[If paper format: Local Trust logo to be displayed]
[If online format: All Participating Trust logos will be displayed]
[Approved version may be printed in alternative formats e.g. booklet]

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Participant Information Sheet

Enhancing the Health of NHS Staff: eTHOS. A randomised controlled pilot trial of an employee health screening clinic for NHS staff.

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

You are being asked to consider taking part in a research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. You can talk to others about the study if you wish.

Please ask us if there is anything that is not clear.

Thank you for taking the time to read this information sheet

What is the purpose of the study?

Working in the NHS can be very rewarding but also very challenging (particularly during the difficult times of the COVID-19 pandemic), and this can affect the health of NHS staff. Absenteeism (unplanned time away from work due to ill health) and presenteeism (coming into work when you feel unwell) is more common in NHS staff than any other sector. The causes of NHS staff absenteeism are known, and include musculoskeletal pain (back, neck or other joint pain), anxiety, depression and stress and health problems related to weight, a lack of exercise, smoking and conditions such as high blood pressure, diabetes and heart problems.

Workplace health clinics have been shown to improve staff health in small research studies, but few have been run in hospitals for NHS staff and none have assessed all of the main causes of NHS staff absenteeism (joint pain, mental health and chronic health conditions). Opening such clinics across the whole of the NHS would be expensive, and so before this kind of service can be offered, we need to assess if such a clinic would improve staff health, and whether it would be valued and used by NHS staff. Currently, it is unclear if a staff health clinic focusing on joint pain, mental health and chronic health conditions could improve the health of NHS staff and reduce the amount of time NHS staff are away from work on sick leave.

Our study will look at whether a health screening clinic for NHS staff will help improve their health and by doing so;

- Reduce unexpected absence from work due to illness
- Reduce staff attending work whilst they are feeling unwell

The first part of this research is a pilot study. This means we are testing if NHS staff would take part in the study, if a larger study of this nature could be run, and to test how we would assess improvements in staff health. If successful, this pilot would lead to a full trial of the NHS Staff Health Clinic, which would test if the staff health clinic improved health and was cost effective for the NHS.

Three NHS Hospital Trusts are taking part in our pilot study. These Trusts are University Hospitals Birmingham NHS Foundation Trust, Birmingham Women's and Children's NHS Foundation Trust, and Wye Valley NHS Trust.

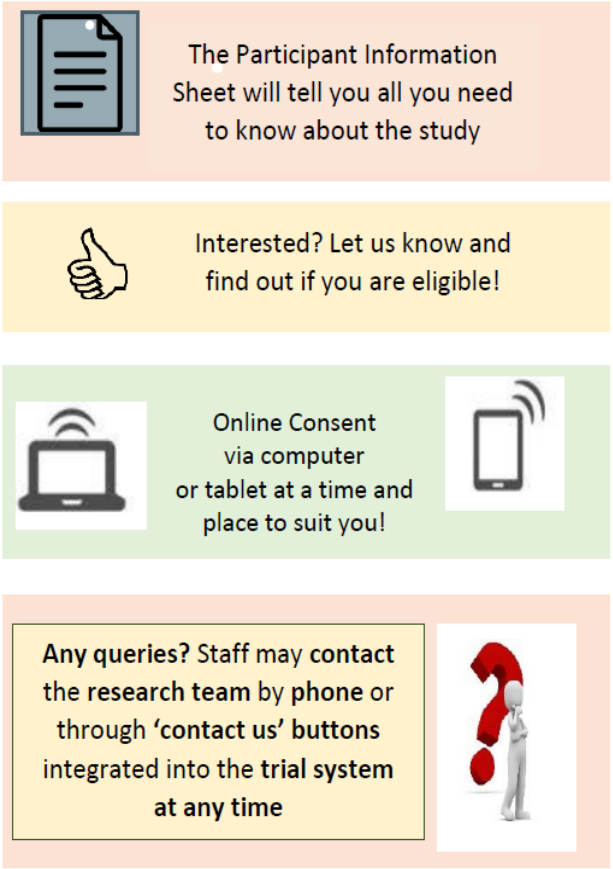
Why have I been invited? Can I say no?

You have been invited because the NHS Trust that you work for is participating in this study. All paid employees from your Trust are eligible to take part in the study **except** those that have already attended the screening clinic at Queen Elizabeth Hospital Birmingham.

We would like 480 members of staff to take part over the course of the study. It is up to you whether or not to take part.
If you are interested in taking part, you will be asked to register your interest in the eTHOS trial. You will then answer some simple questions which will tell us if you are eligible for the trial.

We will ask for your agreement to answer these questions and for your responses to be retained for use in relation to the eTHOS trial. Your responses will remain anonymous unless you provide your consent to join the trial.

As this is a research study, your participation is entirely **voluntary**. If you decide not to take part it will not affect your job, any healthcare services you might access at home or at work, or your occupational health record.



What will happen to me if I take part?

If you are eligible and decide to take part, you will be given a copy of this information sheet to keep and be asked to sign a consent form. This consent form will stay on record in your study file and be available for review by the study monitors.

A copy will also be held at Birmingham Clinical Trials Unit (BCTU), University of Birmingham and one will be made for you to keep. With your consent, we'll also send a copy of your completed Consent Form to your GP.

We will ask for your permission for a record (referred to as medical record) to be created for you within your Trust (if this is your Trust's policy).

This will be used to record your participation in the eTHOS trial in the event that you receive any medical treatment by your Trust during your time in the trial.

When your participation in the eTHOS trial ends, the Trust will retain your medical record as an NHS record. If needed, it will be used to inform of any future medical care by the Trust. Your record will be retained in compliance with your Trust policy.

We would also like collect your NHS number. This is to find out whether it is possible to link to routine health records in the future. It is up to you to decide whether or you would like us to have your NHS number.

We will also collect other personal data from you: your first and last name, date of birth, home address, telephone number (home/mobile/work - as preferred), email address (personal/work – as preferred), your GP surgery and GP's Name (if known). This is required so that we are able to contact both you and your doctor during your participation in the trial if we need to. We will contact you to confirm your GP surgery if these details are not provided to us. If you don't tell us what email we should use so that we may contact you regarding the trial, then we will contact you using your Trust email address (if you have one).

We will then ask some questions about you, your work, your health, medical conditions and any medications you take. It will also be important to understand any recent changes to your job role and lifestyle due to COVID-19, so we will ask you a few questions related to this too.

The consent form and questions that we will ask you to complete are internet based and available in English only. We will also ask you to provide your email address in order to access the trial system. This can be your work or personal email address. You can still participate even if you don't have an email address by going to the trial system and following the instructions that will be shown to you.

The consent form and questions can be completed on a laptop, computer or tablet at a time and location convenient to you. You can also visit the clinic to complete them, where someone will be available to help you if you need it. A member of the research team may also visit you at your work location if this is better for you.
We will need to ask the HR department how much sick leave you have taken in the past two years, and to tell us how much sick leave you take during the time of your participation in the study and the general reasons. We will also ask your HR department how much time you have needed to spend away from work because of COVID-19. For example, you may have to self-isolate or followed advice to shield. We will also ask your HR department to provide us with the following information: your age, sex, and ethnicity, staff group and grade, and how many hours a week that you are contracted to work. If you were to stop working for your Trust during your participation in the trial, we would also ask the HR department to confirm the date that your employment ended. Your HR data will be transferred to the University of Birmingham by secure data link.

All information that we collect from you is confidential and is used for the purposes of this research study only. No information will be shared with your Trust management. We will ask you to provide us with your payroll id or employee number. The reason for this is to link your trial record to your HR absence record, and also to help us to confirm that you are eligible to take part in the trial.

You will be randomly allocated to go into one of two groups:

1 – Intervention group: This means that you will take part in the Staff Health Screening Clinic
2 – Control group: This means that you will not take part in the Staff Health Screening Clinic

There is a 50:50 chance (like tossing a coin) that you will be allocated to either group.

If you are in the **intervention group**, we will make an appointment for you to attend the staff health screening clinic. This visit would take about one hour and it may be possible for this to take place in work time. At the clinic, you will complete some questionnaires about any symptoms you may have of anxiety, depression and stress, and about any symptoms you may have of back or joint pain.
If you are under the age of 40 years old, we will ask you to fill out questionnaires about smoking, how much alcohol you drink, if any, and the levels of exercise you take. We will also measure your height and weight to out your body mass index (BMI)

If you are 40 years of age or over, we will do all of the above, and also check your pulse, your cholesterol and blood pressure. We will use this information about your past and family health to work out your risk of heart disease. We may also take a small blood sample from you. This is to check on your kidney function or risk of diabetes, depending on the results of the initial screening tests.

All of these results will be explained to you, including if they are in the normal, healthy range, or if any extra health care might be needed. If any results are in the abnormal or unhealthy range, we will make plans with you to help to improve your health. This might include seeing a

counsellor (if you have symptoms of anxiety, stress or depression) or discussing taking medicine with your GP (if we find high blood pressure, for example).

If you are in the **control group**, you will not attend the staff health screening clinic, but can visit occupational health or see your GP yourself if you have any health concerns. The control group is very important to the trial. The data collected from this group will help us to determine if the staff health screening clinic is effective in improving the health of NHS staff. We will also learn if the staff health screening clinic helps to reduce unexpected absence from work due to illness, and staff attending work whilst they are feeling unwell

All participants will be followed up in the study for 12 months:
We will contact you again at 6 and 12 months to ask you to complete a questionnaire which asks about any changes in your health or work. This will take about 30 minutes each time and will be completed online at a time and place that is convenient to you.
You may also be asked to take part in some interviews to talk about how you felt about being in the study and the questions we asked about your health. We will provide a separate information sheet and consent form to take part in this, and your participation in this part of the study is entirely **voluntary**.

Are there any benefits to taking part?

When taking part in this study, we may identify a health condition that you might not know that you had. This includes both physical and mental health conditions. Finding this out will allow any health problem to be treated (if needed). The doctors and nurses involved in the study can talk to you about all of the results of the screening clinic.

Alternatively, there may be no direct benefits to you for taking part in this study. However, the results of the trial may lead to an employee health screening clinic being made available for all NHS staff. This may help reduce unexpected absence from work due to illness, and staff attending work whilst they are feeling unwell.
You may also learn more about your general health as part of the study, which you might find beneficial.

Your Trust will make sure that is safe for you to take part in this study. If you to attend the health screening clinic you will find that members of the research team will be wearing appropriate personal protective equipment (PPE) and social distancing will be observed where it is appropriate to do so. All safety processes that are put into place will be in line with your current Trust policy and will be reviewed and updated by your Trust as necessary.

Are there any disadvantages to taking part?

As a result of attending the staff health clinic you may be told you are at risk of a condition you were previously unaware about. This may cause you some concern but we will be referring you to discuss these results with your GP or other relevant service to understand more about it and to be treated appropriately (if needed) to help you in the future.

You may also be asked to have a blood test. This can involve a small amount of discomfort but will be taken by trained staff

Involvement of General Practitioner / other healthcare practitioner
As this study involves screening for medical conditions, we would like to inform your GP about any medical findings we make which might impact on your health. We will also seek your permission to either refer you directly, or ask your GP to refer you to other health services as

needed, such as for physiotherapy (if you had significant joint pains), counselling (if you had symptoms of anxiety or depression) or a pre-diabetes service if you are at risk of diabetes.

As this is an important part of the study you will be asked to agree to us contacting your GP and any other health professional who might help with any health issues we find. To take part in the study you must provide your consent to us contacting your GP. We may also suggest that you are referred to Occupational Health, however this will be entirely voluntary.

What will happen to the samples I give?

If you are in the intervention group, and attend the staff health clinic, a blood test may be taken to check your cholesterol level and potentially assess your kidney function and risk of diabetes (depending on the results of other measurements). These will be processed by your NHS hospital laboratories and any surplus sample destroyed. We will not store any samples taken from you and will not do any additional testing on your samples. If we find a new medical condition, your healthcare team may wish to do further tests, but this would be explained to you by them and those samples would not be part of this study.

What will happen if I do not want to carry on with the study?

You can decide not to continue with the study at any time. If you decide to withdraw from the study, unless you tell us otherwise, we will keep the data obtained from you that has been used in any analysis but we will not use your data in new analysis.

If you wish to withdraw from participating in the trial you may do so by contacting your local research team. Their contact details can be found at the end of this document.

Who is organising and funding the research?

eTHOS is funded by the National Institute for Health Research Health Services and Delivery Research (HS&DR) Programme (Project Number: 17/42/42). It is sponsored by the University of Birmingham and is being organised and run on their behalf by the Birmingham Clinical Trials Unit (BCTU). No member of the research team is being paid for including you in this study.

Have patients and the public been involved in this study?

A group consisting of NHS staff members, NHS patients and members of the public helped to develop this research topic and the research questions that should be asked. Members of NHS staff are also part of the study group and will continue to be involved in the study. Representative members of NHS Staff helped by reviewing this Participant Information Sheet.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). This is to protect your interests. This study has been reviewed and given a favorable opinion by Edgbaston Research Ethics Committee on 13th January, 2020 (REC reference: 19/WM/0378

Will my details be kept confidential?

All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be shared with members of the trial team and your GP. The University of Birmingham is the Sponsor for this study. The University of Birmingham will be using information from your personnel and medical records in order to undertake this study and will act as the data controller. This means that the University of Birmingham is responsible for looking after your information and using it properly.

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The University's Data Protection Officer is Mrs Carolyn Pike OBE, Director of Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT Tel: 0121 414 3916 email: dataprotection@contacts.bham.ac.uk. The University of Birmingham will keep identifiable information about you until the main results of the study have been published. After this time, it will be securely destroyed. Pseudo-anonymised data will be stored securely at the BCTU for at least 25 years after the study has finished. This will allow the results of the study to be verified if needed.

All information collected by the Sponsor will be securely stored in the eTHOS trial office at the University of Birmingham, on paper and electronically and will only be accessible by authorised personnel. Your electronic consent form will be downloaded by BCTU directly from the online trial system. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or audit the data collection process. Your identifiable data will be accessed by the eTHOS trial team in relation to the trial for example when we need to write to you or your GP, or would like to talk to you. There is an open-access eTHOS trial site http://www.birmingham.ac.uk/eTHOS which contains information about the trial. No identifiable information about you will be available on this trial site.

Your NHS hospital will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the trial. With your permission, your GP will be sent a copy of your signed consent form alongside a letter informing them of your participation in the study.

At the eTHOS trial office, you will be identified by a unique study number. In routine communication between your Trust and the eTHOS trial office, you will be identified by your unique trial number, your partial date of birth and the name of your Trust. Data may be provided to the eTHOS research team on paper or electronically.

By taking part in the study, you will be agreeing to allow research staff from the eTHOS trial to look at your study records, including your medical records. It may be necessary to allow authorised personnel from regulatory agencies (e.g. the Sponsor and/or NHS bodies to have access to your medical and research records. This is to ensure that the study is being conducted to the highest possible standards.

Under no circumstances will you be identified in any way in any report, presentation or publication arising from this or any other study. All individuals who have access to your information have a duty of confidentiality to you.

You can withdraw your consent to our processing of your data at any time. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible. Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the eTHOS trial has recorded about you. If you wish to view this information, or find more about how we use this information, please contact The Information Compliance Manager, Legal Services, University of Birmingham Edgbaston Birmingham, B15 2TT.
The University of Birmingham's web page 'Data Protection - How the University Uses Your Data' sets out much of this information, including how to ask any questions you may have about how your personal data is used, exercise any of your rights or complain about the way your data is being handled. (https://www.birmingham.ac.uk/privacy/index.aspx)

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions; their contact details are at the end of this sheet. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure or in writing to the Research and Commercial Services arm of the University of Birmingham. Details can be obtained from PALS (see below for contact details)

In the unlikely event that something does go wrong and you are harmed during the research due to someone's negligence, then you may have grounds for legal action and compensation against the sponsor (the University of Birmingham) but you may have to pay your legal costs. The normal NHS complaints procedures will still be available to you, if appropriate.

What if I do not want to take part?

As this is a research study, your participation is entirely voluntary. If you decide not to take part it will not affect your job, any healthcare services you might access at home or at work, or your occupational health record. If you change your mind and no longer want to take part in the study during the study period, you can withdraw at any time, and without giving a reason. If you withdraw from the study, we will need to use the data collected up to your withdrawal. This will be pseudo-anonymised which means that it is linked to your trial identification number only.

If you become unable to make your own decisions at any point during the study, we will retain and use your data that has been collected up to that point.

Will my travel expenses be reimbursed?
No. All investigations take place at work or through your GP and/or local community services.

What happens if new information becomes available?
Sometimes we get new information about the screening tools being studied in this project, or national guidelines may suggest using different screening tests. Also, sometimes medical advice changes about what to do if an abnormal result is found. If this happens, a member of the research team will tell you and discuss if this might require a different referral to healthcare services. You will have the option to decide whether you wish to continue in this project. If you decide not to carry on, a member of the research team will make arrangements for your standard clinical care to continue with your GP.

What happens when the research study stops?
If you are referred to your GP or to another health service (such as counselling, or for physiotherapy) during the study, they will continue to look after you when the study stops.

What will happen to the results of the research?

At the end of the study, we will report results to the funder of the research. Results will also be published in appropriate academic and professional journals and presented at conferences. We will contact you with the results of the study once it is finished. The publications are made available to the general public on websites such as the NIHR or PubMed, should you be interested. You will not be identified in any publication.

Where can I get further information?
The local trial team involved in the research study will happily answer any questions you might have, and at a time convenient to you. You will be able to contact the research team using the contact details shown below, or you will be able to contact them via the trial site

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Contact Information

If you would like to speak to someone about the study please contact the eTHOS research team on

[site specific contact details]

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS)

Tel: [local PALS contact number(s)] **Email: [local PALS email address]**

If you would like to speak to someone who is independent of the study please contact

Dr Birgit Whitman - Head of Research Governance and Integrity, University of Birmingham

Email: researchgovernance@contacts.bham.ac.uk