ISRCTN13671984 https://doi.org/10.1186/ISRCTN13671984

A study to assess the feasibility of a future trial on the effect of acupuncture and nutritional therapy in addition to usual care for people with atrial fibrillation

Submission date
29/05/2020

Recruitment status
No longer recruiting

Registration date
04/06/2020

Overall study status
Completed

Last Edited
26/02/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 22/02/2021:

Background and study aims
Atrial fibrillation (AF) is a common cardiac rhythm disorder which carries an increased risk of stroke. Risk factors include age, lifestyle factors, other conditions such as diabetes or high blood pressure, and heart failure. The incidence of AF in the UK is increasing rapidly in line with an ageing population and unhelpful lifestyle choices, and current costs are estimated at up to 2.4% of total NHS expenditure. Current treatment options are not always successful in reducing symptoms, with up to 50% of patients experiencing recurrence of symptoms within three months of some treatments. Adverse effects of treatment may affect quality of life for some. Management of AF increasingly focuses on improving quality of life and relieving symptoms.

A small body of evidence suggests that traditional acupuncture and nutritional therapy may reduce symptoms and increase quality of life. This feasibility study will test some aspects of a future large-scale trial.

Who can participate?
Patients, aged between 45 and 70 years, with paroxysmal AF that they are aware of (can feel).

What does the study involve?
Participants are randomly allocated to one of three groups: Acupuncture + usual care; Nutritional Therapy + usual care; Usual care alone. In the Acupuncture group, participants will receive up to eight weekly acupuncture treatments with a private acupuncturist while they continue their usual care for AF; in the Nutritional Therapy group, participants will receive up to three monthly nutrition consultations with a private Nutritional Therapy practitioner while they continue their usual care for AF; in the Usual care group, participants receive their usual NHS care for AF only.

The study is aiming to determine the feasibility of a future larger-scale trial, and this means all assessments from the future trial will be carried out at two measurement points. These are at pre-treatment stage three months. The assessments include: measurements of hip and waist, height, weight and blood pressure; monitoring of medications; questionnaires; takeaway symptom diaries completed over a 7-day period; SMS polling via participants' mobile phones; and interviews for a sub-set of participants who are willing to be interviewed. 33% of all participants will be randomly chosen to wear a small ECG monitor, the CardioSTAT®, for 7 days, twice during the study.

What are the possible benefits and risks of participating?
Participants in the study are contributing to our knowledge about future potential treatments for AF that may help people with AF to have a better quality of life and fewer symptoms. We cannot promise that people who receive acupuncture or nutritional therapy on the study will definitely experience improved quality of life or reduced symptoms – but the information they give will help us to know whether it is feasible to carry out a large-scale trial to understand the effect of these treatments for people with AF.

There are minimal risks for participants in this study. Acupuncture has a good safety record, although there is a risk of superficial bleeding or bruising particularly if you are taking anti-coagulant drugs. Acupuncturists are trained to adapt treatment to maintain safety. Nutritional Therapy does not have an established safety record, but there are few risks that we have been able to discover in the published literature. Nutritional therapy practitioners are also trained to adapt dietary advice to maintain safety.

Where is the study run from?
The Northern College of Acupuncture (UK). Private practitioners of acupuncture and nutritional therapy participating in the study are located within five miles of central York.

When is the study starting and how long is it expected to run for?
From October 2018 to May 2022

Who is funding the study?
The National Institute of Health Research (NIHR), the British Acupuncture Council (BAcC), and the Northern College of Acupuncture (NCA) (UK)

Who is the main contact?
Ms Karen Charlesworth
kc1206@york.ac.uk

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Previous plain English summary:

Background and study aims
Atrial fibrillation (AF) is a common cardiac rhythm disorder which carries an increased risk of stroke. Risk factors include age, lifestyle factors, other conditions such as diabetes or high blood pressure, and heart failure. The incidence of AF in the UK is increasing rapidly in line with an ageing population and unhelpful lifestyle choices, and current costs are estimated at up to 2.4% of total NHS expenditure. Current treatment options are not always successful in reducing symptoms, with up to 50% of patients experiencing recurrence of symptoms within three months of some treatments. Adverse effects of treatment may affect quality of life for some. Management of AF increasingly focuses on improving quality of life and relieving symptoms.

A small body of evidence suggests that traditional acupuncture and nutritional therapy may reduce symptoms and increase quality of life. This feasibility study will test some aspects of a future large-scale trial.

Who can participate?
Patients, aged between 45 and 70 years, with paroxysmal AF that they are aware of (can feel).

What does the study involve?
Participants are randomly allocated to one of three groups: Acupuncture + usual care; Nutritional Therapy + usual care; Usual care alone. In the Acupuncture group, participants will receive up to eight weekly acupuncture treatments with a private acupuncturist while they continue their usual care for AF; in the Nutritional Therapy group, participants will receive up to three monthly nutrition consultations with a private Nutritional Therapy practitioner while they continue their usual care for AF; in the Usual care group, participants receive their usual NHS care for AF only.

The study is aiming to determine the feasibility of a future larger-scale trial, and this means all assessments from the future trial will be carried out at three measurement points. These are at pre-treatment stage, three months and six months. The assessments include: measurements of hip and waist, height, weight and blood pressure; monitoring of medications; questionnaires; takeaway symptom diaries completed over a 7-day period; SMS polling via participants' mobile phones; and interviews for a sub-set of participants who are willing to be interviewed. 33% of all participants will be randomly chosen to wear a small ECG monitor, the CardioSTAT®, for 7 days, three times during the study.

What are the possible benefits and risks of participating?
Participants in the study are contributing to our knowledge about future potential treatments for AF that may help people with AF to have a better quality of life and fewer symptoms. We cannot promise that people who receive acupuncture or nutritional therapy on the study will definitely experience improved quality of life or reduced symptoms – but the information they give will help us to know whether it is feasible to carry out a large-scale trial to understand the effect of these treatments for people with AF.

There are minimal risks for participants in this study. Acupuncture has a good safety record, although there is a risk of superficial bleeding or bruising particularly if you are taking anti-coagulant drugs. Acupuncturists are trained to adapt treatment to maintain safety. Nutritional Therapy does not have an established safety record, but there are few risks that we have been able to discover in the published literature. Nutritional therapy practitioners are also trained to adapt dietary advice to maintain safety.

Where is the study run from?
The Northern College of Acupuncture (UK). Private practitioners of acupuncture and nutritional therapy participating in the study are located within five miles of central York.

When is the study starting and how long is it expected to run for?
From October 2018 to September 2020

Who is funding the study?
The National Institute of Health Research (NIHR), the British Acupuncture Council (BAcC), and the Northern College of Acupuncture (NCA) (UK)

Who is the main contact?
Ms Karen Charlesworth
kc1206@york.ac.uk

Study website
http://www.sante-af.org

Contact information

Type(s)
Scientific

Contact name
Ms Karen Charlesworth

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
268585

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45473, IRAS 268585

Study information

Scientific Title
Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation (Santé-AF): a feasibility study to inform a randomised controlled trial

Acronym
Santé-AF

Study objectives
Current study hypothesis as of 22/02/2021:

There are no hypotheses associated with this trial. This is a feasibility study to reduce the uncertainty associated with certain features of a future trial's design, such as recruitment and retention, and acceptability of outcomes and assessments.

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Previous study hypothesis:

It would be feasible to conduct a larger-scale trial to compare the outcomes of (i) acupuncture + usual care; (ii) nutritional therapy + usual care; (iii) usual care alone, in patients with atrial fibrillation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/11/2020, HRA London - Surrey (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8372; Surrey.rec@hra.nhs.uk), ref: 20/LO/0598

Study design
Three-arm single-centre interventional randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Other therapist office, Telephone

Study type(s)
Treatment

Participant information sheet
https://osf.io/g2zc6

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Current interventions as of 02/05/2023:
Santé-AF is a pragmatic trial and the scope of interventions is broad in order to provide a high degree of generalisability to routine practice. Practitioners delivered interventions within their usual scope of practice.

Group A:
Traditional acupuncture, with scope defined as that recognised and insured by the leading

membership organisation for acupuncturists in the UK, the British Acupuncture Council (BAcC), in its various codes of professional practice. Scope was further defined by BAcC safe practice standards, particularly those relating to work with anticoagulated patients. Participants assigned to Group A were offered up to eight treatments delivered at a frequency determined by the practitioner and participant. Participants were encouraged to take treatments once a week over an 8-week period if possible.

Group B:
Nutritional therapy, with scope defined to correspond with the core curriculum for nutritional therapy as set out by the Complementary and Natural Healthcare Council (CNHC). further defined by the trial's available budget, which precluded the use of functional testing, nutrigenomic techniques or supplementation / nutraceuticals. This meant that nutritional therapists on the trial focused on dietary strategies and lifestyle advice. Nutritional therapists were also required to exercise professional judgement regarding the safety of their recommendations in the context of anticoagulant medication. Participants assigned to Group B were offered up to three consultations delivered at a frequency determined by the practitioner and participant. Participants were encouraged to attend consultations once every 4-5 weeks.

Group C:
Usual care for Santé-AF comprised the care pathway as defined by the NICE guideline on atrial fibrillation (NG 196), delivered via primary care practices in conjunction with hospital consultants and/or other healthcare professionals.

Randomisation:
The researcher enrolled participants and randomly allocated them to one of the three groups. The process used a block design with a list length of 30 and randomly permuted block sizes of 5 and 10. Randomisation was carried out using the Simple+ randomisation facility (sealedenvelope.com), which concealed the allocation from the researcher until the point of assignment. Randomisation used an unequal allocation ratio of 2:2:1 in favour of the active intervention groups.

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Previous intervention as of 22/02/2021:
The feasibility study design has been chosen as an appropriate first step in an overall research programme to test the effectiveness of two interventions in relation to atrial fibrillation (AF). A control arm has been included to compare the relative effectiveness of each group in comparison to the control, in addition to comparison with each other.

Recruitment:
Participants will be identified using a subset of eligibility criteria from a computerised search of medical records held in primary care practices. The records of patients deemed eligible from the computerised search will be screened by medically qualified staff to confirm eligibility for approach. Patients will be sent by post a Permission to Approach pack, returned directly to the researcher. On return of a signed Permission to Approach form, a Participant Information Sheet and the Consent Form will be sent by post, followed by a phone call from the researcher to enable the patient to ask any questions. On receipt of a signed Consent Form, the researcher will carry out a screening phone call with the patient, to determine self-reported eligibility. Patients who are contraindicated to participate will be notified by letter. Patients who are confirmed eligible to participate will be notified by letter and invited to attend the study centre for a baseline assessment.

Randomisation will use the Simple + randomisation facility provided by Sealed Envelope Limited, and will employ a randomly permuted blocked allocation sequence using an allocation ratio of 2: 2:1 in favour of the intervention groups, block sizes of 5 and 10, and a list length of 30. A further simple randomisation list will be created in Microsoft Excel to randomise the participants in each group who will be asked to wear an ambulatory ECG device.

Participants are asked at consent stage whether they are willing to be interviewed, using a semistructured interview format, regarding their experience of AF, their treatment /consultation, and their participation in the study. Purposeful sampling (maximal variation) will be employed to select from the pool of willing participants within each group according to maximum variation possible across four key characteristics: age, gender, length of diagnosis, and previous experience of complementary therapies.

The researcher will send a letter to each participant randomised, to inform them of group allocation. The letters to those in active intervention groups will also contain details of the practitioner to whom the participant has been allocated, and participants will be encouraged to call the practitioner to arrange a first appointment. SMS reminders will be sent. Participants who do not wish to attend their allocated practitioner will be offered an alternative practitioner.

Assessments:
Three assessments will be carried out at baseline and end of intervention (approximately 3 months post-randomisation). These will be carried out online due to COVID-19.

Assessments comprise of: two text messages to ascertain allocation satisfaction and treatment expectation; a self-report questionnaire; anthropometric measures including height, weight, hip /waistline measurements, a blood pressure reading and details of current medications including dosage; a 7-day AF self-reported symptom diary. 33% of participants in each group will be fitted with a CardioSTAT® baseline ambulatory ECG device (AED) to measure frequency, duration and severity of AF episodes objectively.

Assessments are expected to take no longer than 40 minutes, with an additional 40 minutes for interviews if the participant has been selected for interview. Assessments and interviews will be carried out by the researcher.

Sampling strategy and sample sizes
As this is a feasibility study of n=30, it is not powered to support meaningful analysis regarding the interventions' effectiveness; instead, data is collected primarily to investigate the feasibility of data collection methods/instruments.

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Previous intervention:
The feasibility study design has been chosen as an appropriate first step in an overall research programme to test the effectiveness of two interventions in relation to atrial fibrillation (AF). A control arm has been included to compare the relative effectiveness of each group in comparison to the control, in addition to comparison with each other.

Recruitment:
Participants will be identified using a subset of eligibility criteria from a computerised search of medical records held in primary care practices. Patients will be sent by post a Permission to Approach pack, returned directly to the researcher. On return of a signed Permission to Approach form, a Participant Information Sheet and the Consent Form will be sent by post,

followed by a phone call from the researcher to enable the patient to ask any questions. On receipt of a signed Consent Form, the researcher will carry out a screening phone call with the patient, to determine self-reported eligibility.

Eligible patients' records will undergo a final screen by medical staff at the patient's primary care practice, to confirm eligibility. Patients who are contraindicated to participate will be notified by letter. Patients who are confirmed eligible to participate will be notified by letter and invited to attend the study centre for a baseline assessment.

Randomisation will use the Simple + randomisation facility provided by Sealed Envelope Limited, and will employ a randomly permuted blocked allocation sequence using an allocation ratio of 2: 2:1 in favour of the intervention groups, block sizes of 5 and 10, and a list length of 30. A further simple randomisation list will be created in Microsoft Excel to randomise the participants in each group who will be asked to wear an ambulatory ECG device.

The researcher will send a letter to each participant randomised, to inform them of group allocation. The letters to those in active intervention groups will also contain details of the practitioner to whom the participant has been allocated, and participants will be encouraged to call the practitioner to arrange a first appointment. SMS reminders will be sent after 4 days and 8 days. Participants who do not wish to attend their allocated practitioner will be offered an alternative practitioner.

Assessments:
Three assessments will be carried out at baseline, end of intervention (approximately 3 months post-randomisation) and final follow-up (approximately 6 months post-randomisation). These will be carried out at the study centre (Northern College of Acupuncture, York).

Assessments comprise of: two text messages to ascertain allocation satisfaction and treatment expectation; a selfreport questionnaire; anthropometric measures including height, weight, hip /waistline measurements, a blood pressure reading and details of current medications including dosage; a 7-day AF self-reported symptom diary. 33% of participants in each group will be fitted with a CardioSTAT® baseline ambulatory ECG device (AED) to measure frequency, duration and severity of AF episodes objectively.

Participants are asked at consent stage whether they are willing to be interviewed, using a semi-structured interview format, regarding their experience of AF, their treatment/consultation, and their participation in the study. Purposeful sampling (maximal variation) will be employed to select from the pool of willing participants within each group according to maximum variation possible across four key characteristics: age, gender, length of diagnosis, and previous experience of complementary therapies. Assessments are expected to take no longer than 40 minutes, with an additional 40 minutes for interviews if the participant has been selected for interview. Assessments and interviews will be carried out by the researcher.

Sampling strategy and sample sizes As this is a feasibility study of n=30, it is not powered to support meaningful analysis regarding the interventions’ effectiveness; instead, data is collected primarily to investigate the feasibility of data collection methods/instruments. However, a sample size has been calculated to support a decision on progression to a future definitive trial on the basis of a statistically significant difference in the main outcome measures.

Intervention Type
Mixed

Primary outcome measure

Current primary outcome measure as of 05/01/2024:

1. Participants' willingness to be randomised is evaluated using bespoke/validated questionnaires, semistructured interviews and data gathered from primary care practices during recruitment stage, at baseline only
2. Appropriateness of eligibility criteria is evaluated using bespoke/validated questionnaires at baseline only
3. Participant retention is evaluated using study progress data at 3 months; participant compliance adherence data at baseline and 3 months; SMS poll at baseline; bespoke/validated questionnaires at 3 months
4. Acceptability of interventions is evaluated using SMS poll at baseline; bespoke/validated questionnaires, semi-structured interviews and intervention attendance data at 3 months
5. Acceptability of assessments is evaluated using bespoke/validated questionnaires and semi-structured interviews at baseline and 3 months
6. Effect of ambulatory ECG monitors is evaluated using CardioSTAT® ECG monitors, bespoke self-report symptom diary and bespoke/validated questionnaires at baseline and 3 months
7. Experience of study participation is evaluated using bespoke/validated questionnaires and semistructured interviews at baseline and 3 months
8. The feasibility of all objectives during a pandemic is evaluated as a composite of the above 7 objectives

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Previous primary outcome measure as of 22/02/2021:

1. Participants' willingness to be randomised is evaluated using bespoke questionnaires, semistructured interviews and data gathered from primary care practices during recruitment stage, at baseline only
2. Appropriateness of eligibility criteria is evaluated using bespoke questionnaires at baseline only
3. Participant retention is evaluated using study progress data at 3 months; participant compliance data at baseline and 3 months; SMS poll at baseline; bespoke questionnaires at 3 months
4. Acceptability of interventions is evaluated using SMS poll at baseline; bespoke questionnaires, semi-structured interviews and intervention attendance data at 3 months
5. Acceptability of assessments is evaluated using bespoke questionnaires and semi-structured interviews at baseline and 3 months
6. Effect of ambulatory ECG monitors is evaluated using CardioSTAT® ECG monitors, bespoke self-report symptom diary and bespoke questionnaires at baseline and 3 months
7. Experience of study participation is evaluated using bespoke questionnaires and semistructured interviews at baseline and 3 months
8. The feasibility of all objectives during a pandemic is evaluated as a composite of the above 7 objectives

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Previous primary outcome measure:

1. Health-related quality of life measured using the EuroQol Group 5-dimension questionnaire (EQ-5D-5L) and the Atrial Fibrillation Quality of Life Evaluation questionnaire (AFEQT) at baseline, 3, and 6 months

2. AF symptom severity measured using a patient symptom diary and data from CardioSTAT® ambulatory ECG monitors at baseline, 3, and 6 months

Secondary outcome measures
Current secondary outcome measures as of 22/02/2021:

There are no secondary outcome measures

Previous secondary outcome measures:

1. Participants' willingness to be randomised is evaluated using bespoke questionnaires, semi-structured interviews and data gathered from primary care practices during recruitment stage, at baseline only
2. Appropriateness of eligibility criteria is evaluated using bespoke questionnaires at baseline only
3. Participant retention is evaluated using study progress data at 3 and 6 months; participant compliance data at baseline,at 3 and 6 months; SMS poll at baseline; bespoke questionnaires at 3 and 6 months
4. Acceptability of interventions is evaluated using SMS poll at baseline; bespoke questionnaires, semi-structured interviews and intervention attendance data at 3 and 6 months
5. Acceptability of assessments is evaluated using bespoke questionnaires and semi-structured interviews at baseline, 3, and 6 months
6. Effect of ambulatory ECG monitors is evaluated using CardioSTAT® ECG monitors, bespoke self-report symptom diary and bespoke questionnaires at baseline, 3, and 6 months
7. Changes in group means to support a decision on progression to a future trial is evaluated using the Atrial Fibrillation Effect on Quality of Life (AFEQT) questionnaire, the EQ-5D-5L questionnaire, a bespoke symptom diary and the CardioSTAT® ECG monitor at baseline, 3, and 6 months
8. Experience of study participation is evaluated using bespoke questionnaires and semi-structured interviews at baseline, 3, and 6 months

Overall study start date
01/10/2018

Completion date
30/05/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/02/2021:

1. Aged between 45 and 70 years
2. Diagnosis of paroxysmal AF between 6 months and years before enrolment
3. Stroke prevention measures offered/applied where indicated
4. Perceptible paroxysmal atrial fibrillation of at least weekly frequency despite current treatment regime
5. Owner of, and able to use, a mobile phone, and willing to use this to receive and respond to study communications

6. Home broadband of sufficient capacity to sustain NT appointments and study assessments
7. Owner of, and able to use, a device equipped with Microsoft Teams video-calling software OR happy to use study iPad
8. Willing to have traditional acupuncture or nutritional therapy adjunctively to usual treatment for AF, or usual treatment alone
9. Willing to travel up to five miles from York Hospital to attend appointments for acupuncture (£5 flat travel costs offset paid per visit)
10. Willing to wear a CardioSTAT® ambulatory ECG device (AED) for 2 x 7 day periods over the course of approximately 3 months, then return it by freepost to the manufacturer for data analysis
11. Speak/understand English well enough to engage meaningfully with interventions and assessments
12. Able to give informed consent

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Previous inclusion criteria:

1. Aged between 45 and 70 years
2. Diagnosis of paroxysmal AF between 6 months and years before enrolment
3. Stroke prevention measures offered/applied where indicated
4. Perceptible paroxysmal atrial fibrillation of at least weekly frequency despite current treatment regime
5. Owner of, and able to use, a mobile phone, and willing to use this to receive and respond to study communications
6. Willing to have traditional acupuncture or nutritional therapy adjunctively to usual treatment for AF, or usual treatment alone
7. Willing to travel up to five miles from York Hospital to attend appointments for acupuncture /nutritional therapy and assessments (£5 flat travel costs offset paid per visit)
8. Willing to wear a CardioSTAT® ambulatory ECG device (AED) for three, 7 day periods over the course of approximately 6 months, then return it by freepost to the manufacturer for data analysis
9. Speak/understand English well enough to engage meaningfully with interventions and assessments
10. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
30

Key exclusion criteria
Current exclusion criteria as of 22/02/2021:

1. Diagnosed with valvular AF
2. Pacemaker, implantable defibrillator, neurostimulator, any other type of active implantable device fitted
3. Diagnosed with kidney disease levels 4 or 5
4. Diagnosed with terminal or severe illness of any kind
5. Diagnosed with any blood clotting disorder
6. Diagnosed (including self-diagnosis) with any condition or disorder contraindicating suitable moderate exercise
7. Diagnosed (including self-diagnosis) with any eating disorder past or present
8. Pregnant or trying to conceive
9. Currently taking part in other research rendering the participant unable to have either intervention, or which is likely to affect study outcomes, or which renders it unsafe for the participant to continue
10. Currently having or have had in the last six months a course of acupuncture or nutritional therapy
11. Classified as shielding, clinically vulnerable or clinically extremely vulnerable with regard to COVID-19, or living with or bubbled with anyone in any of these categories
12. Regularly using a TENS machine or receiving any kind of energy delivery therapy to the upper torso (diathermy therapy, diagnostic or therapeutic ultrasound, radiation therapy, electrosurgery or x-ray)
13. Any other clinical reason why patient should be excluded, in the clinical judgement of the patient's GP

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Previous exclusion criteria:

1. Diagnosed with valvular or permanent AF
2. Pacemaker fitted
3. Diagnosed with kidney disease levels 4 or 5
4. Diagnosed with terminal or severe illness of any kind
5. Diagnosed with any blood clotting disorder
6. Diagnosed (including self-diagnosis) with any condition or disorder contraindicating suitable moderate exercise
7. Diagnosed (including self-diagnosis) with any eating disorder past or present
8. Pregnant or trying to conceive
9. Currently taking part in other research rendering the participant unable to have either intervention, or which is likely to affect study outcomes, or which renders it unsafe for the participant to continue

Date of first enrolment
06/09/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Northern College of Acupuncture
61 Micklegate
York
United Kingdom
YO1 6LJ

Study participating centre
Priory Medical Group
Priory Medical Centre
Cornlands Road
Acomb
York
United Kingdom
YO24 3WX

Study participating centre
Jorvik Gillygate Practice
Woolpack House
The Stonebow
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United Kingdom
YO1 7NP

Study participating centre
Pocklington Group Practice
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1 Amos Drive
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York
United Kingdom
YO42 2BS

Study participating centre
MyHealth Strensall
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YO32 5UA

Sponsor information

Organisation
University of York

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Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
The British Acupuncture Council

Funder Name
Northern College of Acupuncture

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed scientific journal, conference presentations, and presentations to patient support groups.

Intention to publish date
30/03/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.1	01/05/2020	04/06/2020	No	Yes
Participant information sheet	version v1.4	26/01/2021	22/02/2021	No	Yes
HRA research summary			28/06/2023	No	No
Basic results			11/01/2024	No	No
Protocol file	version 1.5		18/03/2024	No	No
Results article		25/02/2025	26/02/2025	Yes	No