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

Feasibility study to inform a randomised controlled trial

Participant Information Sheet

Version 1.1 – Date 1 May 2020

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 on final page).
- Please feel free to discuss any of this with your family and friends.

Contents

1 What is the purpose of this study?
2 Why have I been invited?
3 How will I know if I am eligible to take part?
4 If I am eligible, what will happen next?
5 What will happen at the assessments?
6 What other things will I be asked to do?
7 What are the three groups in the study?
8 Will I definitely get acupuncture or nutritional therapy?
9 What are acupuncture, nutritional therapy, and usual care?
10 What is the CardioSTAT® heart monitor?
11 What is my total time commitment to the study?
12 Will it cost me money to take part in the study?
13 Are there any benefits to being involved?
14 Can I continue with my therapy after the study has finished?
15 Do I have to take part?
16 Are there any risks or burdens involved?
17 Confidentiality and data protection
18 Who is doing the research?
19 Who has reviewed and approved this study?
20 Your rights
21 What if there is a problem?
22 What do I do now?
23 How to contact us

1 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 if they have a higher level of symptoms, they have a lower quality of life.

We want to do a large trial to see if people with atrial fibrillation have fewer symptoms and a better 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.

University of York

nca Northern College of Acupuncture

HSRGC reference: HSRGC/2019/346/H | IRAS Project ID: 268585 | ISRCTN: XXXXXXXXXX

2 Why have I been invited?

You have been invited to participate in this study because you have been diagnosed with atrial fibrillation at least six months but less than one year ago, and 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 before you were contacted about this study.

3 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 must happen at least once a week (even if you are taking medication or have had any hospital treatments for your AF);
- You must be willing to have either acupuncture or nutritional therapy alongside your usual care (medications, or other NHS treatments for AF);
- You must be willing to come to the Northern College of Acupuncture (NCA) on Micklegate in central York up to three times over the course of about seven months, to carry out some assessments (see "4 What will happen if I am eligible?" on the next page for more information about assessments);
- You must be willing to travel up to five miles from the centre of York to attend your acupuncture appointments (weekly for eight weeks) or nutritional therapy appointments (approximately once a month for three appointments). We will pay you £5 per appointment to help meet your travel costs;
- You must be willing and able to use your own mobile phone to receive and respond to text messages and phonecalls about the study;
- 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, because this 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, or have had in the past, a condition that might make it inadvisable for you to take part – such as a severe illness, a blood-clotting disorder, or an eating disorder;
- Have a pacemaker fitted;
- 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;
- Have any diagnosed condition affecting your ability to give your informed consent, such as dementia or schizophrenia, brain damage or learning difficulties;

- 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.

We will check your eligibility and let you know whether you are eligible to take part.

4 If I am eligible, what will happen next?

Using the details you gave us on the Permission to Contact 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 we will ask you to sign the Consent Form that came to you in the post with this letter, and return it to us in the envelope provided.

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.

When we receive your signed Consent Form, we will telephone you again – this time to ask some questions to check whether you are fully eligible to take part. We will then send you a letter to confirm that you are eligible, and to invite you to attend the Northern College of Acupuncture on Micklegate, central York, for the first of three assessments. Please see **Section 5 What will happen at the assessments?** for information about the assessments and what we will ask you to do.

If the 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.

5 What will happen at the assessments?

If your medical records show that you are eligible to take part, we will send you a letter to let you know. We will ask you to visit the Northern College of Acupuncture on Micklegate in central York so that we can gather some information to enable you to enter the study (a "baseline data collection"). This should take around 40 minutes, and the information we gather will include:

- Measuring your height, weight, waistline, hip circumference and blood pressure.
- Asking you to fill in an anonymised questionnaire about your health, your personal information, your AF, your ways of taking care of yourself, and your quality of life.
- Recording details of your current medication levels (you can just bring your boxes/ bottles with their printed labels and we will record the details from those).
- One third of the people in the study will be randomly assigned to wear a CardioSTAT® heart monitor on their chest for 7 days (please see **Section 10 What is the CardioSTAT® heart monitor?** for more information about this). If you are one of these people, we will fit the CardioSTAT® during this visit.
- We will also ask you to take away an AF symptom diary sheet, so you can write down your AF symptoms over the 7 days after your visit (everyone in the study is asked to

do this, whether they have been asked to wear a CardioSTAT® heart monitor or not). We will give you a stamped envelope to return this in the post.

- If you have told us you are willing to be interviewed about your experience of having AF and your experience of taking part in the study, 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.

We will also ask you to visit NCA twice more for repeat assessments, once about three months after you start the study, and once about six months after you start.

Please note that we will pay you £5 per visit for each assessment, to help meet your travel costs. There is free car parking at the College. If you complete all three assessments, we will give you a £10 retail voucher as thanks for your time. Please see **Section 12 Will it cost me money to take part in the study?** for more information about what we will pay you and how we will pay it.

Study enrolment

After we have collected all your baseline data, and you have returned your AF diary sheet, we will enrol you in the study. This means you will be randomly placed into one of three 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.

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.

6 What other things will I be asked to do?

If you take part in the study, **no matter what group you are randomly placed into**, you will be asked to do the following things three times (once at the start of the study, once about three months after the start of the study, and once more about six months after the start of the study):

1 **Come to the Northern College of Acupuncture (NCA) three times for assessments.** See **Section 5 What will happen at the assessments?** for more information about what happens at each assessment.

2 **Wear a CardioSTAT® heart monitor for 7 days** (if you have been randomly selected to wear these) three times during the study.

3 **Complete a 7-day diary** about your AF symptoms and activities three times during the study, and return these to us in the stamped envelopes provided.

You are also asked to continue with your usual care for AF (in addition to going to 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.**

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.**

7 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 **Section 9 What are acupuncture, nutritional therapy, and usual care?** for details of each kind of treatment in the study, and what they involve.

8 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. We need to compare the groups to find out whether people who are receiving acupuncture or nutritional therapy have fewer symptoms and a better quality of life than people who don't have these types of care. So if you are placed in the Usual Care

group, **it is vital that you come for your assessments**, and complete the 7-day AF diaries we will send you during the study, including wearing a 7-day CardioSTAT® heart monitor three times 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 are helpful 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.

9 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 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 will give this dietary plan to you at your second appointment and support you to follow it. 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 for AF only. These include:

- **medications** including anticoagulation and/or anti-arrhythmic drugs or drugs to control your heart rate;
- **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.

10 What is the CardioSTAT® heart monitor?

The CardioSTAT® is a small electrocardiograph (ECG) heart monitor that you can wear while you go 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 remove the CardioSTAT® and send it back by freepost to Icentia, the manufacturers of CardioSTAT®.

The data collected by the CardioSTAT® will be 'pseudonymised', meaning that it is given a code which does not connect it with your identity. Icentia's technicians will analyse the pseudonymised data from your heart activity and make it available to your GP, who will add it to your medical records. Your data will also be made available in pseudonymised form to the researcher, so it can be included in the study (see "Confidentiality").

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.** If you would prefer not to use the internet, please 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.

11 What is my total time commitment to the study?

You will be involved in the study for a total of approximately 7 months. This includes everything from the time you agree to take part, up to the time you attend for your final follow-up assessment.

On the next page we have set out a table showing how much time you will need to give to the study, over the course of 7 months.

Group A: Acupuncture

If you are randomly placed into the Acupuncture group, your total time commitment during the 7 months will be:

- About **two hours** to attend the assessments, plus a further **two 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 and assessments.

Group B: Nutritional Therapy

If you are randomly placed into the Nutritional Therapy group, your total time commitment during the 7 months will be:

- About **two hours** to attend the assessments, plus a further **two hours** to be interviewed (if you are willing to be interviewed, and you are selected for interview);
- About **four hours** to attend your Nutritional Therapy appointments;
- **Travelling time** to and from your appointments and assessments.

Group C: Usual Care

If you are randomly placed into the Usual Care group, your total time commitment during the 7 months will be:

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

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

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

1. Any costs of travelling to and from your assessments (whatever group you are placed in). Please note that there is free car parking at the Northern College of Acupuncture, where the assessments are carried out. We will pay you £5 for every assessment you attend, to help with your travel costs. We will ask for your bank details so we can pay you this money at the end of your final assessment.
2. If you are placed in the Acupuncture or Nutritional Therapy groups, there is also 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. We will ask for your bank details in order to pay you this money at the end of your treatment period.

13 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 help people with AF to have a better quality of life and fewer symptoms.

We cannot promise that the study will definitely help you, as an individual, improve your quality of life or reduce 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 have a better quality of life and fewer symptoms than 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 all three assessments (at the study start, after three months, and after six months).

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

There is no budget to pay for you to continue having either acupuncture or nutritional therapy after the study has finished.

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 (where you have attended for your assessments during the study). These are teaching clinics, offering low-cost acupuncture and nutritional therapy with support for lifestyle change.

15 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.

16 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. 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, so we are not able to compare this with the usual treatment for AF. However, the dietary strategies that nutritional therapists may use in this study have few risks that we have been able to discover in the published literature. 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.

Burdens of taking part in the study

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

- making the questionnaires as short and easy to understand as possible;
- for the Acupuncture and Nutritional Therapy groups, using some information that your acupuncturist or nutritional therapist will gather as part of your regular appointments.

17 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 by post. You can find contact details on the last page of this Participant 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 diagnosis (made by your practitioner, in terms of acupuncture or nutritional therapy) 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 an identification code. 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 therapist and the researcher have a duty of care to protect you or 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 (including the data from your CardioSTAT® heart monitor if you are asked to wear one), any symptom which in their opinion may require further investigation, they will write to your GP to refer this matter to them. Your GP may contact you to follow this up.

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 secure 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. Processing will be carried out in strict confidence. Your CardioSTAT® data will be shared with your GP (who will add it to your medical records), and with the study's 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 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 study participation or of the therapy you have received, we will audio-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.

18 Who is doing the research?

This study is being carried out by Karen Charlesworth, 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 Emeritus Professor of Acupuncture Research Hugh MacPherson, and is chaired by Professor of Cardiovascular Health Patrick Doherty.

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

19 Who has reviewed and approved this study?

This study has been reviewed by:

University of York Health Sciences Research Governance Committee (HSRGC/2019/346/H)

<Health Research Authority (HRA) Research Ethics Committee name and reference number>

<Northern College of Acupuncture Research Ethics Committee name and reference number>

20 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**.

21 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**.

22 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 do have questions.

If you don't have any questions and you DO want to take part in the study, please fill in the enclosed Consent Form and return it to it to us in the envelope provided.

Once you have returned your signed 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 to take part in the study, we will invite you to attend a baseline assessment at the Northern College of Acupuncture. After this assessment, we will enrol you in the study.

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, although **you do not have to do this**. There is space on the enclosed Consent Form for you to tell us this, because this information is very helpful in designing a better study for the future. 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 this Participant Information Sheet.

Please keep this for your records.

This page is left blank for your own notes

This page is left blank for your own notes

23 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 leaflet.
If you decide to take part, please keep this leaflet for your future reference.