# Title of Project: Cross-validating a measure of the Older Persons for Active Living (OPAL) health related quality of life in community dwelling older adults

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## Invitation and brief summary:

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with family or friends if you wish. We recognise that a lot of information is contained within this document. If you have any further questions, please contact a member of the study team (details are at the end of this information sheet).

It is important that you understand that you do not have to take part in the study and that if you do take part, you are free to withdraw at any time, your clinical care or involvement in PROTECT in any way. If you decide to participate we will ask you to read and sign a consent form on the next page of the website/app.

## Purpose of the research:

The purpose of this project is to develop a new assessment tool to measure the quality of life in older people who are living at home. The measure includes aspects of active aging and active living, as the current tools do not include these important factors. This is part of a larger study called Older Persons for Active Living (OPAL) which is exploring how best to support older adults to live an active life.

This study will collect data using a new quality of life measure, as well as some additional online measures and devices such as wrist-worn technology and smartphone apps. We will use this data to validate the new measure to provide evidence that it can be used in future research. The study will also include people with any medical condition such as, movement disorder , to explore whether the measure is also useful in this group of people, as well as to compare cognitive and physical variables between those with and without a condition.

The study is being led by the University of Exeter.

## Why have I been approached?

We are inviting people over the age of 65 from across the UK to take part in this study. We are looking for 100 people to join the study.

To participate, you will also need to:

- Be over the age of 65 years
- Live independently in the community

- Be able to walk outside with or without a companion, with or without a walking aid
- Achieve a score of at least seven in an eight-question quiz that checks whether you understand the study
- Have access to a computer, tablet or smartphone, and access to the internet
- Be already registered as a participant on the PROTECT-UK research platform, with existing cognitive test and demographic data
- Have a good working understanding of the English language

Unfortunately, if you currently attend one or more weekly hospital visits for treatment, or if you have ever been diagnosed with Dementia, you will not be eligible to take part in this study. We would urge you to self-report any diagnosis of dementia with the study team, if this happens during your participation in the study, unfortunately this would mean you would be withdrawn from the study. You may also be invited to speak with a study doctor should your test scores indicate mild cognitive impairment.

## What would taking part involve?

This study will last for three months. Each assessment point will last up to 8 days where possible. If you decide to take part the following steps will happen:

1. Within the PROTECT app or website you will register for the study on your main PROTECT dashboard. You will be asked to verify that you have read and understood this information sheet before giving consent to take part in this study.

   This will include completing questions to check you understand the study and are eligible to take part.
2. Consent: You will then be asked to sign the online study consent form on the website. This will include giving consent for the PROTECT study team to share your name, address and telephone number with the study team.
3. Complete online data collection: You will be asked to complete a number of questionnaires which will take up to 90 minutes. These are:
   a. Provide your name, age, sex, employment status, and ethnicity
   b. Two questionnaires relating to your quality of life
   c. A questionnaire about lower extremity function i.e. how well your legs function and how they affect your ability to complete day-to-day tasks.
   d. A questionnaire relating to your pain levels
   e. A questionnaire relating to your fatigue levels
   f. A questionnaire relating to your mental well-being
   g. A questionnaire relating to your perception of your own health and well-being
   h. A questionnaire to measure your current experience of apathy.
   i. Questions about any medical conditions you may currently have.
4. **Use of devices and apps to collect additional data about your active living**
   Once you have completed your baseline assessments there will be an option to arrange telephone call(s) to support the physical activity monitoring period. The wrist-worn activity tracker, will be posted with instructions for app download and app use that will collect data about your physical activity. Physical activity monitoring will take place over the next week, where possible, and will include:

a. Physical activity monitoring: We will provide you with a small activity monitor to wear on your wrist for up to eight days. This will measure your movement patterns and allow us to assess how much you are moving, standing, sitting, etc.

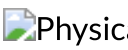


*Figure 1. Wrist-worn physical activity monitor*

b. A specially designed app, StepCatcher, will be used to access step count data that are collected from smartphones, this will run continuously on your smart device for the 8 day period, and will not interfere with the routine functioning of your device.

c. Gait analysis: Using an application called “gait capture” on your smart device you will be asked to stand up from a chair, walk three meters out and back, returning to your seat, with your device in your pocket. This will take approximately 5 minutes.

5. If you have ever been diagnosed with Peripheral Artery Disease, you will be asked to complete the an additional questionnaire. This will take approximately 10 minutes:

    a. A questionnaire about your walking impairment as a result of your symptoms of Peripheral Artery Disease.

6. The data collected above will then be paired with a number of measures you have already completed during your time on the PROTECT study, to gain a fuller picture of your health. These include:

    - Full name
    - Email address
    - Home address
    - Date of Birth
    - Demographics (name, age, sex, employment status and ethnicity)
    - Cognitive tests
    - Physical fitness battery
    - Medical history (health conditions including eye sight, hearing)
    - Mental health (levels of depression and anxiety)
    - Lifestyle (e.g. smoking behaviour and alcohol consumption)
    - Loneliness and social contact
    - Activities of daily living

7. Three-month follow-up: After three months have passed, you will receive a notification from the PROTECT platform to repeat the assessments outlined again, these will need to be completed within 8 days where possible.

8. At the end of the study: We will contact you to let you know the study has finished. When the data has been analysed we will then send you a report on the findings.

## What are the possible benefits of taking part?

The main advantages of this research are that participants will be taking part in an important research study that could provide valuable new knowledge about how we can measure quality of life in older persons. What are the possible disadvantages and risks of taking part?

This is not a clinical trial, and there are no risks associated with any treatment or other intervention. This is an 'observational' study, meaning we only wish to observe how you progress over time. There is a small risk that some people may find the physical activity measures challenging. If you have any mobility issues we recommend you consult your GP prior to taking part in these measures. You may experience slight irritation from the activity monitors wear, although this isn't common.

All the information we collect will be stored securely, according to the law including the UK General Data Protection Regulation (2018) and Data Protection Act (2018). The University of Exeter Medical School Research Ethics Committee has approved this research (Ref: 4880031) and the research will be covered by normal insurance policies at the University of Exeter.

## What will happen if I don't want to carry on with the study?

If you choose to withdraw: You can withdraw from the study at any time without giving a reason. You can do this through the 'Withdraw from Study' link on the app/website or by contacting us on the PROTECT website. If you withdraw from the study, you can choose for us to retain your personal information (email address, home address and full postcode) or for us to destroy that information. Please note we will retain your full name, partial postcode and participant ID number to ensure we have a record of your consent. We will keep all anonymised data you provide through our tests and surveys up to the time you withdraw.

## How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing informationgovernance@exeter.ac.uk. or at http://www.exeter.ac.uk/ig/

As mentioned above, we (the University of Exeter) will need to use existing information about you for this research project, which has been collected within the PROTECT platform. This information includes your:

- Full name
- Email address
- Home address
- Date of Birth
- Demographics (name, age, sex, employment status and ethnicity)
- Cognitive tests
- Physical fitness battery
- Medical history (health conditions including eye sight, hearing)
- Mental health (levels of depression and anxiety)
- Lifestyle (e.g. smoking behaviour and alcohol consumption)
- Loneliness and social contact
- Activities of daily living

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can find out more about how we use your information at

- our privacy policy on the PROTECT website www.protectstudy.org.uk
- by sending an email to HRQL-OPAL@exeter.ac.uk
- by viewing www.exeter.ac.uk/dataprotection
- by emailing dataprotection@exeter.ac.uk.

## Will I receive any payment for taking part?

No payment is available to participants for taking part in this study.

## What will happen to the results of this study?

At the end of the study, and at several points during the study, data will be analysed and published in scientific journals, and presented at national and international conferences. We will also provide you with newsletters and updates about new findings and new studies during and at the end of the study.

## Who is organising and funding this study?

The sponsor for this study is the University of Exeter. It is funded by the Canadian Institute of Health and Care Research and in association with McGill University. The lead investigator for the study is Professor Helen Dawes, and it is part of the wider PROTECT research portfolio - a series of research studies that use digital and remote methods to conduct research to improve and understand brain health.

## Who has reviewed this study?

This project has been reviewed by the University of Exeter Medical School and Health and Care Professions (UEMS & HCP). Research Ethics Committee (Reference Number 4880031).

## Contact for any questions or requests regarding your participation in this research

In the event of queries or requests, you may contact the team using the following contact information.

Please email HRQL-OPAL@exeter.ac.uk. Information and Frequently Asked Questions are also available on the PROTECT website and app. Please note that this helpdesk is for general information and support for the study. It will connect you to a member of the study team who will be able to talk about the study but will not be able to provide medical advice. Please also note that we are not able to give out information about your personal performance or progress in the study as your data are collected for research purposes only.

To contact the Research Ethics Committee please email uemsethics@exeter.ac.uk

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment please email res-sponsor@exeter.ac.uk or

Dr Antony Walsh
Head of Research Governance, Ethics and Compliance
University Corporate Services, University of Exeter
G14, Lafrowda House, St Germans Road, Exeter, EX4 6TJ
DD: 01392 726621 email A.Walsh3@exeter.ac.uk

Thank you for your interest in this project.

# Consent to Take Part

- I understand that taking part involves completing questionnaires, wearing a device for data collection and using smartphone apps for the purposes of research to be included in a research dataset from which I could be identified.
- I understand that I do not have to participate in all the discussions if I do not want to participate.
- I understand that although there are no personal benefits from participating in the study it will benefit others, and that I may have to answer questions that make me feel uncomfortable.
- I understand that relevant sections of the data collected during the study may be looked at by members of the research team, individuals from the University of Exeter, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- In the event that I lose capacity to consent during the period of this research I understand that I would immediately be withdrawn from the study.
- If I chose to withdraw or lose the capacity to consent as described above, I understand that all pseudo anonymised data will be retained in the study, and that I will have the choice to destroy all identifying data about me that is held in the study with the exception of my name, partial postcode and consent form.
- I understand that the data will be stored in a way complying with the provisions of the UK General Data Protection Regulation (2018), Data Protection Act (2018) and other Data Protection Laws.
- I understand that anonymous data from this study may be used by other researchers in the future.
- I confirm that I am happy to be contacted over the telephone and to complete questionnaires over the telephone should the study team deem this appropriate.
- I agree to share personally identifiable PROTECT Data for the project with the research team which will be further processed in pseudo-anonymised form
- I agree to take part in the OPAL study.