INFORMATION SHEET V1 30/10/2020

PATIENT INFORMATION SHEET FOR TAKING PART IN SURVEYS

King's College Research Ethics Committee Ref: XXX

National Institute for Medical Research, Tanzania Ref: XXX

National Health Research Ethics Committee of Nigeria Ref: XXX

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET IF YOU WISH TO TAKE PART

Determining trustworthiness and safety of Remote Consulting in primary Healthcare for chronic illness.

Place of study: Ibadan, Nigeria and Kilombero district, Morogoro, Tanzania

We would like to invite you to participate in this research project on remote consulting (consulting by mobile phone) in primary care for patients with chronic illness. You should only participate if you want to; choosing not to take part will not disadvantage you in anyway. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to ask if there is anything that is not clear or if you would like more information.

1. What is the purpose of the study?

We are undertaking a study to see if we can increase patients' access to health care by using telephone consultations/appointments. We want to know if these healthcare appointments feel safe and trusted to patients accessing health care this way. We are doing this research with patients who have one of these health conditions: Type 2 diabetes, Hypertension, Chronic Obstructive Pulmonary Disease or Coronary Heart Disease. We aim to find out if this model of care is acceptable to patients and health facilities.

We know from previous research that people with chronic illness experience pain, shortness of breath and other physical problems and concerns and may require support with psychosocial or

spiritual care. Through this study we want to find out if receiving care through telephone calls with health workers can help to manage these problems and concerns.

2. Why have I been invited to take part?

We are inviting you to take part because your health facility has told us that you are living with one of these chronic illnesses and that you have had a recent health appointment with the health facility either by telephone or face to face.

3. What will happen if I take part?

If you choose to participate in this study you will be asked to complete two questionnaires with the help of a researcher. This will take place during a telephone call of a face to face meeting on a single occasion. The first questionnaire will ask you how health care providers communicate with you. The second will ask about your knowledge, beliefs and skills and how well you feel able to manage your own condition between visits to the health facility.

The study researcher may need to access some of your medical records for the purpose of this research study, e.g. your medical diagnosis or medical prescriptions.

4. Do I have to take part?

You are free to choose if you want to take part in the research. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

5. Incentives:

There are no incentives for participation in this study

6. Risks and discomforts:

There are no expected risks associated with participation in this study. If you become upset or distressed, we will offer you the chance to take some time out of the study and then either carry on or stop the study completely. The researcher will help you identify someone else to talk to if you continue to feel upset.

7. Benefits

There are no direct benefits to you, though it may have some benefits for future patients.

8. Data handling and confidentiality:

The Human Research Ethics Committee regulations at the University of Ibadan, St. Francis University College of Health and Allied Sciences, King's College London and the General Data Protection Regulation, 2016 (GDPR) will apply to all the information that you provide to this study. Information that could identify you such as your name or phone number, will be stored electronically on password protected computers and encrypted or in a locked cabinets at [*insert University of Ibadan or St. Francis University College of Health and Allied Sciences*]. This information will not leave your country. Once your information has been anonymized, it will be held on a secure cloud storage located at University of Ibadan.

The research team may use your data for future research but any such use of identifiable data would be reviewed and approved by a research ethics committee.

Your identity will not be disclosed to anybody except the Ethics committee and/or regulatory authorities during the course and after completion of the study if required. When we report the findings you will not be identifiable from the information.

Research data will be stored or accessed by the research team and securely archived for 10 years after the study has ended.

9. Data Protection Statement

The data controllers for this project will be King's College London, the University of Ibadan, and SFUCHAS. These institutions will process any data you provide for the purpose of the research outlined above in accordance with the General Data Protection Regulation 2016 (GDPR). Under GDPR, a data controller is responsible for handling personally identifiable data. They decide how and why the data is processed. At King's College London, the data controller for research data is the university itself. For each research project, the Principal Investigator takes responsibility. They have to ensure that only the relevant research team has access to your personal data.The legal basis for processing your personally identifiable data for research purposes under GDPR is a 'task in the public interest'

Researchers also have a common law duty and ethical obligation to gain explicit informed consent from you as a research participant for all aspects of the research. This includes the use of your personal data. You have the right to be informed of the following:

- What data we collect from you.
- How we will ensure the confidentiality of your data.
- How long we will keep your data for, and whether it will be shared with anyone else.

Under GDPR, you have the right of access to any information we hold about you. You can ask for it to be corrected, erased and object to how it is processed. However, this might be restricted in some circumstances. These include compliance with legal obligations. Restrictions might also be applied for scientific research purposes. For example, this might be if the deletion of your data was seriously detrimental to the research. In such circumstances, we may need to keep the information about you that we have already collected. However, the research team are required, under GDPR, to explain why these restrictions might be necessary *before* you agree to take part in the study. This is part of the informed consent process.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, Mr Albert Chan info-compliance@kcl.ac.uk who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) www.ico.org.uk.

10. What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way.

You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You can ask for the information you give to be withdrawn and not used, but this will not be possible from four weeks (one month) after your final interview. If you refuse or withdraw from the study, this will not affect the treatment and care you receive from your Doctor. You will still receive care as usual from health facilities.

11. How is the project being funded?

This study is being funded by UKRI/GCRF/Newton Fund in the UK.

12. What will happen to the results of the study?

The findings of the study will be presented in a report and will be published in scientific journals and at academic meetings. A report will be displayed at the health facility and you will not be identified in the results of the study or any publication that might arise from this study. Anonymised data may also be used in future research studies by appropriately qualified researchers. We will also present the findings from this study at international and national conferences, we will use anonymised data to present these findings so that you should not be identified in anyway. We will use the findings to inform local and international policy makers.

13. Who should I contact for further information?

If you have any questions or require more information about this study, please contact the following:

Akinyinka Omigbodun
Professor of Obstetrics and Gynaecology
University of Ibadan
Email: omigbodun@yahoo.com

Professor Senga Pemba
SFUCHAS
Deputy Principal (Academic, Research and Consultancy)
Email: spemba@sfuchas.ac.tz

Jackie Sturt
Professor of Behavioural Medicine in Nursing
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care
King's College London
James Clerk Maxwell Building
57 Waterloo Rd
London
SE18WA
Email: Jackie.sturt@kcl.ac.uk

14. What if I have further questions, what if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you should contact;

The Secretary
Oyo State Health Research Ethics Review Committee
Oyo State Ministry of Health
Department of Planning, Research & Statistics
Government Secretariat, Agodi, PMB 5027,
Ibadan, Nigeria.

Secretariat
National Health Research Ethics Review Committee
National Institute for Medical Research
2448 Ocean Road
P.O. Box 9653
Dar es Salaam, Tanzania
Tel: +255 22 2121400
Fax: 255 22 2121360

Email: ethics@nimr.or.tz ; nimrethics@gmail.com

The Chair

Psychiatry, Nursing and Midwifery Research Ethics, Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London SE1 9NH, Email: rec@kcl.ac.uk

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET AND CONSIDERING WHETHER TO TAKE PART IN THIS RESEARCH.