



Midlands Partnership University NHS Foundation Trust
Trust Headquarters
St George's Hospital
Corporation Street
Stafford
ST16 3SR

19th April 2023

Dear patient/caregiver,

Re: Invitation to take part in research about severe mental illness and medication reviews

I am writing to you on behalf of my colleague Professor Saeed Farooq from Keele University in Staffordshire. Professor Farooq is conducting research about the experiences of taking anti-psychotic medication by people living with severe mental illness. He has asked me to invite you to take part in a 60-minute research interview.

Before you decide whether or not to take part, please read the enclosed information to understand what the research is about and what it will involve. You do not have to take part and your decision will not affect your current treatment in any way. Please discuss this information with your family and/or caregiver, who may also attend the interview with you. All information that you provide during the research will be treated in confidence. Participants will receive a £20 online shopping voucher for taking part.

Should you have any questions about the research, you can contact a member of the research team by email p.k.kaistha@keele.ac.uk or phone 07584 388 740.

Yours sincerely,

Prachi Kaistha

Research Associate

Email: p.k.kaistha@keele.ac.uk

Enclosed (scroll down):

Participant Information Sheet – Patient-Caregiver interview V1.2 19.04.2023



--- RESEARCH PARTICIPANT INFORMATION SHEET ---

For iSWITCHED Patient / Caregiver interviews

Purpose of information

You are being invited to take part in a research study. Before you decide whether or not to take part, you should understand why the research is being done and what it will involve. Please take time to read the following information and share it with people you know (such as family and caregivers).

Contact details for the researchers are at the bottom of the information sheet if you have any further questions.

Contents of information sheet

- Title of research
- Background to research
- Aim of the research
- Who can take part
- What taking part involves
- Benefits/risk of taking part
- What will happen to my data?
- Research approval and funding
- Key contact details

Title of the research

The full title of the research study is: *Developing and user testing iSWITCHED (implementing SWITCHing Educational intervention) to support switching anti-psychotics to improve physical health outcomes in people with severe mental illness*. We call this the iSWITCHED study for short.

Background to the research

- 500,000 people in England are living with a severe mental illness (SMI) like schizophrenia.
- In addition to coping with psychological symptoms, people with SMI are also at greater risk of developing physical health problems.
- For example, some specific antipsychotics can increase the chance of physical health problems occurring.
- Medication reviews and considering changes to antipsychotics could offer a valuable option for clinicians, patients and caregivers to help support quality of life.
- However, a lack of training and guidance for clinicians and giving priority to psychological symptoms may prevent changes to prescribed medications.

Aim of the research

Our research is looking to develop a new intervention to support medication reviews for people with SMI. The intervention is intended to help guide decision-making about switching of medications and improve communication with patients and caregivers during this process.

Who is carrying out this research?

This study is led by Professor Saeed Farooq at Keele University, supported by colleagues at Keele, Aston University and the universities of Sheffield and Manchester. Midlands Partnership University NHS Foundation Trust (MPFT) is the lead NHS organisation supporting this research.

Who is being asked to take part?

We are looking to speak with people who match the following list of criteria:

- Aged 18 years and over

- Diagnosed with severe mental illness (e.g. schizophrenia, bipolar disorder) and currently experiencing stable symptoms
- Currently or has previously taken oral antipsychotic medication (specifically: olanzapine, risperidone or quetiapine)
- Experienced physical side-effects since starting antipsychotic medication (such as, weight gain, been told they have pre-diabetes or diabetes).

Please take your time to consider whether you think you match these criteria. Please feel free to call a member of the research team if you are unsure whether you could take part or not (see end of document for contact details).

We would also be interested in talking with informal/family caregivers of people that match the above criteria. Caregivers can take part in individual interviews by themselves or join the person that they provide care for.

What does taking part involve?

You are being asked to take part in a research interview with an experienced member of the research team. The interview is expected to last for up to 1 hour. During the interview, you will be asked for your views on the antipsychotic medications that you take, side-effects, your physical health, experiences of treatments, thoughts about medication reviews and switching antipsychotic medications. Your answers during the interview will be kept confidential and will not affect the care that you receive in any way.

The interview will take place either face-to-face (at Keele University or Midlands Partnership University NHS Foundation Trust or Mersey Care NHS Foundation Trust), online (via Microsoft Teams), or by telephone. The choice will be down to you and also the current COVID-19 restrictions. To take part online you will require access to a computer, a broadband connection and email account – you will not require an existing Microsoft account. Participants will receive a £20 shopping voucher for taking part. For face-to-face interviews, reasonable travel expenses will be reimbursed. Please note, we will request confirmation of receipt of the voucher. Should you not confirm receipt, a member of the research team will recontact you by telephone or email.

What are the possible benefits/risks of taking part?

By taking part you will help improve our understanding of patient and caregiver views on current treatments and medication reviews. This may benefit care that other patients receive in the future. Health, and in particular mental health, can be a sensitive topic for some people. If you become distressed during the interview, the researcher will stop the interview and check to see if you are okay. The researcher will provide appropriate signposting to support services, should you require it. They may also look to contact your GP if you raise any concerns about causing harm to yourself or others. Your safety as a research participant is important to us.

Please note: participation in the study will not result in your medication being changed.

Do I have to take part?

You do not have to take part in this study. If you do decide to take part, you are still free to withdraw at any time without giving a reason.

How do I take part?

If you would like to take part in an interview, please contact the research team on email (p.k.kaistha@keele.ac.uk) or by phone (07584 388 740). If you have been handed this information by a member of your clinical team whilst attending a medical appointment the clinical can, with your permission, share your contact details with the research team on your behalf. Once the research team have been notified about your interest a member of the research team will reply to confirm that you meet the eligibility criteria. If you do, the researcher will arrange a suitable time/date for your interview. You will be asked to complete a consent form before the interview starts.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, age, contact details and personal opinions about the research topic. This information will be held by the research sponsor (Keele University). People involved in the research study 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 of your name. 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.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option for your data to be used in future research – this data will not include information that makes you identifiable.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from our website:
<https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/>
- by asking a member of the research team
- by sending an email to p.k.kaistha@keele.ac.uk or
- by ringing us on [07584 388 740].

Who will have access to information about me and how will it be used?

Research team members from Midlands Partnership University NHS Foundation Trust and the universities of Keele, Manchester, Sheffield and Aston will have access to your information for the purposes of the research. The audio recording from the interview will be transferred securely via an online system to an external company to be transcribed. There is a data sharing agreement in place between the transcription service and Keele University to ensure your information is handled in a confidential way.

What will happen to the results of the study?

We plan to publish the results of the study in academic journals and present findings at conferences. We will publish anonymised data only. Participants will not therefore be identifiable in any report, publication or presentation. The findings will help guide future

research conducted by the team and other academic groups. A summary of findings will be made publicly available on our website (<https://www.keele.ac.uk/research/ourresearch/medicine/primarycareresearchthemes/mentalhealth/iswitched/>) as soon as this is practically possible.

Who is funding and organising the research?

The research is funded by the National Institute of Health Research (NIHR134191). The research is organised by jointly by Keele University and Midlands Partnership NHS Foundation Trust.

Who has reviewed this study?

The study has been given a favourable ethical opinion by a Research Ethics Committee (IRAS number: 314725) and NHS permission has been obtained.

Key contact details:

To speak to the research study lead: Prof Saeed Farooq Chief Investigator for iSWITCHED study School of Medicine Keele University Staffordshire s.farooq@keele.ac.uk	For complaints or to speak someone outside of the research team: Head of Project Assurance Directorate of Engagement and Partnerships IC2 Building Keele University ST5 5NH research.governance@keele.ac.uk
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If you have any questions or concerns about taking part in research, you can also contact the NHS England Customer Contact Centre on Tel: 0300 3112233 or email: england.contactus@nhs.net.

To express an interest in taking part in the study or for any other queries please contact the research team:

Email: p.k.kaistha@keele.ac.uk

Telephone: 07584 388 740