heart rate and rhythm;
- **electrical cardioversion**, which is a controlled electrical shock to the heart to restore normal rate/rhythm;
- **catheter ablation**, which is a minimally-invasive procedure to remove parts of the heart tissue that are thought to cause AF.

COVID-19 safety in the Santé-AF study

We have taken the following actions to minimise the risk of COVID-19 transmission during appointments:

Nutritional therapy appointments will be held entirely online with no face-to-face meetings.

Acupuncture appointments have been made as safe as possible. Acupuncturists in the Santé-AF study are all members of the British Acupuncture Council and they are required to follow a COVID-19 code of safety. This covers a full range of measures including increased hand hygiene by participants and acupuncturists, the use of full PPE by acupuncturists, and thorough cleaning of all surfaces and ventilation of rooms between patients. Patients will also be asked to wear masks to their appointments (unless there is a medical reason for not doing so), and to confirm COVID status immediately on arrival.

Please ask if you have any questions regarding the COVID-19 safety of the study. Contact details can be found on the back cover of this information leaflet.

Will I definitely get acupuncture or nutritional therapy?

Every person taking part in the Santé-AF study has a 4 in 5 (80%) chance of being randomly selected to receive *either* acupuncture *or* nutritional therapy.

There is a 1 in 5 (20%) chance of being randomly selected to receive usual care, in which you won't receive either acupuncture or nutritional therapy, but will continue with your usual care as given by your GP or your cardiologist.

If you are placed into the Usual Care group, you are still playing an extremely important role in the study. This is because we need to compare the groups to find out whether acupuncture or nutritional therapy change symptoms and quality of life. So if you are placed in the Usual Care group, **it is vital that you do your online assessments**, and complete the 7-day AF diaries we will give you during the study, including wearing a 7-day CardioSTAT® heart monitor twice if you are selected to do this. By doing this, you are playing an essential role in helping us to discover if acupuncture and nutritional therapy have an impact for people with AF.

The study administrators have no control over which group you are placed in, or whether you are selected to wear the CardioSTAT® heart monitors.

Please feel free to call us at any time to ask any questions you may have regarding this study. You can find contact details at the end of this Information Sheet.

What is the CardioSTAT® heart monitor?

The CardioSTAT® is a small electrocardiograph (ECG) heart monitor that you wear while going about your normal life. It measures your heart activity and collects data on your AF symptoms.

One-third of the people enrolled in this study will be randomly assigned to wear a CardioSTAT® monitor. If you are one of these people, you do not need to make any changes to your daily activities while you are wearing it (in fact, it is important that you continue everything as normal). You can wash and shower as usual. After 7 days, you will be asked to remove the CardioSTAT® and send it back by freepost to Icentia, the manufacturers of CardioSTAT®, who will analyse the data in their laboratory and share it with the researchers and your GP.

The data collected by the CardioSTAT® will be 'pseudonymised', meaning that it is given a code which does not connect it with your identity. Your data will also be made available in pseudonymised form to the researcher, so it can be included in the study (see **Confidentiality and Data Protection** on page 10 for more information).

Every person taking part in the Santé-AF study has a 1 in 3 (33%) chance of getting a CardioSTAT® heart monitor, no matter what group they are randomly placed into. This includes the Usual Care group.

CardioSTAT® is manufactured by a Canadian company called Icentia Inc., whose UK arm, Icentia Limited, is based in York at the Science Park next to the University. You can find out more about Icentia by visiting **https://www.icentia.com/home** and you can find out more about the CardioSTAT® monitor here: **https://www.cardiostat.com/uk/home.** Alternatively, you can get in touch with the researcher to ask more questions about the CardioSTAT®. Contact details can be found at the end of this Information Sheet.

What is my total time commitment to the study?

You will be involved in the study for a total of approximately 4 months. This includes everything from the time you agree to take part, up to the time you attend for your final online assessment.

Below we have set out a table showing how much time you will need to give to the study, over the course of 4 months.

The **Study Roadmap** (page 20-21) gives an at-a-glance summary of the study progress. Please read this for a summary of how the study will move forward, what we will ask you to do, and when we will ask you to do it.

Group A: Acupuncture

If you are randomly placed into the Acupuncture group, your total time commitment during the 4 months will be:

- About **one and a half hours** to attend the assessments, plus a further **one and a half hours** to be interviewed (if you are willing to be interviewed, and you are selected for interview);
- About **nine hours** to attend your acupuncture appointments;
- **Travelling time** to and from your appointments.

Group B: Nutritional Therapy

If you are randomly placed into the Nutritional Therapy group, your total time commitment during the 4 months will be:

- About **one and a half hours** to attend the assessments, plus a further **one and a half hours** to be interviewed (if you are willing to be interviewed, and you are selected for interview);
- About **four hours** to attend online Nutritional Therapy appointments.

Group C: Usual Care

If you are randomly placed into the Usual Care group, your total time commitment during the 4 months will be:

- About **one and a half hours** to attend the assessments, plus a further **one and a half hours** to be interviewed (if you are willing to be interviewed, and you are selected for interview).

Will it cost me money to take part in the study?

There are no costs involved in taking part in the study, except:

If you are placed in the Acupuncture group, there is the cost of travelling to and from your appointments. We will pay you £5 for each appointment you attend, to help you meet your travel costs.

Are there any benefits to being involved?

If you take part in the study, you are contributing to our knowledge about future potential treatments for AF. This is the case even if you are placed in the Usual Care group and do not

receive acupuncture or nutritional therapy. Our hope is that we can use the knowledge we gain in this study to help us design a larger trial that will produce high-quality evidence about whether these treatments change symptoms and quality of life for people with AF.

We cannot promise that the study will definitely change your quality of life or your symptoms; but the information we get from this study will help to answer the question of whether people with AF having acupuncture or nutritional therapy experience a change in their quality of life and/or their symptoms compared with people who are not having these therapies.

We will give you a £10 retail voucher as a thank-you for your time if you complete both assessments (at the study start, and after three months).

Can I continue with my therapy after the study has finished?

The study has no budget to pay for you to continue having either acupuncture or nutritional therapy after the study has finished. Any further treatment you choose to have after the end of the study would be at your own expense.

However, if you would like to continue having treatment after the study finishes, you will be offered the chance to attend the acupuncture or nutritional therapy clinics at the Northern College of Acupuncture, in central York. These are teaching clinics, offering low-cost acupuncture and nutritional therapy with support for lifestyle change.

Do I have to take part?

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time, and your usual care will not be affected in any way whatsoever. You do not need to tell us why you do not want to continue. (We will ask you, because it is very helpful to have this information – but you do not have to answer.)

If you withdraw, we will include in our analyses the information you have given us before your withdrawal, including publications. This information will be completely anonymised and you will not be identifiable in any way.

Are there any risks or burdens involved?

Risks of taking part in the study

There are minimal risks involved in participating in this study.

Acupuncture has a good safety record. Some patients (8.6%) report at least one unpleasant side-effect of acupuncture. For more than half these patients (6.1%) the most common issue is bleeding or haematoma (clotted blood under the skin), while others report pain. There is a risk of superficial bleeding or bruising, particularly if you are taking anti-coagulant drugs, but your acupuncturist is trained to take this into account and will adapt your treatment to maintain your safety. Some people may feel tired after treatments. Your acupuncturist will ask you about any effects you have noticed, and will monitor these carefully.

Nutritional Therapy does not have an established safety record. There is a risk that some dietary strategies may affect the action of anticoagulant medications, but to ensure your safety, nutritional therapists are not permitted to use such dietary strategies in this study. Your nutritional therapist will ask you about any effects you have noticed, and will monitor these carefully.

If you tell the study researcher, or your therapist, about any symptoms that in their opinion may need further investigation, they will write to your GP to ask them to follow this up with you. These symptoms may not be connected with your atrial fibrillation.

In addition, if you are asked to wear the CardioSTAT® heart monitors, and the monitor detects any symptoms that may need further investigation, the researcher will write to your GP to ask them to follow this up with you.

COVID-19 safety in the Santé-AF study

We have taken the following actions to minimise the risk of COVID-19 transmission during appointments:

Nutritional therapy appointments will be held entirely online with no face-to-face meetings.

Acupuncture appointments have been made as safe as possible. Acupuncturists in the Santé-AF study are all members of the British Acupuncture Council and they are required to follow a COVID-19 code of safety. This covers a full range of measures including increased hand hygiene by participants and acupuncturists, the use of full PPE by acupuncturists, and thorough cleaning of all surfaces and ventilation of rooms between patients. Patients will also be asked to wear masks to their appointments (unless there is a medical reason for not doing so), and to confirm COVID status immediately on arrival.

Please ask if you have any questions regarding the COVID-19 safety of the study. Contact details can be found on the back cover of this information leaflet.

Burdens of taking part in the study

All people taking part in the study will experience some additional burden in completing the assessments (questionnaires and other measurements). We have tried to minimise this burden by:

- making the questionnaires as short and easy to understand as possible;
- providing one-to-one guided support throughout the assessments, to make them as easy to carry out as possible;
- providing technology and equipment to assist the online assessment process, to avoid anxiety or stress for participants.

Confidentiality and data protection

The UK Health Research Authority provides generic information regarding how your data is used in research. If you would like to see this, please visit: **bit.ly/hra-patient-data**. If you do not have access to the internet, please ask the researcher for a printed copy to be sent to you. You can find contact details on the last page of this Participant Information Sheet.

Please feel free to call us at any time to ask any questions you may have regarding this study. You can find contact details at the end of this Information Sheet.

Confidentiality

During your treatment period, your personal information, including information about your health that you choose to share, will be known to your acupuncturist or nutritional therapist – just as it would be if you were consulting them privately yourself. If your practitioner works in a multidisciplinary clinic (where more than one practitioner works at the same time), the clinic reception/ management staff will have access to information such as your name and contact details, although they will not be able to access your personal health information.

Some information from your consultations will be shared with the researcher, so that it can be included in the study analysis. Before it is shared, this information will be 'pseudonymised', meaning that it will be given a code instead of your name. All identifying details, such as your name and address, will be removed. All documents will be identified only by this code, and all analysis is carried out using the pseudonymised data, so that no data used in the analysis can be linked directly back to you. Your personal information will be kept strictly confidential, and will not be shared outside of the study.

The only exception to this is if you reveal information either to your acupuncturist or nutritional therapist, or to the researcher during your assessments, that suggests you may be a danger to yourself or to others. In this case your practitioner and the researcher have a duty of care to protect you and the public that overrides confidentiality requirements, and they will inform your GP. This duty of care will be explained to you in your first assessment with the researcher, and your first consultation with your acupuncturist/nutritional therapist.

In addition, if you report either to your acupuncturist or nutritional therapist, or to the researcher during your assessments any symptom which in their opinion may require further investigation, they will write to your GP to refer this matter to them. In addition, if the data from your CardioSTAT® heart monitor, when analysed by Icentia Limited, indicates any symptoms that may require further investigation, Icentia will report these symptoms to the study's consultant cardiologist, Dr Sanjay Gupta of York Teaching Hospital. He will in turn report this to your GP. Your GP may contact you to follow up any of these issues.

How we will use and store your data during the study

All documents, including the 'look-up table' that links your identifying details with your identification code, will be kept securely, either in a locked cabinet in a locked room (paper forms), or on securely managed servers at the University of York (electronic data). This is in accordance with the General Data Protection Regulations (GDPR) and the UK Data Protection Act 2018.

The researcher will use your name and contact details to:

- keep in touch with you about the study;
- inform your GP that you are involved in the study;
- pass relevant information gathered during the study to your GP (including data gathered from your CardioSTAT® heart monitor, if you are asked to use one).

In addition, data from the CardioSTAT® heart monitors (if you are asked to wear these) will be processed by the manufacturers, Icentia Limited. You are identified to Icentia only by a code, and processing will be carried out in strict confidence. Your CardioSTAT® data will be shared with your GP, with the study's consultant cardiologist, and with the researcher.

Additionally, we will use your name and mobile phone number to stay in touch with you, using an SMS messaging management service called FireText. FireText Communications Limited is a Government-approved supplier of secure text messaging services to the NHS and other Government bodies, and stores your information securely according to GDPR.

Because the study is part of a PhD research project, academic assessors may look at your data to check the accuracy of the study. You will remain anonymous to them during this process. They will only access your contact details if they need to contact you regarding the study.

The study's Trial Steering Committee will consider information about you in pseudonymised form in the event of any harm to you arising during the course of the study. You will remain

anonymous to them. Any contact with you will be done via the researcher, who will also share any information regarding harm with your care team.

If you have given us permission to interview you about your experience of having AF or your experience of study participation, we will record the interview, and we will make notes on the interview. We may quote you directly in any study report, publication or presentation. We will take great care not to include in the quotes any information that could identify you directly.

Data protection

The University of York is the sponsor for this study based in the United Kingdom. The University will be using information given by you, and from your medical records, in order to undertake this study, and will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly. The University will securely store your personal information, including your name and contact details, for 10 years after the study has finished. At the end of this time, the information will be securely destroyed.

Our legal basis for processing your health information is Condition (j) in Article 9 (2) of the General Data Protection Regulations and your consent, as given by you in the Consent Form.

Your consent

By signing the Consent Form, you give permission for your data to be stored and used as described above. A copy of your signed Consent Form will be stored securely. You will be given a copy to keep.

Who is doing the research?

This study is being carried out by Karen Charlesworth, who is a PhD student at the University of York and the Research Director of the Northern College of Acupuncture, York. The PhD is overseen by the University of York's Health Sciences department under the supervision of Dr Judith Watson, Senior Research Fellow, and Professor David Torgerson, Head of the York Trials Unit. The Thesis Advisory Panel includes Ms Ada Keding, and is chaired by Professor of Cardiovascular Health Patrick Doherty; it formerly also included the late Emeritus Professor of Acupuncture Research, Hugh MacPherson.

The study's Trial Steering Committee is chaired by Ms Harriet Lansdown and comprises an expert acupuncturist member (Mr John Wheeler), an expert nutritional therapist member (Dr Sonia Williams), and a consultant cardiologist (Dr Sanjay Gupta).

The study is funded by the British Acupuncture Council and the Northern College of Acupuncture, York.

Who has reviewed and approved this study?

This study has been reviewed and approved by the University of York Health Sciences Research Governance Committee (ref: HSRGC/2019/346/H) and the UK Health Research Authority (HRA) and Health and Care Research Wales (HCRW) (ref. 20/LO/0598).

Your rights

In this study, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum possible personally identifiable data.

If you lose the capacity to consent whilst you are taking part in the study, we will withdraw you from the study. We will keep the information about you that we have already obtained, but no further data will be collected and no further research procedures will be carried out.

If you are not happy with the study and want to complain, please contact the Head of the Trial Steering Committee, Harriet Lansdown. You can telephone on 01904 343305 or email on **tsc@sante-af.org**.

What if there is a problem?

If you have any concerns about any unexpected reaction to your acupuncture or nutritional therapy treatment during the study, please contact your acupuncturist or nutritional therapist.

If you have any medical problems or concerns relating to your AF, please contact your care team. In the event of requiring urgent care, you should contact the usual emergency services.

While we anticipate no harm or distress to anyone as a result of this study, it is important to state that there are no special compensation arrangements. In the unlikely event that you suffer injury or illness as a result of participating in this study, indemnity cover will be provided by the individual practitioners, the University of York and your GP practice.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please get in touch with the Head of the Trial Steering Committee, Harriet Lansdown, via the Northern College of Acupuncture. You can telephone on 01904 343305 or email on **tsc@sante-af.org**.

What do I do now?

If you have any questions, please get in touch with us, using the details at the end of this form. Alternatively, we will call you in the next few days to see if you have any questions.

If you don't have any questions and you DO want to take part in the study, please fill in ONE copy of the enclosed Consent Form and return it to it to us in the envelope provided. Once you have returned your completed Consent Form, we will contact you by phone again to check that you are eligible to take part in the study. If you are eligible, we will invite you to do an online baseline assessment at a date and time to suit you. After this assessment, we will enrol you in the study. For more information about how the study will progress, please see the Study Roadmap on page 20-21.

If you do NOT want to take part in the study, you do not need to do anything further. We will not contact you without your permission. If you would like to tell us why you do

not wish to take part, we would be very grateful, because this information is very helpful in designing a better study for the future. Please be aware that **you do not have to do this**. There is space on the enclosed Consent Form for you to tell us this, if you wish. You do not need to give us your name or contact details, or any other kind of information; you will remain completely anonymous. You can return this to us in the envelope provided. We thank you, and will not contact you again.

Thank you for reading.

The following pages are for information only.

You do not have to read them, but they may provide helpful additional information.

Guide to Online Assessments

To reduce the risk of COVID-19, we are carrying out all the study assessments for Santé-AF online. This means that we will use Microsoft Teams video-calling software to guide you through the online study assessment. This section aims to answer your questions about this process.

We aim to make this as easy and unstressful as possible for you.

Please ask if you have any further questions (contact details are on the back page).

How many online assessments do I need to do for the Santé-AF study?

There are two online assessments in the Santé-AF study. The first is at the start of the study, and the second is about three months afterwards. Each assessment will take around 40 minutes. We will do this with you online.

In addition (if you have told us you're willing to be interviewed and you've been randomly selected for interview) we'll carry out your interview during the online assessment. It will take another 40 minutes.

How will I know what to do?

The Santé-AF researcher, Karen Charlesworth, will be online with you throughout your assessments. She will guide you through every part of it, and answer any questions you have.

Who will carry out my online assessments?

The Santé-AF researcher, Karen Charlesworth, will carry out your online assessments. Nobody else will be present or watching the assessment. Karen is a qualified acupuncturist, and is fully trained in carrying out medical assessments.

Will my online assessments be recorded?

If you've been selected for interview, we will record ONLY the interview. No other part of your online assessment will be recorded, although we will write down your measurements and the information you give us.

What technology do I need to do the online study assessments?

We aim to take the stress out of using technology for the study assessments. If using technology is stressful for you, please let us know and we will do everything we can to make this as easy and stress-free as possible.

What technology do I need to do the online study assessments?

We aim to take the stress out of using technology for the study assessments. If using technology is stressful for you, please let us know and we will do everything we can to make this as easy and stress-free as possible.

If you would prefer to use your own device, you will need EITHER:

- **a tablet (such as an Apple iPad or a Samsung Galaxy) with a microphone, speakers and a camera**. Most tablets are equipped with these;

OR

- **a smartphone (such as an Apple iPhone or a Samsung Galaxy) with a microphone, speakers and a camera**. All smartphones are equipped with these;

OR

- **a computer with a microphone, speakers and a camera**. Some computers are NOT equipped with these. We will check this with you during your screening phonecall (see the section **If I am eligible, what will happen next?** on page 3 for more information about the screening phonecall).

If you don't have a device of your own, or if you prefer not to use it, we will lend you the study's iPad for the online assessments. If you aren't familiar with iPads, the researcher will guide you through every step of the process.

You will need to connect the iPad to your home broadband, so please have your broadband name and password handy. The researcher will talk you through the connection process.

What software do I need to do the online assessments?

We will carry out the online assessments using the Microsoft Teams video-calling software. Teams is free to use on all kinds of device. It can be downloaded from the following location: https://teams.microsoft.com/uswe-01/downloads.

If you are using your own device and you don't have Microsoft Teams installed on your device, please go ahead and install this if you feel confident to do so. We'll do a quick test call with you to check everything is working ready for your assessment (see **How will I know it's all working?**).

If you don't have Microsoft Teams installed on your device, we'll lend you the study's iPad to carry out your online assessments. The software is all set up ready for you on the iPad.

We'll check all this with you during your screening phone call (see the section **If I am eligible, what will happen next?** on page 3 for more information about the screening phonecall).

How will I know it's all working?

If you're using your own device, we'll do a test call with you to check everything's working OK. When the researcher calls to carry out the screening phonecall, she will either do the test call with you then if you prefer, or she will agree a different date/time to suit you.

If you're using the study iPad, all you need to do is connect it to your home broadband and it should work without any problems. The researcher will talk you through the connection process. We'll deliver it to you just before your online assessment, and collect it again shortly afterwards, along with the other study equipment (see **Will I need any other equipment to do the online assessment?**).

Will I need any other equipment to do the online assessment?

You'll need some other equipment to take measurements. We'll deliver these to your home just before your online assessment, and we'll collect them again shortly afterwards. The equipment we'll deliver is:

1. Weighing scales;
2. A blood pressure monitor;
3. A tape measure to take your waist and hip measurements.

Even though you may have this equipment yourself, it's important to the study that we use the same equipment for everyone. Every piece of equipment is thoroughly cleaned before and after each use, to minimise the risk of COVID-19.

Things that you will need to provide yourself include:

- **A pen** to fill in the questionnaire;
- **Your reading glasses**, if you use these;
- You might like to have **bathrobe or towel** nearby, to keep you warm and preserve your modesty during the parts of the assessment where you're in your underclothes.

Where should I do my online assessments?

It's important to do your online assessments in a room where you can be quiet and private.

The room will need a table and chair. This is because you'll need to rest your left arm on the table to take your blood pressure. We'll also ask you to keep your device (or the study iPad if you're using that) on the table in front of you during your assessment. When you take a measurement, we will ask you to show the results to us on-screen, so we can check it and record it accurately.

Part of the online assessment involves removing some clothing (so that you are only wearing your underwear when you weigh yourself, for instance). You can turn the camera off for these parts of the assessment if you prefer. You might want to keep a bathrobe or a towel handy, so you can keep warm.

What do I have to do in the online assessments?

These are the things we will do in the online assessments:

1. **Your medications.** The researcher will ask you about your current medications. If you like, you can simply collect your bottles/boxes and show them to the camera. The researcher will write down the names and dosages.
2. **AF symptom diary.** We will give you a copy of an AF symptom diary, which the researcher will ask you to keep with you and complete over the next 7 days. She will explain how to use it, and what to do when you've completed it.
3. **Your height.** The researcher will ask you your height.
4. **Questionnaire.** The researcher will ask you to fill in a questionnaire about your general health and your AF symptoms. If you prefer, she will stay online with you while you do this.
5. **Interview.** The researcher will interview you, if you have told us you're willing to be interviewed and you've been selected for interview.

6. **Your blood pressure.** The researcher will guide you to take your blood pressure. To do this, you'll roll up your left sleeve right to the very top of your arm (you might need to slip your arm out of your sleeve to do this). Then you'll slide the cuff onto your left arm and push it up to the top of your arm. You'll tighten the cuff and turn the machine on. The machine will take 3 readings at 15-second intervals – you will need to sit still while it does this. At the end of this time, the researcher will take details of the reading for the study.

7. **Your weight.** The researcher will guide you to weigh yourself. The researcher will ask you to do this twice or three times, to check for accuracy. For this part of the assessment you'll need to take your shoes off and undress down to your underclothes. You can turn the camera off for this part if you like.

8. **Your waist and hip measurement.** The researcher will guide you to measure your waist and hips. She'll do this while you're in your underclothes, so that your clothing doesn't add any extra to the measurements. You can turn the camera off for this part if you like, although the researcher will ask you to turn the camera on briefly to check that you've positioned the tape measure correctly.

9. **CardioSTAT® heart monitor.** If you've been randomly selected to wear a CardioSTAT® heart monitor for 7 days after each assessment, the researcher will guide you to fit this. The CardioSTAT® is fitted centrally on your chest, just at the top of the breastbone, so female participants might want to keep a bathrobe or towel handy. The researcher will also explain what to do once the 7 days' monitoring are over.

10. **Returning the study equipment.** Finally, you'll collect up all the study equipment and put it back in the cases they came in, along with your completed questionnaire. The researcher will collect these from you shortly after your assessment ends, and the equipment will be thoroughly cleaned, ready for the next participant's online assessment.

I still have questions about online assessments. Who can I talk to?

If you still have questions, the study researcher, Karen Charlesworth, can answer these. She will call you in the next few days. But if you prefer to call the researcher, you can do this on either 01904 343305, or 07544 665882. If you would prefer to email, you can email her on karen.charlesworth@sante-af.org.

If you would like to ask any questions about this study, or about online assessments, please contact:

Karen Charlesworth, Santé-AF Researcher

Northern College of Acupuncture, 61 Micklegate, York YO1 6LJ

Telephone 01904 343305 or 07544 665882

Email karen.charlesworth@sante-af.org

Thank you for taking the time to read this Guide to Online Assessments.

Santé-AF Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation

Feasibility study to inform a randomised controlled trial

Study roadmap

This roadmap gives an outline of the stages in the Santé-AF study. It is only for illustration, and timescales are approximate. An individual pathway may not follow this exact course.

Recruitment phase

Enrolment phase

1 Permission to Approach pack sent by your GP surgery

Example date: 1st March

Information pack received in the post from your GP surgery. You have already completed the Permission to Approach form and returned it to us in the envelope provided.

2 Full information pack sent to you

WHEN: Typically within 5 working days of us receiving your completed Permission to Approach form. Example date: 5th March

The full information pack contains:

- an introductory letter;
- this Participant Information booklet, giving full information about the study;
- a Consent Form (two copies).

3 Phonecall from the researchers

WHEN: Typically within 2 working days of you receiving the full information pack. Example date: 7th March

We will call you to see if you have any questions about the study.

4 Return one copy of the Consent Form to us

WHEN: Typically within 3 weeks of the phonecall. Example date: 21st March

If you want to take part, complete one copy of the Consent Form and return it to us. You should do this within 3 weeks of the phonecall to make sure you are in time to join the study.

5 Screening phonecall from the researchers

WHEN: Typically within 5 working days of us receiving your signed Consent Form. Example date: 25th March

We will call you for a 20 minute conversation to work out whether you are eligible to take part. We'll also make arrangements to deliver the equipment for your online assessments.

6 Eligibility letter sent to you

WHEN: Typically within 3 working days of the screening phonecall. Example date: 28th March

We will send you a letter to confirm your full eligibility to take part in the study.

7 Baseline assessment

WHEN: Typically within 5 working days of you receiving the eligibility letter. Example date: 5th April

We'll guide you through an online study assessment. (Please see **A Guide to Online Assessments** on page 16-19 for more information about this). After the assessment you'll spend 7 days completing an AF symptom diary, and wearing the CardioSTAT® heart monitor if you have been selected to wear one. Please send these back quickly after the 7 days are up.

Enrolment phase

Trial phase

8 Group placement letter sent to you

WHEN: Typically within 12 days of your baseline assessment.
Example date: 15th April

After we have all the data from your baseline assessment we'll write to you again to let you know what group you've been placed into. The groups are: Acupuncture plus Usual Care; Nutritional Therapy plus Usual Care; Usual Care only. If you're in the Acupuncture or Nutritional Therapy groups, we'll include details of your allocated practitioner, and you'll be invited to contact them to make your first appointment.

9 SMS (text) poll sent to you

WHEN: Typically within 2 days of the group placement letter.
Example date: 16th April

We will send two SMS messages (texts) to your mobile phone. The first will ask you to rate your level of satisfaction with the group you've been allocated to. The second will ask whether you expect your AF to improve, stay the same, or get worse during the study.

10 Treatment period

WHEN: Typically the 8-10 weeks after receiving the group placement letter.
Example dates: 20th April – 30th June

During this time you'll be EITHER:

- receiving Acupuncture or Nutritional Therapy along with your usual NHS treatment for your atrial fibrillation (if you're in the Acupuncture or Nutritional Therapy groups)

OR

- receiving your usual NHS treatment for your atrial fibrillation only (if you're in the Usual Care group).

During this period we'll pay you a travel subsidy of £5 per appointment if you're in the Acupuncture group. Towards the end of this period we'll also contact you to arrange a time for your second (final) online assessment.

11 Three-month assessment

WHEN: Typically within 12 weeks of receiving the group placement letter.
Example date: 15th July

We'll guide you through an online study assessment. (Please see **A Guide to Online Assessments** on page 16-19 for more information). After the assessment you'll spend 7 days completing an AF symptom diary, and wearing the CardioSTAT® heart monitor if you have been selected to wear one. Please send these back quickly after the 7 days are up. Once we've received your symptom diary and the data from the CardioSTAT® monitor if you're wearing one, we'll send you a £10 retail voucher as a thank-you for your time.

12 End of study

WHEN: After the end-of-intervention assessment.
Example date: 15th July

Once you have completed the end-of-intervention assessment, you have finished the study. We'll send you a complimentary copy of the study results when these are available (currently anticipated in the autumn of 2022). **Thank you for your time!**

If you have any questions about the study, please contact the Santé-AF researcher, Karen Charlesworth, on 01904 343305 or 07544 665882, or by email on karen.charlesworth@sante-af.org.

Notes

Notes

Santé-AF

Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation

Feasibility study to inform a randomised controlled trial

Northern College of Acupuncture, 61 Micklegate, York YO1 6LJ
Telephone 01904 343305 or 07544 665882
Email karen.charlesworth@sante-af.org

How to contact us

If you would like to ask any questions about this study, please contact:

Karen Charlesworth, Santé-AF Researcher
Northern College of Acupuncture, 61 Micklegate, York YO1 6LJ
Telephone 01904 343305 or 07544 665882
Email karen.charlesworth@sante-af.org

If you have concerns about the study or wish to make a complaint, please get in touch with the Head of the Trial Steering Committee:

Harriet Lansdown, Head of the Trial Steering Committee
Northern College of Acupuncture, 61 Micklegate, York YO1 6LJ
Telephone 01904 343305
Email tsc@sante-af.org

Thank you for taking the time to read this information booklet.
If you decide to take part, please keep this leaflet for future reference.

University of York

nca Northern College of Acupuncture

HRA/HCRW & NHS REC ref: 20/LO/0598 | IRAS Project ID: 268585 | ISRCTN13671984