

The effectiveness of sustained acupuncture in addition to group counselling and nicotine replacement therapy in a smoking cessation clinic: a pilot study

Submission date

19/09/2006

Recruitment status

No longer recruiting

Registration date

30/10/2006

Overall study status

Completed

Last Edited

16/05/2007

Condition category

Mental and Behavioural Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0184158213

Study information

Scientific Title

Study objectives

Pilot study: to test accrual, compliance, adverse events, outcome measures.

Underlying hypotheses: that acupuncture reduces either nicotine withdrawal symptoms and/or use of Nicotine Replacement Therapy (NRT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval granted 8 March 2005 (reference: 04/Q2103/154).

Study design

Randomised controlled trial with three arms.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

1. Acupressure with two beads
2. Acupressure with one bead
3. No additional intervention

All participants receive standard intervention with group therapy and NRT.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nicotine replacement therapy

Primary outcome measure

1. Counts (accrual, use of beads, adverse events)
2. Mood and Physical Symptoms Scale
3. NRT consumption

Secondary outcome measures

Not provided at time of registration

Overall study start date

04/04/2005

Completion date

20/07/2005

Eligibility

Key inclusion criteria

1. Smoke more than ten cigarettes/day
2. Were aged 18 years or over
3. Intended to stop smoking on the quit date
4. Chose NRT rather than bupropion
5. Gave informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

Key exclusion criteria

1. History of current otitis externa or other pathological condition of the ear
2. History of a poorly controlled relevant medical condition
3. Currently taking anti-depressant or anti-psychotic medication
4. History of allergy to adhesive dressing
5. Belief of pregnancy
6. Already participating in a research project

Date of first enrolment

04/04/2005

Date of final enrolment

20/07/2005

Locations

Countries of recruitment

United Kingdom

Study participating centre

N32 ITTC Building

Plymouth

United Kingdom

OK6 8BX

Sponsor information

Organisation

Peninsula Medical School (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04dtfyh05>

Funder(s)

Funder type

Government

Funder Name

Supported by the DH-National Co-ordinating Centre for Research Capacity Development (NCC RCD); and by the Smoking Advice Service, Plymouth PCT (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	14/03/2007		Yes	No