

Exercise and manual auricular acupuncture: a single-blind, feasibility, randomised controlled trial exploring the effectiveness of a combined approach for chronic low back pain

Submission date 16/05/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/10/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Exercise and manual auricular acupuncture: a pilot assessor-blind randomised controlled trial.
(The acupuncture and personalised exercise programme (APEP) Trial)

Acronym

APEP

Study objectives

Does the addition of manual auricular acupuncture to an individually tailored and supervised exercise programme improve treatment outcomes for people with chronic low back pain?

Ethics approval required

Old ethics approval format

Ethics approval(s)

To be submitted to the Office for Research Ethics Committees Northern Ireland (ORECNI) and has been reviewed and approved by the relevant filter committee of the University of Ulster, Northern Ireland

Study design

Single-blind, feasibility, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic low back pain

Interventions

Patients are randomised to receive individually-tailored and supervised exercise with or without manual auricular acupuncture

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

None - as this is a feasibility study

Secondary outcome measures

1. Baseline questionnaire
2. Numeric rating scale (NRS) (0-10 cm)
3. Oswestry disability questionnaire
4. Physical activity monitoring
5. Holistic complementary and alternative health questionnaire
6. Fear avoidance beliefs questionnaire
7. Back beliefs questionnaire
8. Seven-day recall questionnaire
9. Daily activity or analgesic intake log book
10. Exit questionnaire

Overall study start date

01/06/2006

Completion date

31/05/2008

Eligibility**Key inclusion criteria**

1. Patients with chronic or recurrent low back pain (LBP), with or without radiation to lower limb
2. Males or females between 18-65 years
3. No spinal surgery within previous 12 months
4. Patients suitable for exercise and acupuncture treatment
5. Patients willing to attend for six weeks of exercise +/- manual auricular acupuncture
6. Fluency in English
7. Access to a telephone

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Patients currently or having received treatment for chronic low back pain (CLBP) in last three months
2. Red flags indicating serious spinal pathology
3. Radicular pain indicative of nerve root compression, spinal stenosis, spondylolisthesis, fibromyalgia, systemic or inflammatory disease
4. Contraindications to acupuncture treatment
5. Acute or sub-acute LBP patients
6. Patients having previously received auricular acupuncture
7. Any other confounding conditions
8. Patients with multiple body and/or ear piercings

Date of first enrolment

01/06/2006

Date of final enrolment

31/05/2008

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre

Room 01F118

Northern Ireland

United Kingdom

BT37 0QB

Sponsor information**Organisation**

University of Ulster (UK)

Sponsor details

c/o Mr Nick Curry (Research Office)
Room 01H12
University of Ulster
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Newtownabbey
County Antrim
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Sponsor type

University/education

Website

<http://www.ulster.ac.uk/>

ROR

<https://ror.org/01yp9g959>

Funder(s)

Funder type

Government

Funder Name

Department for Employment and Learning (Strategic Priority Fund), Northern Ireland, 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	06/03/2008		Yes	No

