Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation (Santé-AF): a feasibility study

Basic results summary

IRAS: 268585
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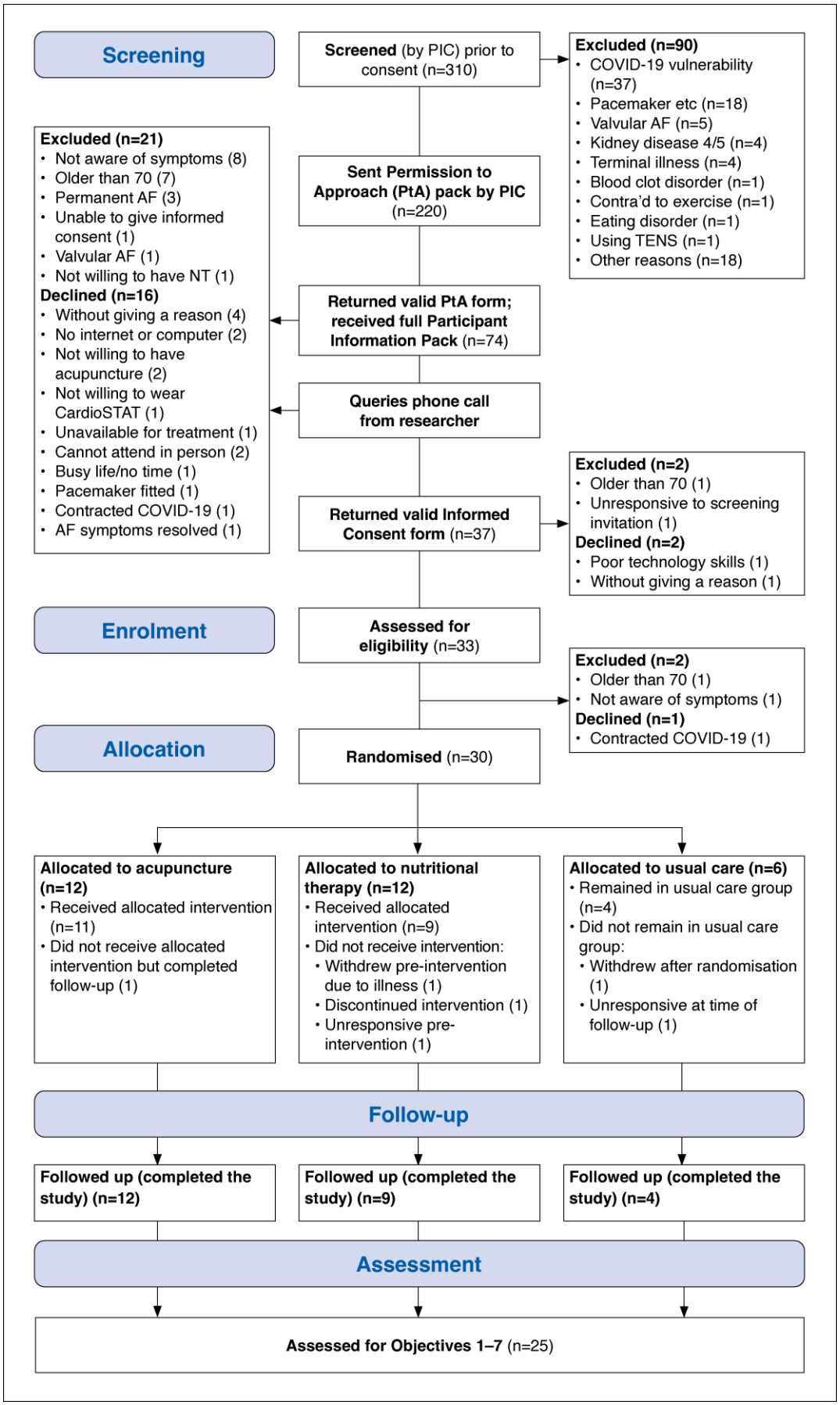
London Surrey NHS REC reference: 20/LO/0598



Participant flow diagram

Baseline characteristics of participants, per group

	Acupuncture (n=12)	Nutritional Therapy (n=11)	Usual Care (n=6)
Age	61.1±4.9	61±5.5	56.3±8.9
Sex			
Male	7 (24.1%)	10 (34.5%)	5 (17.2%)
Female	5 (17.2%)	1 (3.4%)	1 (3.4%)
Ethnicity			
White	12 (41.4%)	11 (37.9%)	6 (20.7%)
Average duration of AF, months	41.3±23.9	38.8±17.5	28.3±18.8
Average AFEQT score (higher = better)	71.1±20.4	76.2±13.9	63.4±32.3
BMI	31.3±6.1	28.4±5.1	31.8±3.7
Waist-hip ratio			
Male	0.97±0.03	1.00±0.06	1.02±0.04
Female	0.89±0.04	0.92*	0.90*
Blood pressure, mmHg			
Systolic	142.8±23.4	146.4±20.8	144±18.5
Diastolic	92.8±6.9	94.9±12.4	91.3±8.3
Comorbidities			
Average number comorbidities per participant	1.1±1.4	1.3±1.4	1.8±2.3
Anaemia	–	–	1 (3.4%)
Angina	–	–	1 (3.4%)
Cardiomyopathy	–	–	–
COPD	–	–	1 (3.4%)
Coronary heart disease	–	1 (3.4%)	–
Diabetes	1 (3.4%)	3 (10.3%)	–
Enlarged prostate	1 (3.4%)	–	–
GORD	–	–	1 (3.4%)
Heart failure	–	–	–
Hyperlipidaemia	1 (3.4%)	2 (6.9%)	–
Hypertension	3 (10.3%)	5 (17.2%)	3 (10.3%)
Hyperthyroid/Graves	–	–	–
Myocardial infarction	1 (3.4%)	–	–
Obesity	1 (3.4%)	1 (3.4%)	–
Parkinson's Disease	1 (3.4%)	–	–
Peripheral vascular disease	–	–	–
Prior CVA or TIA	–	2 (6.9%)	–
Sarcoidosis	–	1 (3.4%)	–
Sleep apnoea	2 (6.9%)	–	2 (6.9%)
Tinnitus	–	–	1 (3.4%)
Smoking			
Current smoker	0	0	0
Ever smoker	9 (31.0%)	7 (24.1%)	4 (13.8%)
Time since cessation, mo	287.7±192.6	287.3±195.5	277.6±181.4

Table continued overleaf

	Acupuncture (n=12)	Nutritional Therapy (n=11)	Usual Care (n=6)
Units alcohol/week	23.9±24.9	22.6±17.1	14.0±16.4
Medication			
Average number of medications per participant	3.8±2.3	3.7±2.0	3.8±1.9
5-alpha reductase inhibitor	2 (6.9%)	–	–
ACE inhibitor	2 (6.9%)	3 (10.3%)	1 (3.4%)
Alpha blocker	1 (3.4%)	2 (6.9%)	–
Analgesic	1 (3.4%)	–	–
Antacid	–	1 (3.4%)	–
Anti-arrhythmic	–	–	1 (3.4%)
Anti-hypertensive	–	–	1 (3.4%)
Antihistamine	1 (3.4%)	–	–
Anti-hyperglycaemic	–	2 (6.9%)	–
Antimuscarinic	–	1 (3.4%)	–
ARB/ARNI	1 (3.4%)	1 (3.4%)	2 (6.9%)
Beta-3 adrenergic agonist	1 (3.4%)	–	–
Beta-blocker	11 (37.9%)	5 (17.2%)	3 (10.3%)
Bronchodilator	–	–	3 (10.3%)
Calcium channel blocker	4 (13.8%)	2 (6.9%)	2 (6.9%)
Carbonic anhydrase inhibitor	–	1 (3.4%)	–
Corticosteroid	–	1 (3.4%)	1 (3.4%)
Diuretic	1 (3.4%)	1 (3.4%)	1 (3.4%)
Hormone replacement therapy	1 (3.4%)	–	1 (3.4%)
Insulin	–	1 (3.4%)	–
Nitrate	1 (3.4%)	–	1 (3.4%)
NOAC	7 (24.1%)	8 (27.6%)	5 (17.2%)
Other anticoagulant	1 (3.4%)	1 (3.4%)	–
Proton pump inhibitor	3 (10.3%)	3 (10.3%)	1 (3.4%)
SSRI	1 (3.4%)	–	–
Statin	5 (17.2%)	7 (24.1%)	–
Thyroid hormone	1 (3.4%)	–	–
Xanthine oxidase inhibitor	–	1 (3.4%)	–

Figures are means ± standard deviation or count data (with percentage of total N in trial)

* Figure applies to the single female participant in this group (therefore figure is not a mean, and no standard deviation is given)

ARB/ARNI angiotensin receptor blocker/angiotensin receptor/neprilysin inhibitor; **ACE** angiotensin-converting enzyme; **COPD** = chronic obstructive pulmonary disease; **CVA** cardiovascular accident; **GORD** gastro-oesophageal reflux disease; **mo** months; **NOAC** novel oral anticoagulant; **SSRI** selective serotonin reuptake inhibitor; **TIA** transient ischaemic attack

Outcome measures: results

Objective number	Description	Measurement	Feasibility threshold	Level achieved	Feasibility of domain
1	Participants' willingness to take part	Percentage of eligible participants randomised	≥90%	96.8%	Yes (green)
2	Appropriateness of eligibility criteria	Percentage of identified participants eligible	≥60%	14.1%	No (red)
3	Participant retention	Percentage of randomised participants retained	≥80%	83.3%	Yes (green)
4	Acceptability of interventions	Participant report of allocation satisfaction @ 7–10 on 10-point scale*	≥75%	75.0%	Yes (green)
		Participant report of intervention acceptability @ 1–3 on 7-point scale**	≥75%	95.0%	Yes (green)
5	Acceptability of assessments	Completeness of main outcomes data	≥80%	90.0%	Yes (green)
		Participant report of assessment acceptability @ 1–3 on 7-point scale**	≥90%	88.0%	No (amber)
6	Utility of CardioSTAT® monitor	Participant report of monitor influence on participation @ 1–2 on 5-point scale***	≥50%	11.1%	(abandoned as inappropriate)
		Correlation between AF episodes recorded by ECG monitor and symptom diary	≥1 episode	–	(abandoned as analysis not viable)
7	Participant experience of study participation	Participant report of participation acceptability @ 1–3 on 7-point scale**	≥75%	96.0%	Yes (green)

* higher numbers = greater satisfaction ** lower numbers = greater acceptability *** lower numbers = greater influence

Adverse events

Participant	Description	Classification	Duration	Reported at appt. number
2/163/A	Median nerve sensation while needling lower forearm	Adverse reaction	Transient	7
3/156/A	Slight headache during needling	Adverse reaction	Transient	2
1/557/A	More tired than usual	Adverse reaction	Previous week	2
1/557/A	More tired than usual	Adverse reaction	Previous week	3
1/557/A	More tired than usual	Adverse reaction	Previous week	4
1/661/A	Mild bruising on lower forearm	Adverse reaction	Previous week	2
1/661/A	Mild bruising on left upper chest	Adverse reaction	Previous week	3
3/641/A	Bruising on left lower forearm and left 11th rib	Adverse reaction	Previous week	3
4/142/NT	Muscle fatigue and tiredness worsening over 4 weeks	Adverse reaction	4 weeks	2