

# The impact of adverse childhood experiences on sensation and pain in people living with multiple long-term health conditions and chronic pain

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<b>Registration date</b> 03/07/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/01/2025	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Some people experience negative or adverse childhood experiences (ACEs) when growing up. These people often have health problems in adulthood, including chronic pain. The body builds a pain-relieving system that helps reduce pain. The study team are researching whether ACEs alter how that inbuilt pain-relieving system works.

### Who can participate?

Patients aged 18 years and older with chronic pain with and without multimorbidity and multimorbidity without chronic pain, plus healthy volunteer controls; participants do not need to have a history of ACEs

### What does it involve?

Participants will be asked to attend one 3-hour session at Ninewells Hospital in Dundee. They will complete a consent form and some questionnaires (including on ACEs). Tests of their sensations (like temperature, light touch, and pin-prick) will also be undertaken. One of the tests involves putting their hand in cold water. The tests are designed to test normal or mildly painful sensations. They do not test the maximum amount of pain the participant can tolerate.

### What are the possible benefits and risks of participating?

Taking part in the study might not benefit the participant directly, but it is hoped that it will aid the understanding of how ACEs influence long-term health. These data may help convince doctors and other healthcare professionals to consider ACEs when dealing with their patients (something called "trauma-informed healthcare"). It may also identify whether people with ACEs need different types of pain-relieving treatment. Participants will receive a gift card for taking part and will their travel expenses reimbursed.

### What are the risks of taking part?

ACEs are a sensitive subject, and not everyone feels comfortable talking about them. It is

possible that taking part in this study may trigger unpleasant thoughts or memories. The study aims to be as sensitive as possible when collecting this information and to be considerate of our participants' experiences. Participants do not have to share this information if they prefer not to, and they can stop taking part in the study at any time. A member of the research team will be on hand for the entire session to provide immediate support, and participants will be provided with contact details for organisations that can provide further support beyond the session. Participants will also be encouraged to bring along a study partner for support if they feel it will help them feel more comfortable.

Where is the study run from?

The University of Dundee, UK

The study visits will take place at the Ninewells Hospital & Medical School campus of the University of Dundee, UK

When is the study starting?

December 2023 to November 2025

Who is funding the study?

The Wellcome Trust, through the Multimorbidity Doctoral Training Programme for Health Professionals

Where can I find out more information?

Dr Dhan Senaratne, ACE-MAPStudy@dundee.ac.uk

The Chief Investigator is Prof Lesley Colvin

### **Study website**

<https://www.dundee.ac.uk/projects/ace-map>

## **Contact information**

### **Type(s)**

Public, Scientific

### **Contact name**

Dr Dhaneesha Senaratne

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### **Type(s)**

Principal Investigator

### **Contact name**

Prof Lesley Colvin

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

337622

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Wellcome Trust grant number 223499/Z/21/Z, protocol 2-007-24, IRAS 337622, CPMS 61937

## Study information

**Scientific Title**

The impact of Adverse Childhood Experiences on sensory thresholds in adults living with Multimorbidity And chronic Pain; a feasibility study (the ACE-MAP study)

**Acronym**

ACE-MAP

**Study objectives**

Adverse childhood experiences (ACEs) are associated with lowered thresholds in quantitative sensory testing (QST) and conditioned pain modulation (CPM) testing regimes (i.e. experience of pain with milder stimuli) in adulthood, and this association is stronger in adults with a history of multimorbidity and/or chronic pain.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 09/05/2024, Scotland B Research Ethics Committee (Research Ethics Service, 2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0) 7814609032; [manx.neill@nhslothian.scot.nhs.uk](mailto:manx.neill@nhslothian.scot.nhs.uk)), ref: 24/SS/0031

**Study design**

Single-site feasibility study with a cross-sectional design

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital, Internet/virtual, Telephone, University/medical school/dental school

**Study type(s)**

Other

**Participant information sheet**

Patient information material can be found at: <https://www.dundee.ac.uk/download/159981/media>

**Health condition(s) or problem(s) studied**

Multimorbidity and chronic pain

**Interventions**

The primary aim of the ACE-MAP study is to assess the feasibility and acceptability of the proposed study procedures. The secondary aim is to generate preliminary data to understand the impact of ACEs on QST and CPM parameters in people with multimorbidity and/or chronic pain.

Potential participants will be provided with a participant information sheet by email or post (depending on participant preference) before attending their assessment session. They will be given at least 24 hours to consider their participation and will have the opportunity to ask questions (via email or telephone) before the session.

Written informed consent will be obtained at the start of the assessment session, before the completion of any study assessments.

Next, participants will be asked to complete a series of questionnaires on:

- Demographics, including year of birth, sex assigned at birth, ethnicity, recruitment stream, Scottish Index of Multiple Deprivation (SMID), level of education, employment status, and household income;
- Health behaviours, using the General Practice Physical Activity Questionnaire (GPPAQ) and the World Health Organization's Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST);
- Long-term conditions;
- Chronic pain, using the CAPE pain questionnaire (in the final stages of development);
- Adverse childhood experiences, using the CAPE ACE questionnaire (in the final stages of development);
- Medication.

Next will be the completion of physical measurements:

- Weight;

- Height;
- Quantitative sensory testing (QST) on each hand, including thermal thresholds, mechanical thresholds, vibration thresholds, pressure-pain thresholds, stimulus-response function, and wind-up ratio;
- Conditioned pain modulation (CPM) using the dominant hand for the test stimulus (heat pain threshold and pressure pain threshold) and the non-dominant hand for the conditioning stimulus (cold water bath at 10 C).

Finally, participants will be asked to complete a questionnaire on study acceptability, using a questionnaire

There is no planned follow-up for this study.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Recruitment feasibility measured per stream by calculating the overall recruitment rate (number of participants successfully recruited to the study per week) and the recruitment proportion (number of participants successfully recruited to the study divided by the number of potential participants approached) using study records at the end of the study
2. Acceptability measured using a modified version of an acceptability questionnaire administered to study participants at the end of the assessment session. The data will be presented as counts and proportions, with free-text comments presented as either themes or original anonymised quotes.

## **Secondary outcome measures**

The following outcome variables are collected at the assessment session:

1. Demographics measured using questionnaires
2. Long-term conditions measured using questionnaires
3. Chronic pain measured using the CAPE pain questionnaire
4. Adverse childhood experiences (ACEs) measured using the CAPE ACE questionnaire
5. Medication measured using questionnaires
6. Quantitative sensory testing (QST) on each hand, including thermal thresholds, mechanical thresholds, vibration thresholds, pressure-pain thresholds, stimulus-response function, and wind-up ratio
7. Conditioned pain modulation (CPM) using the dominant hand for the test stimulus (heat pain threshold and pressure pain threshold) and the non-dominant hand for the conditioning stimulus (cold water bath at 10 C)

## **Overall study start date**

01/12/2023

## **Completion date**

01/11/2025

# **Eligibility**

## **Key inclusion criteria**

Four groups of participants aged  $\geq 18$  years old are eligible for recruitment:

1. Chronic pain with multimorbidity

1.1. Has  $\geq 1$  of the LTCs listed below

1.2. Has a diagnosis of chronic pain AND/OR has had persistent or recurring pain lasting >3 months

2. Chronic pain without multimorbidity

2.1. Has a diagnosis of chronic pain AND/OR has had persistent or recurring pain lasting >3 months

3. Multimorbidity without chronic pain

3.1 Has  $\geq 2$  of the LTCs listed below

4. Healthy volunteer controls

List of long-term conditions (LTCs):

Cardiovascular disease: stroke, coronary artery disease, heart failure, peripheral artery disease, heart valve disorders, arrhythmia, venous thromboembolic disease, aneurysm, hypertension (treated and untreated).

Metabolic and endocrine disease: diabetes, Addison's disease, cystic fibrosis, thyroid disorders.

Respiratory disease: chronic obstructive pulmonary disease, asthma, bronchiectasis.

Neurological disease: Parkinson's disease, epilepsy, multiple sclerosis, paralysis, transient ischaemic attack, peripheral neuropathy.

Cancer: solid organ cancers, haematological cancers, metastatic cancers, melanoma, benign cerebral tumours that cause disability.

Mental and behavioural disorder: dementia, schizophrenia, depression, anxiety, bipolar disorder, drug or alcohol misuse, eating disorder, autism, post-traumatic stress disorder.

Musculoskeletal disease: connective tissue disease, osteoarthritis, long-term musculoskeletal problems due to injury, osteoporosis, gout.

Digestive disease: chronic liver disease, inflammatory bowel disease, chronic pancreatic disease, peptic ulcer.

Urogenital disorder: chronic kidney disease, end-stage kidney disease, endometriosis, chronic urinary tract infection.

Haematological disorder: anaemia (including pernicious anaemia and sickle cell anaemia).

Eye disease: vision impairment that cannot be corrected.

Ear disease: a hearing impairment that cannot be corrected, Meniere's disease.

Infectious disease: human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS), chronic Lyme disease, tuberculosis, post-acute Covid-19.

Congenital disease: congenital disease or chromosomal abnormalities.

**Participant type(s)**

Healthy volunteer, Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Unable to read or speak English to a sufficient standard to complete questionnaires or to follow instructions for sensory tests,
2. Lacks the capacity to consent to participate in the study
3. Chronic pain without multimorbidity: Has  $\geq 1$  of the LTCs
4. Multimorbidity without chronic pain: Has a diagnosis of chronic pain AND/OR has had persistent or recurring pain lasting  $>3$  months
5. Controls: Has  $\geq 2$  of the LTCs; A diagnosis of chronic pain AND/OR has had persistent or recurring pain lasting  $>3$  months

**Date of first enrolment**

14/07/2024

**Date of final enrolment**

01/11/2025

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Ninewells Hospital**

Ninewells Avenue

Dundee

United Kingdom

DD1 9SY

## **Sponsor information**

**Organisation**

University of Dundee

**Sponsor details**

Research Governance, Tayside Medical Science Centre (TASC), Ninewells Hospital & Medical School

Dundee

Scotland

United Kingdom

DD1 9SY

None provided

tasgovernance@dundee.ac.uk

**Sponsor type**

University/education

**Website**

<https://www.dundee.ac.uk/>

**ROR**

<https://ror.org/03h2bxq36>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Dundee

**Alternative Name(s)**

Dundee University, Oilthigh Dhùn Dè

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

**Results and Publications**

Publication and dissemination plan



Results from the study will be presented at scientific conferences, published in a peer-reviewed journal, and shared with patients and members of the public through other media streams.

**Intention to publish date**

01/07/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to the highly sensitive nature of the subject material.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		07/01/2025	10/01/2025	Yes	No