

Patient PIS for Vendor cRCT
Version 0.5 25 SEP 2018



DEPARTMENT OF COMMUNITY MEDICINE
FACULTY OF MEDICINE AND ALLIED SCIENCES
RAJARATA UNIVERSITY OF SRI LANKA

PARTICIPANT INFORMATION SHEET FOR PATIENTS

STUDY ON WHETHER PESTICIDE VENDOR TRAINING CAN REDUCE PESTICIDES SELF-POISONING IN RURAL SRI LANKA

We would like to invite you (on behalf of your relative or your child) to participate in a research project. Please read this leaflet carefully, and if you have any questions about the study do not hesitate to ask from the research assistant. Feel free to discuss the project with your family or friends before you make a decision on whether to participate.

What is the purpose of the study?

This is a study about whether pesticide vendor training can reduce pesticides self-poisoning in rural Sri Lanka. This research project is a collaborative project with several Universities including: Rajarata University of Sri Lanka, University of Edinburgh, Northeastern University, University of Bristol, University of Oxford, University of Kelaniya and University of Copenhagen. This research project has been funded by the American Foundation for Suicide Prevention and the study has been approved by the Research Ethics Committee of Rajarata University of Sri Lanka.

Why have I been invited?

You have been selected for this study because you (or your relative / child) have (has) admitted to a study hospital following a self-harm attempt in or just outside of the boundary of the North Central Province.

Must I take part?

No. Participation is entirely voluntary. There is no obligation for you to take part, and if you do not want to take part, this will have no effect on your or your relative's / child's medical care or affect you or them in any way. It is also possible for you (or your relative / child) to withdraw from the interview or withdraw data at any point without giving any reasons and without any penalty. As we are conducting this research to test the pesticide vendor training reduces pesticide self-poisoning in rural Sri Lanka, we would greatly appreciate your (or your relative's / child's) participation.

What will the research involve?

You (your relative /child) will be asked to take part in an interview. One of our trained research assistants will interview you (or your child) to obtain some of the information about your (or your relative's / child's) self-harm event. We will collect information such as address, divisional secretariat, source (access point) of pesticides, method of self-harm, the ingested poison, and

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- if the person bought the pesticide - the shop's name and location. We will use your phone and contact details to monitor location. The interview will take about 20 minutes of your time.

We would like to keep your name and address on record and to then contact you again in the future. We will do this to assess the effects of any poison you may have ingested over the next few years. You do not need to do this - you can just complete the interview and ask us not to contact you again.

Are there any risks?

We do not envisage any harm from this study. However, it is likely that engaging with this research may encourage you to consider your (or your relative's / child's) circumstances in detail. We hope that this will be a positive experience but we cannot rule out any negative feelings that may occur. All your contributions will be kept confidential.

Are there any benefits?

There will be no direct benefits for participating. However, this will be an opportunity to share your (or your relative's / child's) experiences and to contribute to the study. Studying whether pesticide vendor training reduces pesticides self-poisoning might benefit many people in future in rural Sri Lanka and across South Asia. Therefore, we believe that this will be an interesting opportunity for you (or your relative / child).

Will my or my child taking part in the study be kept confidential?

Yes, all information you give is strictly confidential. The information you give may be used for a research report or publications, but it will not be possible to identify you (or your relative / child) in any way from this.

Consent

The study researchers can answer any questions you may have about the study. They will take your consent for the interview and follow-up. You will have about 60 min to make a decision about whether to have the interview. Please do take the opportunity to discuss it with your family and friends.

If you have any further questions, please ask:

Investigator: Manjula Weerasinghe

Telephone: 077 3230888

If you would like to discuss this study with someone independent of the study team please contact:

Dr Janaka Pushpakumara on telephone: 0094 077 3565144 or email janakatechno@gmail.com

If you have any complaints about this research or its conduct, please contact:

Secretary, Ethics Review Committee, Faculty of Medicine and Allied Sciences,
Rajarata University of Sri Lanka. Phone number: +94(0)25 2053633 (please contact during working
hrs 8 am – 4 pm). E-mail: ethicsreviewcommittee@gmail.com

or

the University of Edinburgh's Research Governance team via email at: resgov@accord.scot

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Data protection

The University of Edinburgh is the sponsor for this study based in Sri Lanka. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The sponsor will keep identifiable information about you for 10 years after the study has finished.

As a university, we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.