

Knee OA: Linking Activity and Pain (Koalap): Participant Information Sheet

Study Title: Cloudy with a Chance of Pain and Knee Osteoarthritis: Linking Activity and Pain.

You are being invited to take part in two connected research studies. The first, Cloudy with a Chance of Pain, has been running since January 2016 and seeks to explore the association between weather and symptoms in people with arthritis and other chronic pain. The second, Koalap (Knee Osteoarthritis: Linking Activity and Pain) focuses on the relationship between activity and pain. While one of the questions in the Cloudy with a Chance of Pain study asks about exercise levels, introducing the use of smartwatches that can passively collect activity data brings increased accuracy and additional useful information about physical activity.

Before you decide whether you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish before deciding whether or not to take part. Email the study team koalap@manchester.ac.uk if there is anything that is not clear or if you would like more information, or call 0161 275 5696. Thank you for taking the time to read this.

Summary of what is involved:

- **To take part you need to: be aged 50+, own an Apple or Android smartphone, be diagnosed with knee osteoarthritis, and live in Greater Manchester.**
- **Answering questions about your pain on your own smartphone and a loaned smartwatch (a few minutes a day).**
- **Wearing a smartwatch from morning until bedtime for 3 months.**
- **Reimbursement of travel expenses.**
- **Attend at the University of Manchester at the start and end of the study.**
- **Complete online questionnaire at the University (and possibly an interview) in your second visit.**

Detail:

Questions	Cloudy with a Chance of Pain	KOALA-P (Knee Osteoarthritis: Linking Activity and Pain)
Who will conduct the	This project is being undertaken by the University of Manchester and is funded by Arthritis Research UK.	The project is being undertaken by the University of Manchester. Smartwatches are being loaned by Google, who will also be in

research?		attendance when participants come to the University to be set up with the study.
What is the purpose of the research?	<p>Each year, a fifth of the population consult their GP for a musculoskeletal condition. Up to 80% of these people believe their symptoms are influenced by the weather, yet there is no scientific consensus about whether such an association exists. Researchers have previously tried to work out this association, but no definite answers have been found. One reason is the limited data quality they have had access to: addressing this research question requires regular information about symptoms over long periods of time, with linked high quality data about the weather where the person is located. However, the increasing uptake of smartphones and tablets provides a possible solution. Developing a clearer understanding of the relationship has potential for patient benefit in a number of ways, from predicting symptom changes (symptom forecasts) through to new interventions and treatments targeted at effects of aspects of the weather such as pressure.</p>	<p>The study aims to explore the use of smartwatches to collect activity data for health research projects.</p> <p>The study team will:</p> <ul style="list-style-type: none"> • Compare the daily symptom data recorded by the participant with a weekly questionnaire. • Examine the relationship between self-reported measures of osteoarthritis and activity data collected by the smartwatch. • Identify patterns of physical activity behaviour in patients with osteoarthritis (e.g. overall steps; gait speed; bursts of walking and rest) and their relationship with pain. • Because worsening arthritis often displays as a reduction in physical activity, measurement of physical activity could become a way of passively monitoring disease for clinical practice or research. The research team will explore the development of a new way of assessing the condition of arthritis patients using passively measured physical activity data with pain scores.
Why have I been chosen?	<p>You have been chosen to take part because you have told us that you are aged 16 years or over, you have pain and that you have had your pain for at least three months and you have an Apple or Android smartphone. Your symptoms are not being monitored for clinical purposes. If you are concerned about your health you should contact your GP. More information on chronic pain is available from Arthritis Research UK (http://www.arthritisresearchuk.org/).</p>	<p>As well as meeting the criteria for taking part in Cloudy with a Chance of Pain, you are also aged 50 years or over, have been diagnosed with knee osteoarthritis and live in Greater Manchester.</p>

What would I be asked to do if I took part?



You will be asked to attend a session at the University of Manchester where you will be asked to complete a baseline questionnaire that will ask you some details about your current health. You will then be asked to download the study application (app) to your smartphone. Using the study app you will be asked to report daily symptoms. The app will ask you about 10 symptoms and will take approximately 1-2 minutes to complete (see image).

We will ask you to complete this for 3 months. Meanwhile, your device's Global Positioning System (GPS) will gather data from the nearest weather station every hour.

All data will be uploaded over Wi-Fi or 3G/4G. The amount of data used is no more than a low-use routine app that most people have on their phones and should not impact on data plans if data is transferred over 3G/4G mobile phone networks as opposed to Wi-Fi. You will also be able to view graphs of your reported symptoms and the weather changing over time and as part of a Citizen Science project you will be able to submit hypotheses about the patterns that you see.

You will be asked to attend a session at the University of Manchester where the study team and Google will help you to set up the phone app and smartwatch. The watch being used for the study is the [Huawei Watch 2](#), which Google is loaning participants for 3 months. You are expected to return this to us during your second visit to the University at the end of data collection (and will be asked to sign an agreement relating to this).

You will be asked some questions at the start of the study about your osteoarthritis, which will be completed on the watch. Please make sure you are comfortable with being able to select responses to questions on a smartwatch. You will also be asked to fill in a short paper questionnaire, which will be used to select a wide range of people to be interviewed. If selected, you will be asked to attend the University for an interview (you will be reimbursed for travel expenses, up to £15, and for your time, in the form of a £10 high street shopping voucher). The interviews will be carried out by a University health researcher and should take around one hour. Please note that you do not have to agree to be interviewed to take part in the study. For those interviewed early in the study, you will be expected to attend for a further interview at the end of the study.

Twice daily you will receive notifications on the watch prompting you to answer some questions about how your knee pain is affecting your daily activities: with 1 question to answer at lunchtime, and a further 3 questions in the evening. Your answers will be completed on the watch itself and should take no longer than 2 minutes.

Once a week you will be asked to answer 3 questions on the smartwatch about the severity of your knee pain and how this has affected your usual activities. Again, this should only take a maximum of 2 minutes.

Once a month you will be asked to answer 26 questions on the smartwatch about your arthritis symptoms, taking around 10-15 minutes.

You will be expected to wear the smartwatch every day, and charge it overnight. It is important that the watch is taken off as close to bedtime as possible, and put back on again on waking.

The watch does not need to be paired with your smartphone and will function independently.

After recording your data for 3 months we will arrange a date for you to return the smartwatch to the University of Manchester, in person. At this point you will complete a 30 minute online questionnaire about your experience using the smartwatch



About the Huawei Watch 2:

- The smartwatch is water resistant to a maximum depth of

		<p>1.5m for up to 30 minutes</p> <ul style="list-style-type: none"> - Weight: 57g - Dimensions: 45 x 48.3 x 12.6mm - The watch comes with a 22mm strap and may feel cumbersome on those with small wrists.
What happens to the data collected?	<p>The research team will analyse the data, looking for associations between the many weather variables and the reported symptoms. Your anonymous research data may be shared beyond the research team but only if you agree and tell us that you agree by ticking the box that says “I consent to my anonymous research data being shared beyond the research team” on the consent form. If you do not agree, your data will not be shared beyond the research team.</p>	<p>Self-reported data and data collected passively by the watch will be transmitted securely from the smartwatch to the Google Cloud database. Google will not collect any personal information that could identify you, such as name, address or email and no personal information will be stored on the watch. For this reason, the watch is not password protected or encrypted.</p> <p>Your anonymous research data may be shared beyond the research team but only if you agree and tell us that you agree by ticking the box that says “<i>I consent to my anonymous research data being shared beyond the research team</i>” on the consent form. If you do not agree, your data will not be shared beyond the research team. Your data may also be used in subsequent studies.</p> <p>Any answers you provide to both the online questionnaire and interviews (including any audio recordings) will not be shared with Google, but they will receive a copy of a report summarising responses. No one will be able to identify you from the report.</p>
How is confidentiality maintained?	<p>All study information will be held by uMotif on a secure database. uMotif are a digital health company who work with the NHS, universities and central government. The data will be sent by uMotif to the research team at the University of Manchester for analysis and to the Office for Creative Research (OCR), experts in data presentation and engagement. When uMotif send data to the research team at Manchester and OCR all identifying information will be removed. The data sent to Manchester and OCR will be held</p>	<p>Smartwatch data will be transferred to the University of Manchester from Google and will not contain anything that can identify you to the research team. The data sent to Manchester will be held on secure databases.</p> <p>You will be given a unique Koalap code (in the form of a temporary Google account) that means that your data cannot be personally identified by the research team in Manchester. All sensitive data sets are kept on a secure server and access will be restricted. Access to all</p>

	on secure databases. You will be given a unique code that means you cannot be identified. All sensitive data sets are kept on a secure server and access will be restricted. Access to all research data sets will password-protected. Data will be processed in line with the Data Protection Act, 1998 and in accordance with Medical Research Council guidelines for ethical research, data will always be anonymised, held securely and archived for at least ten years.	research data sets will password-protected. Data will be processed in line with the Data Protection Act, 1998 and in accordance with Medical Research Council guidelines for ethical research. Data will always be anonymised, held securely and archived for ten years.
What happens if I do not want to take part or if I change my mind?	It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. Your data will be withdrawn at the time of publication of the study results.	You are able to withdraw from the study at any time and do not need to state a reason. If you wish to withdraw please email koalap@manchester.ac.uk and provide the unique Koalap study ID (in the form of a temporary Google account) issued to you. You will then be asked to return the smartwatch using a prepaid postage label.
Will I be paid for participating in the research?	There is no payment for taking part in this research.	We are able to cover reasonable travel expenses when attending the two sessions and interviews at the University of Manchester, up to the value of £15 per session. Should you require a taxi we are able to cover costs up to £30 per session. There will be a payment (in Love 2 Shop voucher) of £10 for questionnaire completion, and a further £10 for those who are interviewed (per interview).
What is the duration of the research?	You will be asked to provide daily data on your symptoms for 3 months or until 20 April 2017. You will also be invited to take part in a Citizen Science Experiment by submitting your own hypotheses about the relationship between the weather and symptoms.	3 months.
Will the outcomes of the research be published?	Yes, the results of the study will be published in academic journals, it will be presented at scientific conferences, and we will present the results at public events.	Yes, the results of the study will be published in academic journals, and presented at scientific conferences and public events. We will email all participants the results, once known.
Who has reviewed the	The project has been reviewed and approved by the University of Manchester Research Ethics Committee 4.	The project has been reviewed and approved by the University of Manchester Research Ethics Committee 3.

research project?	UREC reference number 15522.	UREC reference number: 2017-0165-1919
Who do I contact if I have any questions or need help during the study?	For questions about the study you can contact the research team at cloudypain@manchester.ac.uk . For technical help with the app, contact the uMotif app developers at cloudy@umotif.com .	For questions about the study or technical support for the smartwatch contact koalap@manchester.ac.uk .
What happens if I lose or damage the watch?		You will not be held liable for any loss or accidental damage to the watch, but must advise the study team as soon as possible by emailing koalap@manchester.ac.uk .
What if I want to complain?	If there are any issues regarding this research you should contact the research team in the first instance cloudypain@manchester.ac.uk . If you wish to make a formal complaint about the conduct of the research you can contact a Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 8093.	If there are any issues regarding this research you should contact the research team in the first instance koalap@manchester.ac.uk . If you wish to make a formal complaint about the conduct of the research you can contact a Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 8093.