



## **Work And Vocational advice (WAVE) in primary care: a randomised controlled trial**

### **PARTICIPANT INFORMATION SHEET - WAVE TRIAL**

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#### **We would like to invite you to take part in our research study**

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You are being invited to take part in the WAVE study. Before deciding if you would like to join the study please take time to read the information in this leaflet and please discuss the study with your family or friends if you want to. If you need any more information please contact us using the contact details below.

Whatever decision you make about joining WAVE, or not, you can rest assured that your health care will not be affected in any way.

**Thank you for taking the time to read the following information.**

#### **Why is the WAVE study important?**

Being at work has many benefits not only to your finances and your health but also to your overall well-being. When someone's health affects their work they may be given a fit note by their healthcare practitioner. But general practice teams are not really in a position to provide support to return to work, often called "vocational advice".

The WAVE study is testing a new way to provide vocational advice to patients whose health is impacting their work. We want to know whether adding a new vocational advice service, provided by a Vocational Support Worker (VSW), helps patients return to work. We also want to find out if this service might be cost effective for the NHS.

#### **Why have I been invited?**

You have been invited to take part in the WAVE study because you have recently been given a fit note certifying you absent from work recently.

#### **Do I have to take part?**

No, it is up to you to decide if you want to take part. If you decide not to take part, the usual care you receive from your general practice team will not be affected in any way.

If you do agree to take part and then change your mind, you can withdraw from the study at any time without having to give a reason and without affecting your care or legal rights.

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

If you wish to take part, please fill in the consent form and return this and the questionnaire to our research team.

You will then be randomly allocated to one of the two WAVE study groups. Like the flip of a coin, you will have an equal chance of being allocated to one of two groups, either the:

- **Usual Care Group** – you will continue to be offered health care as usual
- **WAVE Intervention Group** – you will continue to be offered health care as usual but will also be offered access to a Vocational Support Worker (VSW), who will support you to manage your health and work



You will receive a telephone call from a VSW to introduce themselves and agree on the best time for the first vocational support session. At this session the VSW will ask about your health and work and develop a plan to support you. Where appropriate, further phone calls, face to face meetings or video-conference calls (such as Skype or Microsoft Teams) will be arranged to further support your health and work.

#### We will ask you to:

##### Complete questionnaires

You will be asked to complete 3 questionnaires over 6-months period asking about how your health condition is affecting your work.

Even if your health conditions improve or you return to work, it is still important to complete both questionnaires so that we can understand how you are doing.

##### Reply to SMS text messages every 2 weeks

Each message will ask you to answer 2 questions and should take no more than 5 minutes. You may receive these messages for a maximum of 6 months or until you have been back to work for 4 continuous weeks. These messages will be sent by Keele CTU at Keele University. Look out for this sender so that you know the message is genuine.



You will be charged for sending SMS texts at your standard message rate.

##### Optional medical record review

If you give consent, authorised members of the study team will review your medical record to look at your fit notes over a limited time. This review will be very carefully monitored to ensure confidentiality is maintained at all times.

##### Optional invitation to take part in an interview

We would also like to interview some people who take part in the study and you may receive an invitation to take part in an audio-recorded interview with a researcher to discuss your health and work, and your experience of the vocational support. It is up to you whether or not you take part in the interview.

## Will anyone else be able to access my data?

Information you provide during the study will **not** be shared with your employer or healthcare team. We are committed to protecting the privacy and security of the personal information of all participants in our research and adhere to appropriate regulations in the storage and management of data: for more information about how we manage your data please visit our website

<https://www.keele.ac.uk/ctu/researchportfolio/activeresearch/wave/wavetransparency>.

## What are the possible benefits of taking part in the WAVE study?

The direct benefits to research participants are not currently known. We hope that the insight we gain from this research will lead to improvements in patient care, better support for those who are issued a fit note and therefore help patients in the future.

## What might the risks be of taking part?

We are not anticipating any risks in taking part in the WAVE study. The care you receive from your general practice team will not be affected whether you take part or not.

If you would like to speak to somebody about your health condition(s) at any time then you should contact your general practice team as you would normally do. Alternatively, if you would like to speak to somebody about the research study please call the WAVE Study Team during office hours on 01782 732950.

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

We hope the results will lead to an improvement in patient care and better support for patients who are given fit notes.



Key findings will be sent to your general practice and will be published on Keele University's School of Medicine website [www.keele.ac.uk/medicine](http://www.keele.ac.uk/medicine) The results will be published in medical journals and reports.

## Who has approved this study?

The West of Scotland Research Ethics Committee 5 has reviewed and approved this study (REC Number: 20/WS/0127).

The study is supported by the National Institute for Health Research (NIHR). The study is led by researchers in the School of Medicine at Keele University and managed by Keele Clinical Trials Unit. The research team work with researchers based at Guy's and St Thomas's NHS Foundation and the University of Southampton.

## CONTACT DETAILS



If you have any questions or would like any further information please contact the WAVE Research Team at Keele CTU on 01782 732950 or by email to [ctu.wave@keele.ac.uk](mailto:ctu.wave@keele.ac.uk)

If you have any concerns or complaints you can contact Keele University's Head of Project Assurance on email: [research.governance@keele.ac.uk](mailto:research.governance@keele.ac.uk)

Alternatively, you can contact NHS England on telephone: 0300 311 2233, email: [england.contactus@nhs.net](mailto:england.contactus@nhs.net)

**Thank you for taking the time to read this information sheet and for considering taking part in this research study.**

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