# PARTICIPANT INFORMATION SHEET

University of Dundee

CAPE Consortium Against Pain inEquality

wellcome

## The ACE-MAP Study

The impact of **A**dverse **C**hildhood **E**xperiences on sensory thresholds in adults living with **M**ultimorbidity **A**nd chronic **P**ain; a feasibility study.

**We are inviting you to take part in a research study.**

We want to explain why we are doing this study and what will be involved if you decide to take part. Please feel free to ask us any questions. You can contact us by email or phone at:

**ACE-MAPStudy@dundee.ac.uk | 01382 385 374 (Mon-Fri 9am-5pm)**

## Study Summary

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|  | **What is it about?** Some people experience negative or **adverse childhood experiences** (ACEs) when growing up. These people often have health problems in adulthood, including chronic pain. We all have an inbuilt pain-relieving system that helps reduce pain. We are researching whether adverse childhood experiences alter how our inbuilt pain-relieving system works. |
|  | **Who can take part?** Anyone aged 18 years or older. We are looking for a broad range of people. You do not need to have a history of adverse childhood experiences. |
|  | **What does it involve?** You will be asked to attend a single 3-hour session at Ninewells Hospital in Dundee. We can arrange this to suit your schedule. You will complete a consent form and some questionnaires (including on adverse childhood experiences). We will also do some tests of your sensations (like temperature, light touch, and pin-prick). One of the tests involves putting your hand in cold water. The tests are designed to test normal or mildly painful sensations. They do **NOT** test the maximum amount of pain you can tolerate! |
|  | **Do I have to take part?** No, this study is entirely optional. Your decision will not affect your normal healthcare. If you do choose to take part you will receive a £25 gift card. We will also reimburse you for the cost of travel to attend the session at Ninewells Hospital. |
|  | **Isn't this a sensitive subject?** We understand that not everyone will feel comfortable talking about their childhood, and it is possible that taking part might trigger unpleasant thoughts or memories. People who have had adverse childhood experiences have helped us design this study to be as considerate as possible. This leaflet explains how we will be sensitive and provides the details of organisations that can provide additional help if you need it. |
| | **Where can I find out more information?** This participant information leaflet explains the study in more detail. If you have any questions, or you would like to take part, then please contact us using the details above. We would love to hear from you! |

Or point your smartphone camera here to find out more.

## Why are we doing this study?

Our experiences in childhood shape our entire lives. Unfortunately some people are exposed to negative or **adverse childhood experiences** (ACEs), and the effects of these can last into adulthood. An adverse childhood experience might be something done to you (like being abused), something not done for you (like being neglected), or something happening around you (like domestic violence).

For many people this is a very sensitive issue and it is often not something that they discuss openly. However, recent research has suggested that people with adverse childhood experiences are more likely to have poor health in adulthood than people without adverse childhood experiences. This may be because they develop multiple long-term health conditions (known as multimorbidity), or because specific conditions are more severe (for example chronic pain). The more research we can do on adverse childhood experiences, the better we can understand how they influence our long-term health.

We all have an inbuilt pain-relieving system that helps reduce pain. Strong pain-relieving medications like morphine work by activating this system. In this study we are researching whether adverse childhood experiences alter how our inbuilt pain-relieving system works. We will do this by measuring how we respond to sensations like temperature, light touch, vibration, or pin-prick. This knowledge is important, as it may help us understand whether people with adverse childhood experiences need different types of pain-relieving treatment.

This study is a feasibility study, also known as a pilot study. This means we are testing how the study is designed and run, so that we can plan a full-scale study to be as effective as possible. Your input at this stage will be crucial in determining our long-term success!

## Why have I been contacted?

We are contacting as many adults (aged 18 years and older) as possible in the Tayside and Fife regions to take part in this study. You do not need to have a history of adverse childhood experiences, long-term health conditions, or chronic pain to take part. We are looking for a broad range of people, with different life experiences.

## Do I have to take part?

No! It is your choice – taking part in this study is entirely up to you. If you choose to take part, you can stop at any time. You do not have to give a reason for not taking part, or for stopping. If you do not want to take part, or want to stop taking part, your normal medical care and your relationship with the healthcare professionals looking after you will not be affected.

## What do I have to do if I take part?

You will be asked to attend a single 3-hour session at Ninewells Hospital & Medical School in Dundee. We can arrange this to suit your schedule, and we can offer reimbursement of travel costs.

At this session we will:

- Review the details of the study with you and ask you to complete a consent form (5-10 minutes).
- Ask you to complete a series of questionnaires, including on adverse childhood experiences, long-term health conditions, and chronic pain (30 minutes).
- Note down your medications (if you take any) and their doses (5-10 minutes).
- Measure your height and weight (5 minutes).
- Test your sensation:
    - These sensory tests have been used in research around the world, including in a study with cancer patients currently taking place in Dundee. They are designed to test normal sensations and mildly painful sensations. They do **NOT** test the maximum amount of pain you can tolerate!
    - Quantitative sensory testing (QST) – a series of simple tests to examine how your nerves are working. This includes checking how you feel sensations like temperature, light touch, vibration, and pin prick. We will perform this on each hand/arm (45-60 minutes).
    - Conditioned pain modulation (CPM) – we will repeat the simple tests above but with the other hand in cold water. This tests how your inbuilt pain-relieving system is working. We will perform this on each hand/arm (45-60 minutes).

You can choose a "study partner" to help you with this study. This could be a friend or family member, or we can help you find someone to support you through our connections with local support groups and charities. Your study partner can attend the session with you to help and support you.

## What are the possible benefits of taking part?

Taking part in our study might not benefit you directly, but we hope that it will help us understand how adverse childhood experiences influence our long-term health. Our data may help convince doctors and other healthcare professionals to take adverse childhood experiences into consideration when dealing with their patients (something called "trauma-informed healthcare"). It may also identify whether people with adverse childhood experiences need different types of pain-relieving treatment.

You will receive a £25 gift card for taking part. We will also reimburse you (and a study partner if chosen) for the cost of travel costs to attend the session at Ninewells Hospital.

## What are the possible risks of taking part?

Adverse childhood experiences 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. We aim to be as sensitive as possible when collecting this information, and to be considerate of your experiences. You do not have to share this information if you prefer not to, and

you 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 we can provide you with the contact details for organisations that can provide further support beyond the session. These details are also listed below. Bringing along a study partner may also help you feel more comfortable.

The sensory tests are designed to test a range of sensation types, including temperature, light touch, vibration, and pin prick sensation. You may find some of these mildly uncomfortable or painful, but they are not designed to cause severe pain. **If you find the experience too uncomfortable then we can stop testing at any point.**

## Where can I go for more support?

Some of these topics can trigger unpleasant thoughts or memories. If you would like more support then the following organisations can help:

**Wellbeing Scotland** – wellbeingscotland.org | 01324 630 100 (Mon-Fri 9am-5pm). A voluntary organisation with services across Scotland. They provide a wide range of holistic services for individuals and families whose life experiences have negatively impacted on their wellbeing.

**MIND** – mind.org.uk/need-urgent-help | 0300 123 3393 (Mon-Fri 9am-6pm). A charity that provides free advice and support for mental health. Their website has good resources for those in a mental health crisis.

**Breathing Space** – breathingspace.scot | 0800 83 85 87 (Mon-Thu 6pm-2am, Fri 6pm-Mon 6am). A free and confidential phone/webchat service for anyone in Scotland over the age of 16 experiencing low mood, depression, or anxiety.

**The Samaritans** – samaritans.org | 116 123 (24 hours a day, 365 days a year). Provide emotional support for anyone who is struggling to cope, who needs someone to listen without judgement or pressure. They are available 24/7, 365 days a year.

**Help for Adult Victims of Child Abuse (HAVOCA)** – havoca.org. A community of adult survivors of child abuse, providing support and advice for any adult who has been affected by child abuse.

## What will happen to the information I give you?

We will keep all the information you provide safe and secure.

We will need to keep some of your information to help us run the study. This includes your name, date of birth, address, contact details, and community health index (CHI) number. This information will be stored in a protected database within the University of Dundee, and it will only be available to certain members of the research team.

The information you provide during the study itself will be pseudononymised. This means that it will not be associated with your name, contact details, or any other information that can be used to identify you directly. Instead, the information you provide will be linked to a code number. Only

certain members of the research team will have the link between your code number and your personal information.

We may share pseudononymised information with other researchers, but any information that could identify you will be removed before we share it. Other researchers may be from commercial companies, or may be from outside of the UK. Representatives of the study sponsor (the University of Dundee) or the regulatory authorities may access your pseudonymised data to perform study monitoring, audits, and inspections.

Your information will be kept securely in a protected database maintained by the University of Dundee. It will be kept for at least 10 years after the end of the study. After 10 years, any information that identifies you will be destroyed, but your anonymised data will be kept by the research team.

We will ask your permission to write to your GP to tell them that you are taking part in this study.

## Where can I find out more about how my information is used?

You can find more information about how we use your information here:

hra.nhs.uk/information-about-patients

dundee.ac.uk/information-governance/data-protection

## What happens if I want to stop taking part?

You can stop taking part in the study at any time. You do not have to give a reason for stopping. However, if you choose to share your reason for stopping then it will help us design better research studies in the future. If you decide to stop taking part in the study, we would like to keep your anonymised information that you provided up to that point. It is important for the research that we use all information collected. However, if you do not want us to do this then we will remove the information collected when you were taking part in the study.

## What if I am concerned about taking part in the study?

If you have any concerns our research team are happy to discuss the project in more detail. Please feel free to ask us any questions. You can contact us by email or phone at:

**ACE-MAPStudy@dundee.ac.uk | 01382 385 374 (Mon-Fri 9am-5pm)**

If you would like to discuss the project with someone independent of the study team then please contact Dr Gail Gillespie (Consultant in Pain Medicine, NHS Tayside; phone: 01382 496 450).

If you have a complaint about your participation, please get in touch with the research team at the above email address first. If you are not satisfied, you can make a formal complaint to the Complaints & Feedback Team (address: Complaints & Feedback Team, NHS Tayside, Ninewells Hospital, Dundee DD1 9SY; email: tay.feedback@nhs.scot; phone 0800 027 5507).

## Who is involved in running this study?

The Chief Investigator of the study is **Professor Lesley Colvin**, a Professor of Pain Medicine and an Honorary Consultant in Anaesthesia & Pain Medicine based at the University of Dundee and NHS Tayside. The Study Co-ordinator is **Dr Dhan Senaratne**, a Clinical PhD Fellow in Anaesthesia & Pain Medicine based at the University of Dundee and NHS Tayside.

This study is funded by the Wellcome Trust and sponsored by the University of Dundee. The University of Dundee holds clinical trials indemnity cover which covers the University's legal liability for harm caused to participants.

The study is part of a larger body of research undertaken by the Consortium Against Pain InEquality (CAPE). CAPE is a large multi-centre collaboration that is looking at the impact of adverse childhood experiences on chronic pain and responses to treatment. CAPE is led by the University of Dundee, and involves researchers from the University of Aberdeen, the University of Edinburgh, the University of Stirling, and University College London.

## How have patients and members of the public been involved in this study?

Eight members of the public (each with experience of adverse childhood experiences, chronic pain, and long-term health conditions) have helped to design the study, including how to research adverse childhood experiences in a sensitive and respectful manner. They have also reviewed the study documents, including this Participant Information Sheet.

## Who has approved the study?

This study has been reviewed and approved by the Scotland B Research Ethics Committee.

## Where can I get more information?

You can see more information about the study here:

**dundee.ac.uk/projects/ace-map**

Or point your smartphone camera here to find out more.

You can contact the research team by email or phone at:

**ACE-MAPStudy@dundee.ac.uk | 01382 385 374 (Mon-Fri 9am-5pm)**

## I'm interested, how do I sign up?

That's great! Contact us by email or phone and we will take you through the next steps.

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