ISRCTN18237656 https://doi.org/10.1186/ISRCTN18237656

African pesticide intervention studies project

Submission date
07/07/2023

Recruitment status
No longer recruiting

Registration date
01/09/2023

Overall study status
Completed

Last Edited
09/05/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Educational interventions on pesticide handling to smallholder farmers aim to protect human health and the environment from negative effects of pesticides in low-and middle-income countries. However, the entire scope of the effects and the mechanisms of such interventions has not been assessed systematically such as how these change smallholder farmers' behavior, pesticide exposure and health.
The aim of this study is to test whether an educational intervention on safe pesticide handling and text messages based on the risks, attitude, norms, abilities and self-regulation (RANAS) model of behavior change increase safe pesticide handling, the use of personal protective equipment (PPE) and prevent pesticide exposure of smallholder farmers in Uganda. The researchers further aim to investigate which psychological factors explain the mechanisms of the interventions towards using PPE.

Who can participate?
Smallholder farmers aged over 18 years in 12 subcounties in two districts of rural Uganda, who actively sprayed pesticides in the past 12 months at baseline and grow one of the following crops (most sprayed crops): watermelon, passion fruit, tomato or cabbage

What does the study involve?
Participants are randomly allocated to one of the three groups: 1) educational intervention or 2) educational intervention + RANAS-based text messages or 3) a control group. The 2-day information dissemination was delivered in group workshops with farmers and based on a curriculum that has been developed by the Danish NGO Dialogos and adapted by the Ugandan NGO Uganda National Association of Community Occupational Health (UNACOH) in Uganda from 2010 to 2020. It comprises five modules including an introduction to pesticides, pesticides and human health, pesticides and the environment, integrated pest management and application methods and equipment. The RANAS-based text messages targeted relevant psychological factors towards PPE use that had been identified as relevant at baseline (e.g. social norm). Knowledge, attitude and practice (KAP) scores, PPE use behaviour, RANAS factors regarding PPE use, using gloves as PPE, pesticide exposure-intensity scores, and health symptoms associated with pesticide poisoning are assessed in structured face-to-face interviews before the intervention (baseline) and 12 months after (follow-up).

What are the possible benefits and risks of participating?
Participants will benefit by receiving the interventions to protect themselves and their families from pesticide exposure. The study will contribute to a better understanding of the effectiveness and mechanisms of interventions towards reducing pesticide exposure among smallholder farmers. The insights from this study could further be used to strategically plan and implement similar interventions in order to protect human health and the environment from the negative effects of pesticides in low- and middle-income countries. No risks are expected for the participants.

Where is the study run from?
Swiss Tropical and Public Health Institute (Switzerland)

When is the study starting and how long is it expected to run for?
May 2019 to December 2023

Who is funding the study?
1. Leading House Africa
2. Swiss National Science Foundation (SNSF) (Switzerland)
3. Swiss Government Excellence Scholarships (ESKAS) (Switzerland)

Who is the main contact?
Prof. Samuel Fuhrimann, samuel.fuhrimann@swisstph.ch

Contact information

Type(s)
Principal investigator

Contact name
Prof Samuel Fuhrimann

ORCID ID
https://orcid.org/0000-0002-1861-1737

Contact details
Swiss Tropical and Public Health Institute
Kreuzstrasse 2
Allschwil
Switzerland
4123
+41 (0)612848619
samuel.fuhrimann@swisstph.ch

Additional identifiers

Protocol serial number
HDREC 846

Study information

Scientific Title
Evaluating and enhancing educational interventions using behavior change techniques to reduce smallholder farmer's exposure to pesticides: a cluster-randomized controlled trial in Uganda

Acronym
APSENT

Study objectives
1. Farmers who receive the educational intervention or educational intervention + RANAS (risk, attitudes, norms, ability and self-regulation) based text messages improve smallholder farmers' knowledge, attitudes and practices of pesticide handling compared to farmers in the control group at follow up
2. Farmers who receive the educational intervention or educational intervention + and RANAS-based text messages indicate reduced frequency and intensity of exposure to pesticides during application and re-entry work compared to farmers in the control group at follow-up
3. Farmers who receive the educational intervention or educational intervention + RANAS-based text messages indicate reduced acute pesticide-related health signs and symptoms compared to farmers in the control group at follow-up
4.1. Farmers who receive the educational intervention increase their use of personal protective equipment (PPE) compared to farmers in the control group at follow up
4.2. Farmers who receive the educational intervention plus RANAS-based risk, attitudes, norms, ability, self-regulation) text messages increase their use of PPE compared to farmers in the control group at follow up
4.3. Farmers who receive the educational intervention plus RANAS-based text message reminders increase their use of PPE compared to farmers who receive the education intervention only at follow-up
To understand the mechanisms of the intervention on PPE use, we will investigate which RANAS factors were changed by the information dissemination compared to control and by the RANAS-based text message intervention compared to the educational intervention. We will also estimate which RANAS factors explain behavior change related to PPE use across groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/02/2021, Higher Degrees Research and Ethics Committee (HDREC) at Makerere University School of Public Health (New Mulago Hill Road, Mulago, Kampala, PO Box 7072, Uganda; +256 (0)393 291 397; hdrecadmin@musph.ac.ug), ref: HDREC 846

Study design
Multi-center single-blinded three-arm cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of pesticide exposure in smallholder farmers in Uganda

Interventions
Simple randomization using Microsoft Excel generated-random numbers was used to randomize the clusters (subcounties) to the study arms (cluster randomized trial). 12 clusters (geographical administrative sub-counties) with 45 farmers each were randomly assigned to the three arms 1) an educational intervention on safe pesticide handling or 2) an educational intervention on safe pesticide handling + RANAS-based text messages or 3) a control group, accounting for 180 farmers per arm. The study participants were blinded for their allocated arm, masking the researchers was not possible (single-blinded).

According to their assignment, farmers in the intervention groups receive either the educational intervention only or educational intervention with additional text messages based on the Risks, Attitudes, Norms, Abilities, and Selfregulation framework (RANAS) model of behavior change (Mosler, 2012). Farmers in the control group receive neither the educational intervention nor the RANAS-based text messages.

Educational intervention:
In November 2020, a 2-day training is held in groups by one health and pesticide handling professional and one agricultural extension worker based on a curriculum that has been developed by the Danish NGO Dialogos and adapted by the Ugandan NGO, Uganda National Association of Community Occupational Health (UNACOH) in Uganda from 2010 to 2020. The educational intervention involves providing information to the farmers on safe pesticide handling, short videos, practical demonstrations and group exercises based on five modules: 1. Introduction to pesticides; 2. Pesticides and human health; 3. Introduction to integrated Pest Management 4) Pesticides and the environment; 5. Pesticide application methods and equipment. Farmers at the end of the intervention receive posters which are visually summarizing the key information of the training in their respective local languages.

RANAS-based text messages:
Text messages were based on the risks, attitude, norms, abilities and self-regulation (RANAS) model of behavior change aim to motivate farmers to buy and use PPE. The relevant psychological factors to target in the SMS are selected according to factors that explain higher PPE use at baseline. A total of 20 text messages are sent to farmers in two phases: the first phase is implemented from February to March 2021 with the purpose of motivating farmers to buy PPE before the commencement of the pesticide spraying season. The second phase is carried out from April to September 2021 with an emphasis on the use of PPEs while handling pesticides during the spraying season.

Intervention Type
Behavioural

Primary outcome(s)
The co-primary outcomes of the study are:
1. Farmers' knowledge, attitudes and practices (KAP) assessed based on three scores which contain 16 items each for knowledge, attitudes and practice at baseline and 12-month follow-up. The KAP items were developed based on other KAP assessments in the PESTROP survey (Staudacher et al., 2020) and another study (Gautam et al., 2017) and adapted in a way that they assessed KAP related to the training modules of the educational intervention curriculum that was tested in this study. For every correct answer, one point will be added to the knowledge, attitudes and practice score, resulting in final scores ranging between 0 and 16 (as proposed by Riccò et al., 2019 and Riccò et al., 2020).
2. Using PPE to cover all body parts, assessed via behavioral frequency measures, as common in

behavioral science (e.g. Verplanken & Orbell, 2003): Farmers indicated how often they used 15 specific PPE items in the past year, such as gloves and gumboots, at baseline and 12-month follow-up. The response options ranged from "never using the respective PPE item" (1) to "always using the respective PPE item" (5). The PPE items will be categorized into eight groups, representing different body parts: eyes, mouth, hands, arms, legs, feet, trunk, and head. To calculate the total frequency of PPE use across all body parts, we will add up the average frequencies of using PPE for each category. For example, the total frequency of using PPE will be the average frequency of using items to cover hands, plus the average frequency of using items to cover mouth, and so on for each body part.

Key secondary outcome(s))

1. Psychosocial factors of PPE use (RANAS factors) assessed using the measurements proposed by the RANAS approach (Contzen & Mosler, 2015; Mosler, 2012). The RANAS model describes 17 psychosocial factors that are of potential relevance to change behavior that are grouped into five factors categories (Risk, attitude, norm, ability, and self-regulation). The items assessed these 17 RANAS factors asking participants to rate their degree of agreement or feeling related to certain RANAS questions, using a 5-point Likert scale: not at all (1) to very much (5) at baseline and 12-month follow-up. Risk factors contained a mean of two items on health vulnerability and a mean of two items on severity, e.g. “Imagine you are suffering from acute symptoms of pesticide usage; how severe do you rate the consequences for your own health?” – “not at all severe” to “very severe”. Attitudes factors contained five single items on beliefs about cost benefits. Norm factors contained a mean of two items on others’ behavior (descriptive norm), the mean of two items on others’ (dis)approval (injunctive norm), as well as the mean of two items on personal importance. Ability factors contained one item on how-to-do-knowledge and the mean of three items on confidence. Self-regulation factors contained two items on action planning, one item on barrier planning and the mean of three items on commitment.
2. Frequency of using gloves. As hands are the most exposed body parts during pesticide handling (Fuhrimann, Staudacher et al., 2020) the study assessed the mean frequency of using PPE covering hands using common behavioral frequency assessment (e.g. Verplanken & Orbell, 2003) at baseline and 12-month follow up. Participants were asked about the frequency of using PPE to cover their hands in the past 12 months, with answer options; never (1) to always (5).
3. Pesticide exposure measured using the exposure intensity scores developed by Fuhrimann, Staudacher et al. (2020) at baseline and 12-month follow-up. These scores were derived from calculating a semi-quantitative exposure algorithm developed and validated for low- and middle-income countries (Fuhrimann, Staudacher et al., 2020).
4. Exposure modified by PPE use assessed by using the modifying PPE variable from the pesticide exposure algorithm at baseline and 12-month follow-up (Fuhrimann, Staudacher et al., 2020). This variable accounts for the materials of PPE being used and the exposure risk of different body parts. For example, hands account for 40% of pesticide exposure, while eyes only account for 10% of exposure.
5. Farmer’s health assessed using a checklist for the frequency of 31 symptoms associated with neurological acute pesticide poisoning experienced e.g., dizziness, anxiousness, nausea, vomiting, sleeping difficulties, weakness of the limbs, and changes in taste and smell (as proposed by Farnham et al., 2021) at baseline and 12-month follow-up.

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. Smallholder farmers who actively sprayed pesticides in the past 12 months at baseline
2. Grow one of the following crops (most sprayed crops), watermelon, passion fruit, tomato or cabbage
3. Above 18 years of age
4. Able to read and write
5. Have a phone in their household

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Share a household with another eligible farmer
2. Not part of the UNACOH-led pesticide training
3. Too sick to participate

Date of first enrolment
05/10/2020

Date of final enrolment
26/10/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Ssembabule district
Ssembabule Town Council
Masaka
Uganda
PO Box 986

Study participating centre

Kumi district
Kumi Town Council
Kumi
Uganda
PO Box 3

Sponsor information

Organisation
Leading House Africa mandated by the Swiss State Secretariat for Education, Research, and Innovation (SERI)

Funder(s)

Funder type
Other

Funder Name
Leading House Africa

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Funder Name
Swiss Government Excellence Scholarships

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Samuel Fuhrimann (samuel.fuhrimann@swisstph.ch)

Dates of availability: Not yet certain but probably at the publication of the first study.
Whether consent from participants was required and obtained: informed, written participant consent or fingerprint was required and obtained by the research assistants that collected the data in personal interviews prior to the baseline assessment.
Comments on data anonymization: The wording in the informed consent sheet was as follows: “All the answers you provide to the questions, and the results of the tests and samples, will be identified with a unique number and not with your personal data (name, last name, phone number, address). Only the local Research Ethics Committee (REC) and Uganda National Council for Science and Technology (UNCST) as entities and the study investigators Ms Ruth Mubeezi, Mr Aggrey Atuhaire, Dr Samuel Fuhrimann, Dr Shala Chetty-Mhlanga, Dr Prof. Martin Röösli have access to documents that contain your personal information. We will not tell anyone that you are participating in the study and not give out your personal information without your permission. In the publication of research results, your information will be handled confidentially.”
Any ethical or legal restrictions: Ethical approval of the study was secured from the Higher Degrees Research and Ethics Committee (HDRE) at Makerere University in Uganda (reference number 846). Written informed consent was obtained from all study participants prior to the baseline interview. Participants' data may be shared but with confidentiality (without personal information).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/05/2024	09/05/2024	Yes	No