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Gatekeeper training for vendors to reduce pesticide self-poisoning in rural South Asia: a study protocol for a stepped-wedge cluster randomised controlled trial

Manjula Weerasinghe [ORCID],[1,2] Melissa Pearson,[1,3] Nicholas Turner,[4] Chris Metcalfe [ORCID],[4] David J Gunnell,[4] Suneth Agampodi,[2] Keith Hawton [ORCID],[5] Thilini Agampodi,[2] Matthew Miller,[6] Shaluka Jayamanne,[7] Simon Parker,[8] Jayakody Arachchige Sumith,[9] Ayanthi Karunarathne,[10] Kalpani Dissanayaka,[11] Sandamali Rajapaksha,[11] Dilani Rodrigo,[11] Dissanayake Abeysinghe,[11] Chathuranga Piyasena,[11] Rajaratnam Kanapathy,[11] Sundaresan Thedchanamoorthy,[12] Lizell Bustamante Madsen,[13] Flemming Konradsen,[13] Michael Eddleston[1]

Correspondence to
Dr Manjula Weerasinghe;
manjugaya@yahoo.com

ABSTRACT

Introduction Pesticide self-poisoning kills an estimated 110 000–168 000 people worldwide annually. Data from South Asia indicate that in 15%–20% of attempted suicides and 30%–50% of completed suicides involving pesticides these are purchased shortly beforehand for this purpose. Individuals who are intoxicated with alcohol and/or non-farmers represent 72% of such customers. We have developed a 'gatekeeper' training programme for vendors to enable them to identify individuals at high risk of self-poisoning (gatekeeper function) and prevent such individuals from accessing pesticides (means restriction). The primary aim of the study is to evaluate the effectiveness of the gatekeeper intervention in preventing pesticide self-poisoning in Sri Lanka. Other aims are to identify method substitution and to assess the cost and cost-effectiveness of the intervention.

Methods and analysis A stepped-wedge cluster randomised trial of a gatekeeper intervention is being conducted in rural Sri Lanka with a population of approximately 2.7 million. The gatekeeper intervention is being introduced into 70 administrative divisions in random order at each of 30 steps over a 40-month period. The primary outcome is the number of pesticide self-poisoning cases identified from surveillance of hospitals and police stations. Secondary outcomes include: number of self-poisoning cases using pesticides purchased within the previous 24 hours, total number of all forms of self-harm and suicides. Intervention effectiveness will be estimated by comparing outcome measures between the pretraining and post-training periods across the divisions in the study area. The original study protocol has been adapted as necessary in light of the impact of the COVID-19.

Ethics and dissemination The Ethical Review Committee of the Faculty of Medicine and Allied Sciences, Rajarata University, Sri Lanka (ERC/2018/30), and the ACCORD Medical Research Ethics Committee, Edinburgh University (18-HV-053) approved the study. Results will be disseminated in scientific peer-reviewed journals.

Trial registration number SLCTR/2019/006, U1111-1220-8046.

Strengths and limitations of this study

► The study provides a pragmatic evaluation of the 'gatekeeper' training, which will be introduced more generally if found to be effective.

► A potential limitation of the stepped-wedge design is susceptibility to confounding by secular trends in pesticide self-poisoning rates during the study period.

► The observed treatment effect may be diluted if individuals attempt to purchase pesticides from a shop outside of their division of residence (contamination).

► The intervention can potentially only prevent a proportion of pesticide self-poisoning cases (15%–20% of cases purchasing pesticides for the act), requiring a large study to provide sufficient statistical power to detect a modest total treatment effect.

INTRODUCTION

Pesticide self-poisoning is one of the most frequently used global means of suicide,[1] equalling 15%–20% of all global suicides, or an estimated 110 000–168 000 deaths annually.[2] Many of these deaths occur among people living in rural areas of low and middle-income countries (LMIC),[3 4] who may ingest pesticides impulsively in a moment of crisis.[5]

► *Shop cases*: We defined a shop case as an incidence of self-harm which fulfils each of the following criteria with regard to the purchase of the pesticide: (1) the purchase was made by the individual who ingested it, (2) the purchase occurred at a pesticide shop, (3) the purchase was made within 24 hours of self-poisoning. We also collected data on whether the person bought the pesticide with the intention of ingesting it. However, we did not include intention within the definition of a shop case, as intention is subjective and may be unreliable.

► *Pesticides*: A pesticide was defined as an agrochemical (herbicide, insecticide, fungicide or rodenticide) used to control agricultural pests, or a chemical used to control domestic pests.

► *Self-harm patient*: A self-harm patient in the study was defined as a permanent resident, temporary resident or guest/visitor in the study area at the time of the self-harm episode, who was admitted to one of the study hospitals during the study period due to suicide attempt.

► *Pesticide shop*: Seasonal shops (open only in agricultural season) or non-seasonal shops that are selling pesticides throughout of the year, regardless of whether they hold a government licence to sell pesticides.

► *Pesticide vendor*: Either a full-time or part-time vendor who is directly involved in the sale of pesticide to customers in the study area during the study period.

Pesticides are often available in the community, meaning they can be accessed and ingested with little thought at moments of crisis or anger.[4 6]

In Sri Lanka, pesticide shops are widespread in agricultural areas, making pesticides freely available for over-the-counter purchase and providing easy access for self-poisoning.[7 8] In South Asia, 14%–20% of attempted suicides[6 9 10] and 33%–49% of completed suicides involve pesticides[11] and occur shortly after individuals purchase the pesticides from a shop for the specific purpose of self-harm (a 'shop case', box 1). To the best of our knowledge, no interventions have been aimed at pesticide shops to support vendors in preventing individuals from accessing pesticides for self-poisoning. However, several interventions have been tested to prevent suicides involving a range of other means of self-poisoning methods by reducing access to means at the point of sale in different countries—analgesic packaging restrictions[12 13] and physical barriers to purchases of charcoal.[14]

Over a period of 3 years, we have designed an intervention following the UK Medical Research Council's guidance on development of complex interventions[15] through a series of studies. We first identified major risk factors for buying pesticides for self-harm using a case–control design, noting in particular being intoxicated with alcohol at the time of purchase (OR 36.5; 95% CI 1.7 to 783) or being a non-farmer purchasing pesticides (OR 13.3; 95% CI 1.8 to 100) as key risk factors—one and/or other of these factors characterised 72.0% of cases.[16 17] We then explored the acceptability of possible interventions with stakeholders including pesticide vendors, and finally tested the most acceptable intervention in a qualitative feasibility study. Focus group and stakeholder discussions favoured a vendor-based gatekeeper approach identifying, and refusing to sell to, high-risk individuals.[18] A feasibility study showed good vendor acceptance and provided preliminary evidence that it may prevent self-poisoning.[19] Finally, an ex ante cost analysis and a cost-effectiveness threshold analysis of the gatekeeper programme were conducted, showing it to have a very high potential of being cost-effective.[20]

Previous studies have dramatically demonstrated the potential for vendor gatekeeper training to reduce the incidence of pesticide self-poisoning. Because such purchases contribute to many pesticide self-poisoning attempts and death cases worldwide, preventing these purchases, as part of a multifaceted suicide prevention effort, should make a significant contribution to preventing deaths in LMICs and to lowering global suicide. However, before this approach is further pursued, a large-scale trial is required to determine its effectiveness.

OBJECTIVE

The main objective of the study is to test the effectiveness of the gatekeeper intervention in preventing pesticide self-poisoning in Sri Lanka. This study, furthermore, aims to identify method substitution and to assess the cost and cost-effectiveness of the intervention.

METHODS AND ANALYSIS
Design

This study is a single-blinded, stepped-wedge cluster randomised controlled trial (s-w cRCT) of a public health intervention involving pesticide shops. A stepped-wedge design was selected to provide a pragmatic evaluation of this low-risk intervention. Definitions used in the trial design are presented in box 1. This paper complies with the Standard Protocol Items: Recommendations for Interventional Trials reporting guideline for standard protocol items for clinical trials.[21]

Setting

The study is being carried out in two areas (zones) populated by about 2.7 million people (census, 2019) in 70 divisions, primarily from six districts (Anuradhapura 22 divisions, Polonnaruwa 7, Matale 11, Vavuniya 4, Batticaloa 14 and Trincomalee 11) and one division (Dehiattakandiya) from Ampara District (figure 1). Divisions are government administrative regions with populations of ~40 000 people.

Our previous research during 2011–2016 found the incidence of pesticide self-poisoning in the South-West Mahaweli H section of North Central Province (NCP, zone 1) to be over 250 per 100 000 person-years.[3] This study was originally designed with this case incidence and included 29 NCP divisions (zone 1 districts: Anuradhapura, Polonnaruwa; population 1.5 million). However, initial case collection over the first 6 months (April to
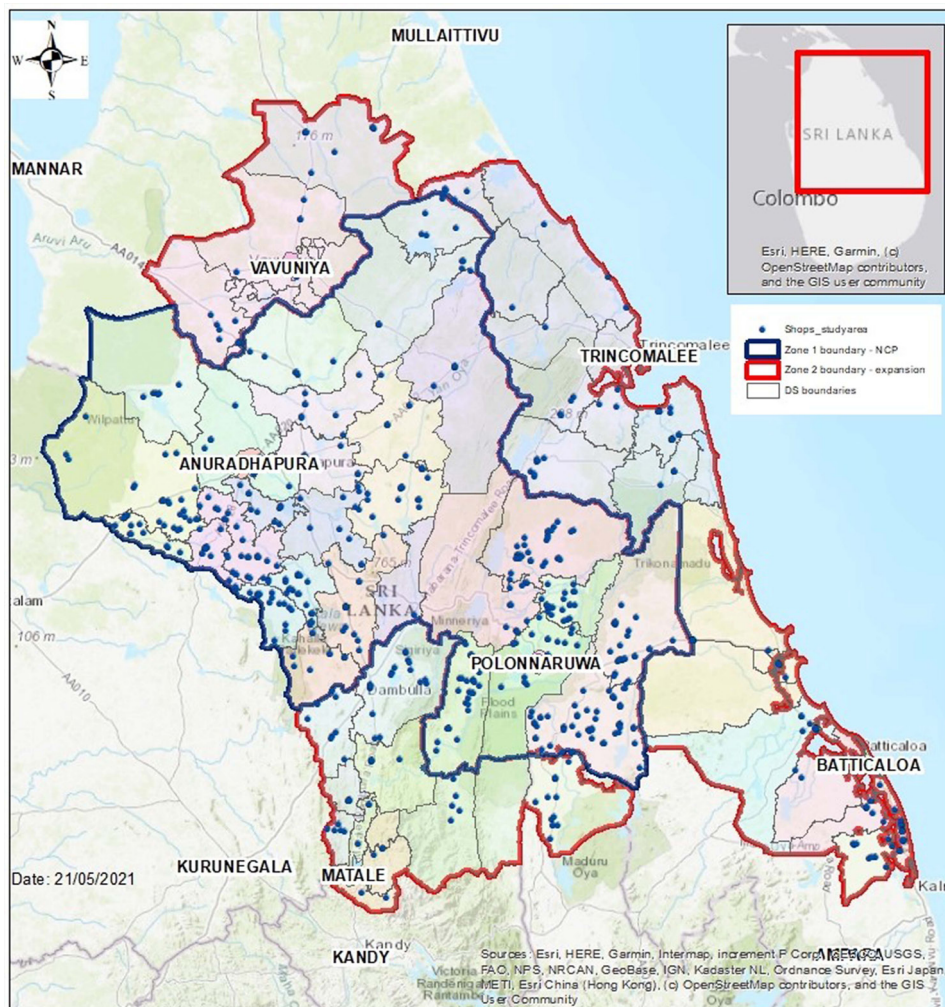
Figure 1 Study area—spatial distribution of pesticide shops across the two zones. DS, Divisional Secretariat; NCP, North Central Province.

September 2019) showed a markedly lower incidence of pesticide self-poisoning at around 130/100 000 per year. The study was therefore expanded into a second area including 41 divisions to the north and east of the initial study area (expansion area, zone 2 districts: Matale, Batticaloa, Trincomalee, Vavuniya and part of Ampara; population 1.2 million) to allow recruitment of sufficient cases. Because involvement of the two zones started at different times, they are run as parallel studies; the data will be combined for analysis at the end of the study.

Participant enrolment

No up-to-date and comprehensive record of pesticide shops and vendors is available. We therefore carried out a baseline mapping exercise identifying all shops selling pesticides, including seasonal shops, both registered and non-registered with the Department of Agriculture. This survey identified 669 shops and 1406 pesticide vendors in the study area. During the study, regular surveys are being carried out to identify shops that close or open to ensure an up-to-date list of pesticide shops in the study area. Shops that are missed at initial training in their division will receive training as soon as their presence is noted.

Inclusion and exclusion criteria

All pesticide shops and vendors directly involved in pesticide sales in the study area during the study period are eligible for the intervention. It is likely that some people living close to division boundaries cross cluster boundaries to buy pesticides in non-study areas. Therefore, our initial zone 1 design included training of vendors in shops located within 5 km of divisional boundaries, outside of the NCP study area. However, after 6 months of data collection, review of out-of-division purchases revealed that cross-boundary purchases within 5 km were minimal (1.3% of all purchases). Since we were expanding the study into contiguous areas, around the north and east study area boundary, a decision was made to discontinue training of vendors outside cluster boundaries. Vendors who are aged under 18 years (<1%) are excluded, as well as cashiers and other store workers in larger pesticide shops who do not directly interact with pesticide-purchasing customers.

Randomisation

The unit of randomisation (cluster) is one or more (usually two) divisions. The intervention is being introduced in

each of 30 time periods ('steps' of the stepped-wedge design) in the two zones, so training will proceed at each step in two or more divisions (the cluster).

Cross-border contamination, that is, people crossing into a division with discordant training status from their home division to purchase pesticides, is recognised, particularly where multiple pesticide shops exist along a shared boundary (usually a major road). We therefore identified neighbouring divisions with multiple pesticide shops along such a shared boundary and combined them into a pair, into which the intervention would be introduced during the same step. We expected this approach to reduce contamination.

Random allocation was conducted by a member (NT) of the study team based outside of Sri Lanka once the mapping of pesticide shops and pairing of divisions had been completed, so ensuring allocation was controlled and intervention staff informed 2 weeks before the start of training (so that logistic plans could be made and maps updated as required). The clusters have been listed in a randomly generated order (using Stata statistical software: StataCorp, College Station, Texas, 2017), and the intervention rolled out into each cluster in turn following this random sequence.

In zone 1's 29 divisions, the intervention was initially introduced at 78-day intervals; this was reduced to 67-day intervals following COVID-19 pandemic lockdown in March to June 2020. In zone 2's 41 divisions, the intervention was initially planned to introduce at 66-day intervals. However, as zone 2 started later, after the lockdown, the intervention was introduced at 42-day intervals. Zone 2 intervals are shorter to ensure all training is completed by the time that zone 1 training is complete. Before the first intervention, a monitoring period (160 days in zone 1 and 61 days in zone 2) was established, during which a baseline number of pesticide self-poisoning cases were recorded.

Overall, the intervention is being rolled out in 15 steps in zone 1 over 39 months and in 15 steps in zone 2 over 23 months (figure 2).

The intervention

The intervention is a modified 'gatekeeper' training and involves helping pesticide vendors to identify a person at
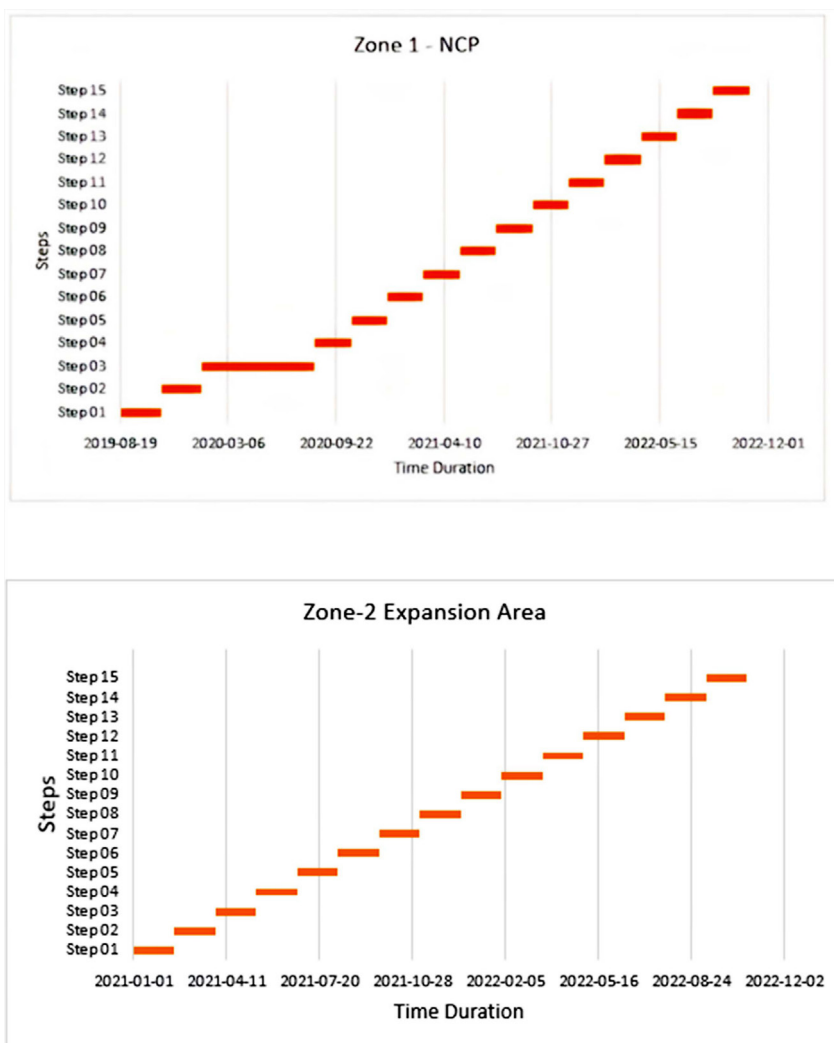
Figure 2 Schematic of the timing of the intervention across the study area and period. NCP, North Central Province.
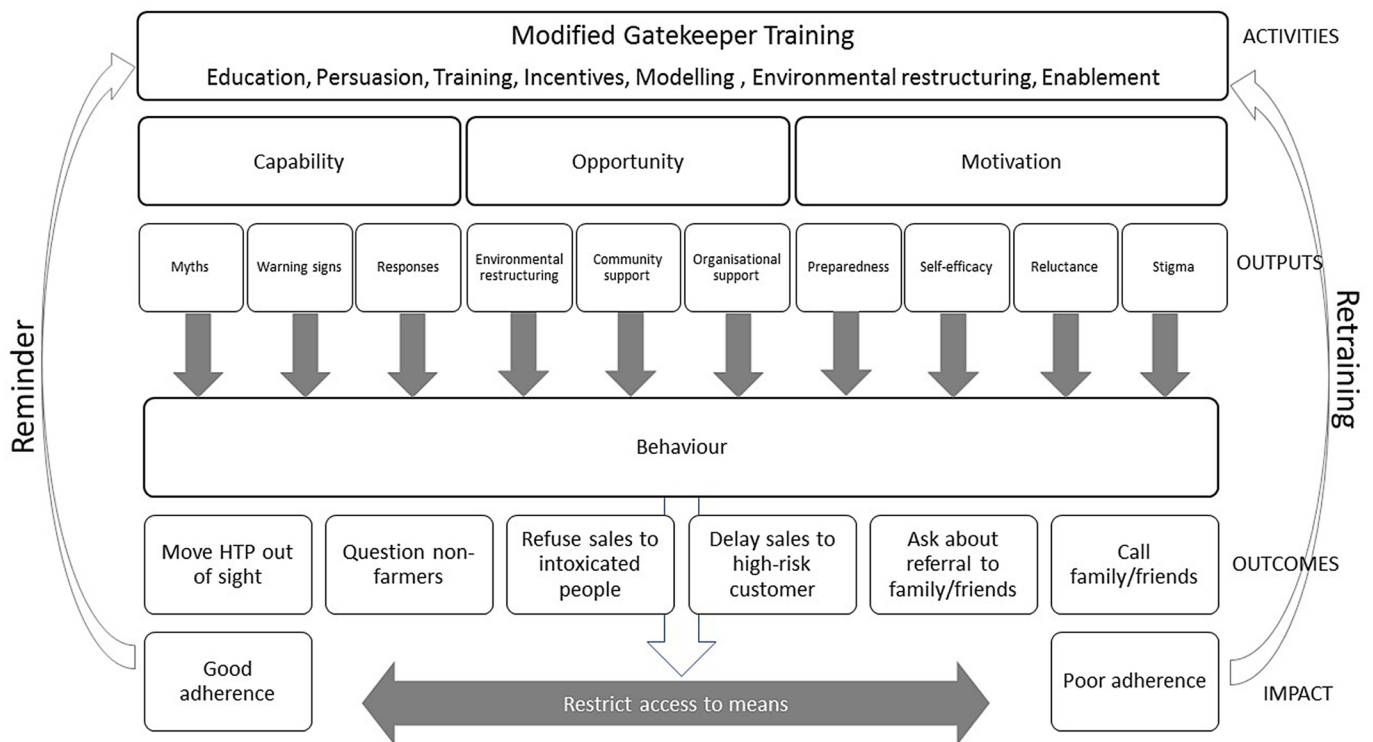
Figure 3 Behaviour change model for the modified 'gatekeeper' training intervention of pesticide vendors in rural Sri Lanka. HTP, Highly Toxic Pesticides.

high risk of purchasing a pesticide for the purpose of self-poisoning (gatekeeper function), in order to then refuse to sell pesticides to this individual (means restriction).[19] We have used the Capability, Opportunity, Motivation and Behaviour model of behaviour change to plan our intervention for modified 'gatekeeper' training.[22] Using the findings from our pilot work,[19] we developed a theoretical model of the behaviour change (figure 3). The intervention employs seven strategies: education, persuasion, incentivisation, training, environmental restructuring, modelling and enablement. The characteristics of the intervention have been detailed and a manual produced.

The intervention consists of a 1-hour discussion with small groups of vendors (maximum 10 participants) on their experience with self-poisoning clients, followed by a 1-hour interactive presentation and discussion on how to identify and respond to high-risk clients. Vendors are trained to observe customer for any unusual behaviours[8] such as sadness or nervousness, and for intoxication, and to ask questions on agriculture for which farmers would be expected to know the answer. Short training films have been produced to standardise the presentation of information and training across different shops (https://vimeo.com/user14558312). The training uses role-plays to aid development of skills learnt in the training. The session is performed at a central location within the cluster and/or at pesticide shops in daytime or in evenings, depending on the vendors' preference for the venue and time, and on travel restrictions during the COVID-19 pandemic. The vendors are ideally trained in

groups to increase vendor interaction and cross-learning; however, this is not always possible and had to be stopped during lockdowns in 2020 and 2021.

The intervention is delivered by experienced trainers with extensive local knowledge, assisted by project staff who coordinate the timing and location of training and follow-up training. The trainers were trained using a Train-the-Trainer model in this specific programme by a public health researcher (MW), based on his pilot work. During the COVID-19 partial lockdowns, teaching was run virtually using videoconference calling with a laptop delivered to the shop for a training session, run by MW from home (see below).

Due to a high level of turnover of both shops and vendors, we continuously monitor for new shops and vendors across the study area to arrange catch-up training as required. No financial incentives are provided to participants; however, transportation for the training and a folder of materials are provided.

A sticker with key messages from the training is provided to each shop, to be pasted onto the cash machine or drawer, not visible to customers. Trained shops do not receive other documents that can be displayed in shops as these could potentially unblind potential purchasers.

Follow-up training

Brief follow-up reminders are provided during the first 6 months at 1-month intervals to reinforce the skills taught during the training. Contact is provided by telephone

calls, short text messages (Short Message Service (SMS)) or postcards.

Data collection procedures
Intervention data
Registered pesticide shops are identified based on records maintained by the Office of the Registrar of Pesticides and mapped using Global Positioning System. Unregistered shops are identified and surveyed by field researchers through a snowballing method (an initial group of vendors to nominate, through their social networks, other pesticide vendors nearby) and through discussions with local communities, representatives of farmer organisations and pesticide companies, as done in our pilot work.[23] Pesticide shop and vendor information is updated throughout the study. This information is used for cluster allocation and to invite vendors to the training sessions.

We assess pretest and post-test knowledge and practise at the beginning and end of the training session and again at 6, 12 and 24 months using a survey based on our previous work,[24] modified for use in this trial. After training, information on compliance assessments is obtained through interviews to assess vendors' practices following training.

Surveillance data
Self-harm cases are routinely collected at each hospital as part of health information system in Sri Lanka. However, this system has generally been a low priority and no system exists for the vital registration of self-harm cases as exists for other inpatient data. Therefore, we established a separate prospective surveillance system to identify all inpatient self-harm cases reported to study hospitals and police stations.

In zone 1, surveillance data collection started on 1 April 2019 and will last for 42 months. In zone 2, data collection started on 1 November 2020 and will last for 24 months. Surveillance researchers record all fatal and non-fatal self-harm cases admitted to the wards of 118 study hospitals across the region (figure 4). Following our previous household pesticide storage study processes,[25] researchers prospectively record self-harm patients through frequent visits to small primary hospitals (7–80 beds), at least weekly, and by telephone calls from hospital staff when patients are admitted. In secondary and tertiary care hospitals, researchers attend the medical wards daily and other wards at least weekly to identify patients with other (less common) non-poisoning means of self-harm in surgical, paediatric and intensive care units, as well as morgues. During the study set-up, we explored where study area patients presented to hospital and ensured that all accessed hospitals were surveyed, both in and out of the study area.

There are no minimum or maximum age limits for inclusion. Non-residents of the study area will be excluded from the final analysis.

Data collected include demographic data for all self-harm cases (sex, date of birth, place of residence and farming status) and event-specific information (date and time of self-harm event, method of self-harm, whether the individual was alcohol intoxicated at the time of purchase and time of hospital admission and whether the individual died). For pesticide poisoning cases, additional data are collected on how the individuals accessed pesticides (whether they bought the pesticides from a shop
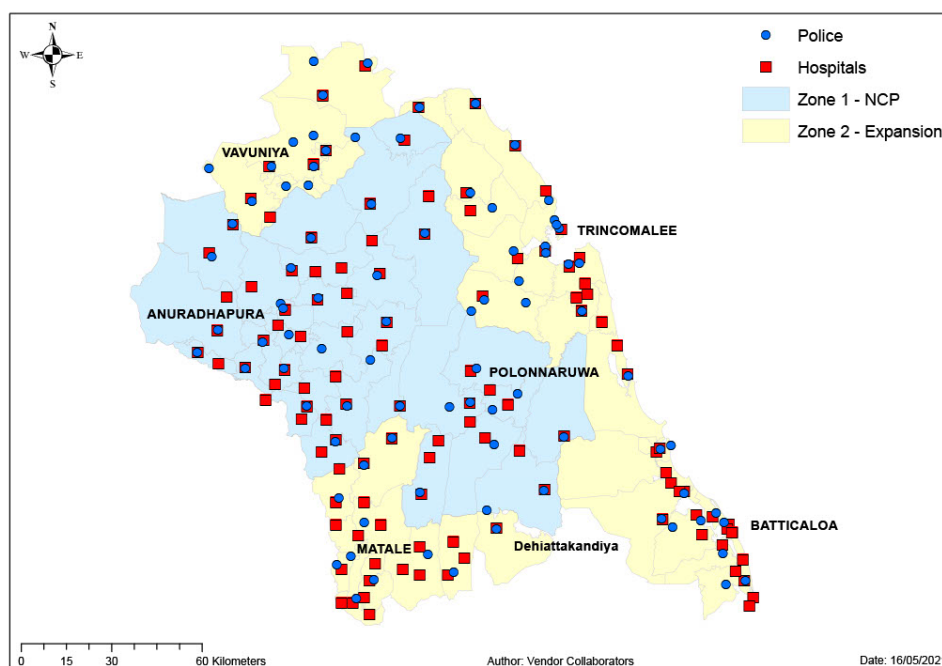
Figure 4 Map of the hospitals and police stations being surveyed across the study area. NCP, North Central Province.

or accessed them from home or nearby). Specific information collected for shop cases includes whether the individual or someone else bought pesticides, the individual's intent at the time of pesticide purchase (self-harm or agricultural purpose), date and time of the pesticide purchase and the division location of the pesticide shop.

We record all self-harm deaths occurring outside hospital settings through a network of 90 police stations and judicial medical officers. The researchers visit these sources every 3 months to extract data about self-harm events, namely the home address, method of self-harm and the source of any pesticide used. Where patients leave hospital before they can be interviewed or non-hospitalised deaths occur, address details of the individuals are obtained from the hospital or police station and permission requested from the patient or family to interview them in their homes about the source of pesticide used in the poisoning.

Field researchers are supervised by experienced senior research staff (KD, DR and DA) who have undergone training in research ethics. Both the surveillance team and the patient (or patient's family) are blind to the training status of the pesticide shop from which the pesticide was purchased. The surveillance team is also kept separate from the intervention team carrying out the training of vendors to reduce the risk of unblinding.

Outcome events

This intervention is directed towards a subpopulation of individuals who self-poison using pesticides bought for this purpose from a shop in the preceding 24 hours ('shop cases'). However, the effectiveness of the intervention will be estimated by comparing the total number of fatal and non-fatal pesticide self-poisoning episodes identified from surveillance of hospitals and police stations (primary outcome) between the pretraining and post-training periods across the divisions in the study area. Secondary outcomes include:

► Number of pesticide self-poisoning patients (fatal and non-fatal cases) presenting to study hospitals or identified through police stations who used pesticides purchased within 24 hours of the act.
► Total number of hospital-presenting self-harm cases involving any method of self-harm.
► Total number of suicides involving any method of self-harm.

Data management

Study data are collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at University of Sydney.[26 27] REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with

external sources. Data are collected into REDCap case record form by research staff following the same protocol as for the household pesticide storage study.[25] Two REDCap databases are used: intervention and surveillance databases. A data coordinator (SR) is responsible for database maintenance, security and review of data entry on a weekly basis to identify missing data. The trial manager (MP) reviews a weekly data summary. All databases are password protected. At the end of the study, a final anonymised data set will be sent to the University of Bristol for analysis and then to the University of Edinburgh for archiving.

Statistics and data analysis

Sample size calculation

The primary outcome measure is the total number of pesticide self-poisoning cases, while the intervention is directed towards a subpopulation of 'shop cases' who self-poison using pesticides bought for this purpose from a shop in the preceding 24 hours. The subpopulation affected by the intervention is likely to be about 20% of all primary outcome cases. We aim to identify any effect of the intervention on all primary outcome events. Sample size calculations were conducted using the 'stepped-wedge' procedure.[28]

Initially, the study was powered taking the mean division population of 15+ year-olds to be 35 000, the rate of pesticide self-poisoning without intervention to be 250 cases per 100 000 person-years and the coefficient of variation in rates of pesticide self-poisoning across the divisions to be 0.55 (calculated from our ongoing provincial and study area hospital surveillance). In this case, a stepped-wedge design with the intervention introduced into 29 divisions in two districts at each of 15 steps separated by 78 days (7479 person-years of follow-up of each district at each step) would detect a true 11.5% reduction to 221 cases per 100 000 person-years with 90% power at the 5% significance level. To achieve this 11.5% reduction overall requires a 58% reduction among shop cases, assuming shop cases make up 20% of all cases in the absence of the intervention. A smaller 10% reduction would be detected with 80% power, all else being equal.

However, after 6 months, the rate of pesticide self-poisoning in the study area was observed to be 130 cases per 100 000 person-years. To achieve an acceptable level of statistical power with this lower incidence rate we decided to approximately double the study area. Assuming for zone 2 that the intervention would be introduced into 41 divisions in four districts at each of 15 steps each of 66 days' duration, then for zones 1 and 2 combined (with an average 6750 person-years of follow-up of each district during each step) a 11.5% reduction from 130 to 115 pesticide self-poisoning cases per 100 000 person-years would be detected with 88% power at the 5% significance level.

Data analysis

A signed and dated statistical analysis plan will be written and made publicly available online before release of the data for analysis.

In our previous Safe Storage cluster randomised trial[25] in the same context in Sri Lanka, the refusal rate of self-harm patients or their family members for inclusion in the study was very low (<1%). This level of refusal will not cause bias and does not need to be addressed in the statistical analysis. The division of residence of the patient and date of self-harm event will be used to allocate cases to the correct study condition. The primary analysis will follow the intention-to-treat principle, comparing the observed incidence of pesticide self-poisoning between periods/areas with and without the intervention in place. A Poisson regression model will be used to estimate the intervention effect as an incidence rate ratio, with variation between areas accommodated as a random effect, and any secular or seasonal time trends accommodated as covariates. This approach will be adapted for the secondary event-based outcomes.

The COVID-19 situation in Sri Lanka is still unfolding. Therefore, we will include sensitivity analyses that investigate the impact of COVID-19 measures introduced during the study period on intervention effectiveness.

Implementation analysis

We will employ a mixed methods approach to evaluate the implementation of the intervention based on the REAIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework,[29] employing quantitative tools to measure reach, effectiveness, adoption, implementation and maintenance, and qualitative tools to identify contextual factors that may help explain the effectiveness or lack of effectiveness of the intervention. REAIM dimension variables and measures are described in table 1.

Economic evaluation

Cost and cost-effectiveness analyses are being conducted concurrently with the trial to assess the cost-effectiveness of the intervention. The cost-effectiveness of implementing the training programme on a national level is also being assessed through modelling. A governmental perspective is adopted for the economic evaluations, that is, only cost and outcomes that impact on government as a third-party funder are included. In the economic evaluation of the intervention, a 3-year time horizon is applied. This time horizon will be expanded to 5 years when modelling a full national roll-out of the 'gatekeeper' training intervention.

All costs are expressed in US$ and measured in real prices for the reference year (2019) using the gross domestic product deflator. If this is not available, the consumer price index will be used. The discounting of costs is undertaken at the recommended real rate of 3% to take into account the timing of costs and health outcomes of the intervention that does not occur in the present.[30 31]

All participants recruited in the s-w cRCT will be included in the economic evaluation of the 'gatekeeper' training intervention. When determining the potential cost-effectiveness of the intervention on a national scale, data will be extrapolated to the total Sri Lankan population, taking into account the population at risk in rural and urban populations.

In accordance with the study perspective, all direct costs related to the implementation of the 'gatekeeper' training intervention and to the healthcare system will be included in the analysis. Effectiveness data (ie, number of pesticide self-poisoning cases and deaths prevented) will be identified through the trial. Data from the 'gatekeeper' training intervention will also be used as basis for costing the intervention. All costs associated with the implementation, delivery and follow-up of the intervention will be included. Research costs associated with the trial will be excluded from the analyses.

All relevant costs and cost offsets are being identified, quantified and ascribed a unit cost. The cost components for the intervention are divided into five categories: capital costs, personnel costs, overhead, consumables and transportation costs. Unit costs and prices will be obtained from official statistics, health facilities, the Medical Supply Division of the Ministry of Health and the Provincial Department of Health.

One-way sensitivity analyses will be undertaken to assess how variable uncertainties impact on the cost-effectiveness of the strategies, thereby identifying the factors affecting the total cost of implementation.[31] Multivariate sensitivity analyses will also be performed to assess how simultaneous changes of several variables affect the cost-effectiveness ratio. Probabilistic uncertainty analyses will be performed to explore the impact of variability in input variables that can be measured, and input variables for which there is an underlying probability distribution.

Patient and public involvement and engagement

While the pilot Safe Storage studies[32 33] were ongoing, we decided to explore whether we could take a complementary approach by working with pesticide vendors. The design and development of the 'gatekeeper' intervention for pesticide vendors was done based on a series of community engagement studies, which took place over several years. As part of the intervention developing process, we conducted a stakeholder analysis with key stakeholders (farmers, pesticide vendors, pesticide company representatives, agricultural officers, public health experts and general community) to identify the most promising method to prevent access to pesticides from shops for self-poisoning.[34]

A separate feasibility pilot study was conducted with pesticide vendors to understand any concerns they had about the gatekeeper intervention.[23] For the current trial, we have offered opportunities for pesticide vendors to express their perspectives, priorities and issues related to

Table 1 REAIM dimension variables and measures

Domain	Description	Measures
Reach	The absolute number, proportion and representativeness of individuals or settings who are willing to participate in a given initiative.	Exclusion criteria (% excluded or characteristics). Per cent of individuals who participate. Characteristics of participants compared with non-participants or to target population. Reasons contributing to the participation/non-participation of the participants.
Efficacy	The impact of an intervention on important outcomes, including potential negative effects, quality of life and economic outcomes.	Measure of primary outcome. Measure of robustness across subgroups (eg, sex, age, experience, education). Measure of short-term attrition (%) and differential rates by vendor characteristics or shop characteristics. Qualitative assessment of contextual factors contributed to the results.
Adoption	The intention, initial decision or action to try or employ an innovation or evidence-based practice. Adoption also may be referred to as 'uptake'. Adoption occurs in the early to mid-implementation stage and is assessed from the setting or staff level.	**Setting level** Shop exclusions (% or reasons). Per cent of shops approached that participate (valid denominator). Characteristics of participating shops compared with non-participating shops. **Individual level** Vendor exclusions (% or reasons). Per cent of vendors invited who participated. Characteristics of vendors participating versus non-participating vendors. Barriers to adoption. Vendor satisfaction with training. Trainer feedback.
Implementation	At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol. This includes consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients/target populations' use of the intervention strategies.	Per cent of shops which completed training (adherence). Adaptations made to intervention during study. Cost of intervention (time or money). Consistency of implementation across trainer/time/settings/subgroups. Contextual factors linked to the intervention. Trainer/vendor attitudes towards the intervention. Barriers and facilitators of the intervention.
Maintenance	The extent to which a programme or policy becomes institutionalised or part of the routine organisational practices and policies. At the individual level, maintenance has been defined as the long-term effect of a programme on outcomes after 6 or more months after the most recent intervention contact.	**Individual level** Measure of training effectiveness immediately following training. Robustness data—reassessment of training outcomes at 6 months. Measure of long-term attrition (%) and differential rates by shop and vendor characteristics. Individual feedback on intervention and assessment of their willingness to maintain adherence in long term. **Setting level** If and how the programme was adapted long term (which elements retained AFTER programme completed). Some measure/discussion of alignment to organisation mission or sustainability. Shop and vendor feedback on intervention, barriers and facilitators, and willingness to maintain change.

the research problem and intervention process. We also discuss and collaborate with the Department of Agriculture at group meetings to allow them to express views on the proposed intervention.

ETHICS AND DISSEMINATION

Ethical approval was granted by the Ethical Review Committee of the Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka (reference:

ERC/2018/30) and the ACCORD Medical Research Ethics Committee, University of Edinburgh (reference: 18-HV-053). This study is sponsored by the Academic and Clinical Central Office for Research Development (reference: AC 18099) at the University of Edinburgh.

Study approval was received from the national Ministry of Health, the provincial Departments of Health Services and Agriculture in the NCP, Eastern Province, Northern Province and Central Province, the Office of the Registrar of Pesticides and the Pesticide Technical and Advisory Committee (PeTAC) of Sri Lanka.

The study will be published through both scientific peer-reviewed journals. The outcome will be presented to the provincial Departments of Health Services and Agriculture and PeTAC. Opportunities to disseminate the results both nationally and internationally will be taken including presentations at scientific conferences.

Consent
Agreement to participate is being sought from each vendor eligible for the training once details of the study have been provided in the vendor's own language. Individuals identified through case finding are asked to provide informed consent for their information to be used in the research. If the patient is too ill to give consent, or under age (less than 12 years old), consent is requested from a relative (or guardian). If the patient is between 12 and 18 years old, consent from both patient and relative/guardian is requested as per standard Sri Lankan practice (online supplemental file 1).

Both vendors and self-harm patients are provided with an information sheet containing an introduction to the research, its objective, the people involved, the benefits and disadvantages of participating and contact information of the research group (online supplemental file 2). We also seek written agreement from vendors to participate in follow-up assessments. Vendors are under no obligation to practise what they have learnt. The participants are free to withdraw from the study at any point.

The main risk of this study is that discussion concerning self-harm might cause distress. We therefore provide contact information for a local counselling service to the self-harm patients immediately after their interviews. A sensitive data collection technique is used, and ethical issues are being considered throughout the study.

Data monitoring
An independent data monitoring committee (DMC) has been established to oversee the safety of trial participants and collection of high-quality data. The DMC aims to meet annually.

Data availability
Anonymised data will be made available after publication of the trial's results on submission of a request to the principal investigator (m.eddleston@ed.ac.uk).

Modifications due to COVID-19
Following the outbreak of COVID-19, the Government of Sri Lanka implemented a national curfew and a ban on gatherings and non-essential movements. This led to a suspension of all research activities for a period of nearly 3 months (17 March 2020 to 7 June 2020). This period of 'lockdown' had implications for both the intervention and surveillance elements of the study.

During the lockdown, we were unable to gather people for training sessions and so the intervention was suspended. This delay resulted in the steps for zone 1 being reduced from 78 to 67 days. The intervention had not commenced in zone 2 by the time lockdown started and so was delayed. It is now being delivered in a compressed time frame of 42 days per step. Further changes may be required as the COVID-19 situation in Sri Lanka is still ongoing. We also developed remote versions of the training, limiting staff numbers and participants to ensure we complied with the local public health guidance. As local outbreaks have occurred since June 2020, there have been additional localised restrictions placed on movements.

During the lockdown, access to all Sri Lankan hospitals was severely restricted and research personnel not permitted on-site. The surveillance team remained in contact with hospitals where possible to set up systems for continuing surveillance, such as daily logs, telephone interviews and setting aside records for review after opening up. Once the curfew was lifted, the team gained access to the records and made telephone calls where possible or visits to households to gather data. Continuing local restrictions on access to hospitals have recurred and individualised systems have been developed in each hospital to minimise the disruption to data collection.

Study dates
In zone 1, recruitment started on 30 September 2019 and should be completed on 27 October 2022. In zone 2, recruitment started on 18 January 2021 and will be completed in November 2022. The protocol version is 2.1; 11 February 2021.

Author affiliations
[1]Centre for Pesticide Suicide Prevention, and Pharmacology, Toxicology and Therapeutics, Centre for Cardiovascular Science, University of Edinburgh, Edinburgh, UK
[2]Department of Community Medicine, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka, Anuradhapura, Sri Lanka
[3]Faculty of Medicine, Central Clinical School, University of Sydney, Sydney, New South Wales, Australia
[4]Population Health Sciences, University of Bristol, Bristol, UK
[5]Centre for Suicide Research, Department of Psychiatry, University of Oxford, Oxford, UK
[6]Northeastern University, 360 Huntington Avenue, Boston, Massachusetts, USA
[7]Department of Medicine, Faculty of Medicine, University of Kelaniya, Ragama, Sri Lanka
[8]Edinburgh Medical School, University of Edinburgh, Edinburgh, UK
[9]Office of the Registrar of Pesticides, Peradeniya, Sri Lanka
[10]Tertiary Care Services, Ministry of Health, Colombo, Sri Lanka
[11]South Asian Clinical Toxicology Research Collaboration, Faculty of Medicine, University of Peradeniya, Peradeniya, Sri Lanka

[12]Department of Clinical Sciences, Faculty of Health Care Sciences, Eastern University, Batticaloa, Sri Lanka

[13]Global Health Section, Department of Public Health, University of Copenhagen, Copenhagen, Denmark

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Competing interests KH is joint chair of the Prevention of Pesticide Self-Poisoning Special Interest Group of the International Association for Suicide Prevention. He declares having received a small grant from Syngenta for a study of safer storage of pesticides in Sri Lanka. DJG, FK and ME were expert advisers to WHO's consultation on cost-effectiveness of suicide prevention interventions, including pesticide regulation (Geneva, 2019). They provided technical assistance for the development and publication of Preventing Suicide: A Resource Guide for Pesticide Registrars and Regulators (WHO, May–June 2019). DJG was a member of the scientific advisory group for a Syngenta-funded study to assess the toxicity of a new paraquat formulation (2002–2006); a member of the scientific advisory group for a pesticide storage project funded by Syngenta (2005–2007); and chaired the DMEC for a Syngenta-funded trial of the medical management of paraquat poisoning (2007–2010); he received travel costs to attend research meetings but no other fees. DJG was an expert adviser to WHO's First Consultation on Best Practices on Community Action for safer access to pesticides (Geneva, 2006). ME is a WHO member of the FAO-WHO Joint Meeting on Pesticide Management and received an unrestricted research grant from Cheminova (2012) and travel expenses from Syngenta to attend study meetings (2005–2006). ME is affiliated with the Centre for Pesticide Suicide Prevention, which is funded by an Incubator Grant from the Open Philanthropy Project Fund, an advised fund of Silicon Valley Community Foundation, on the recommendation of GiveWell, USA.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iDs
Manjula Weerasinghe http://orcid.org/0000-0002-6105-7989
Chris Metcalfe http://orcid.org/0000-0001-8318-8907
Keith Hawton http://orcid.org/0000-0003-4985-5715

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