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BeSafe: A safety programme to increase machine-related safety on farms

Submission date	Recruitment status	[X] Prospectively registered
18/07/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/05/2024	Other	

Plain English summary of protocol

Background and study aims
BeSafe is a safety intervention that aims to reduce machine-related hazards on farms. This study is the fourth phase of a project that aims to develop a behaviour change intervention to improve machine-related safety on farms. The previous phases involved:
1. A systematic review to identify the behaviour change techniques present, their impact, high-risk demography, the most common type of farm machine accidents and gaps in the existing studies
2. A focus group study to explore farmers' perspectives on the facilitators and barriers to adopting safer habits and safety guidelines
3. A co-design workshop to gain consensus about the most important behavioural practices to be addressed by the intervention, potential intervention techniques and delivery mode to develop the safety intervention

Based on the findings from the previous phases, the research team has identified five farm safety practices related to addressing blind spots of tractors. The focus of the intervention is to promote these five practices.
The current study aims to evaluate the acceptability, feasibility and fidelity of the active ingredients present in the intervention.

Who can participate?
Part-/Full-time adult farmers in Ireland

What does the study involve?
For participants, the study involves:
1. Online introduction session
2. BeSafe intervention
3. SMS survey
4. Online evaluation session

What are the possible benefits and risks of participating?
Increased safety of tractor operation on the participants’ farms. Potentially increase in status among fellow farmers. Participation will be compensated with vouchers redeemable for a

variety of products and services to a maximum of 100 euros. Risks include physical risk during tractor exercises, but this is less than during a typical farming day and in the presence of trained facilitators.

Where is the study run from?
National University of Ireland, Galway (Ireland)

When is the study starting and how long is it expected to run for?
January 2022 to October 2023

Who is funding the study?
Department of Agriculture, Food and the Marine Research Stimulus programme (Ireland)

Who is the main contact?
Ms Aswathi Surendran (Scientific contact) (Ireland)
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Dr Denis O'Hora (Principal investigator) (Ireland)
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Study website
https://osf.io/ayxvs/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessing the feasibility, fidelity and acceptability of a behaviour change-based intervention to increase tractor-related safety on farms

Acronym
BeSafe Tractor

Study objectives
The primary objective of this feasibility study is to assess the acceptability, feasibility and fidelity of active ingredients of a farm safety intervention initiative designed to reduce tractor-related accidents on farms.
The objectives of the feasibility study are:
1. To assess the feasibility of recruiting the participants and delivering the programme, which includes the recruitment, retention, adherence and completion of the program
2. To assess the fidelity of the design, training, delivery, receipt and enactment of the intervention
3. To evaluate the acceptability of the active ingredients among the participants
4. To identify barriers and enabling factors with participants to the completion of the programme

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2022, National University of Ireland (NUI), Galway, Research Ethics Committee (NUI Galway Research Ethics Committee Office of the Vice President for Research NUI Galway, University Road, Galway, Ireland, H91 TK33; +353 91 524411; ethics@nuigalway.ie), ref: 2022.05.009

Study design
Single-group multi-centre pre-post study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
https://osf.io/x7gsq/?view_only=9fd52556c98445f288e5b059d49122e3

Health condition(s) or problem(s) studied
Increase tractor related safety on farms

Interventions
This feasibility study involves:
1. Online introduction session
2. BeSafe intervention
3. SMS survey
4. Online evaluation session

Recruitment procedure:
Teagasc/Agriculture and Food Development Authority (the Irish state agency providing research, advisory and education in agriculture) regularly conduct discussion groups with farmers across Ireland, which the Teagasc farm advisors facilitate. Teagasc advisors will make the primary contact to contact the farmer's discussion groups. Once the group indicate their interest, advisors send invitation letters, participant information sheet and consent form to the farmers. Advisors will share the details of the interested participants along with their convenient time for the pre-intervention interview with the research team. All interested participants will be contacted.

1. Online introduction session (estimated time: 15-20 minutes)
Once the farmers accept the invitation and provide the necessary consent, the research team will set up a 15-minute phone interview when convenient. The online introduction session will be scheduled 1-7 days prior to the in-person event based on participant convenience. This call aims to clarify the questions farmers have regarding the project, collect the demographic data, investigate if they have any special needs for the demonstration day (hearing/visual aids, dietary restrictions, etc), and create a rapport with the participants.

2. BeSafe intervention (estimated time: 3-4 hours)
This session involves an in-person meeting with selected participants to demonstrate blind spots, their impact and strategies to mitigate them. A facilitated discussion will be conducted once the demo session is completed, in which the farmers are encouraged to discuss their barriers to implementing these strategies at home and the benefits of adopting them at their own farms. Based on the observation and input from the demo and facilitated discussion, safety protocol will be filled along with participants. The safety protocol aims to create a tailored and personalized safety plan for the implementation of the safety strategies (target behaviours) at home. Participants will be asked to rate their confidence in performing these tasks at home. The completed document would be shared with the participants at the end of the in-person event. At the conclusion of the event, participants will be requested to complete an exit poll.

The research team will provide the materials to perform the demonstration and set up the visibility zone at home for the participants. The materials include but not limited to spray paint, picture of the visibility zone, blind spots from the demo session and safety protocol.

3. SMS Survey (estimated time: 5 minutes)
As previously agreed with the participants on the day of the in-person event, the research team will send an SMS survey to track the progress in their adoption of safety goals/target behaviours.

3. Online evaluation session (estimated time: 1 hour)
At the end of the demonstration day, the research team will set up a slot for the online evaluation session and it involves a one-on-one interview with participants who attended the BeSafe session. The session will be scheduled 7-14 days after the intervention based on the participant's convenience. The objective of this semi-structured call is to:
3.1. To assess the acceptability of the programme and its delivery among participants
3.2. To assess the acceptability of each active ingredients and its delivery among participants
3.3. Assess the Fidelity sub-constructs (a receipt of treatment & enactment of treatment skills)

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, on the day of the intervention and after the completion of the post-intervention interview, using audio recordings, reports from recruiters and memos of facilitators:

1. Feasibility-related outcomes (measure following criteria based on the pre-established checklist):
1.1. Recruitment and retention rates
1.2. Time required to recruit target sample size
1.3. Rate of completion of the intervention (number of participants who completed all the tasks of the intervention & how many participants completed each task)
1.4. Representation of farm population: farm type, age, gender
1.5. Barriers & facilitators (facilitators): Arranging the location, demonstration, and data collection
1.6. Home task completion status
1.7. Delivery mode
1.8. Structure of the program (length and content)

2. Acceptability-related outcomes: Assessment of acceptability of the intervention, its components and the delivery will be based on the theoretical framework for the acceptability of health care interventions:
2.1. Experienced acceptability of the intervention programme among participants.
2.2. Experienced acceptability of each key ingredient among participants

3. Fidelity-related outcomes: Fidelity will be measured using a pre-established checklist created based on the study design, purpose and fidelity framework for behaviour change research:
3.1. Fidelity of Intervention Design
3.2. Fidelity of Treatment providers
3.3. Fidelity of Treatment delivery
3.4. Fidelity of Receipt of Treatment
3.5. Fidelity of Enactment of Treatment Skills

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
08/01/2022

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Currently working on farms part/full time
2. Aged 18 years old and over
3. Have opportunities to demonstrate the learnings from the studies to a non-participant farmer, including family members, neighbours or co-workers

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
A minimum of 16 participants and a maximum of 25 participants selected using purposive sampling strategy. Four identical in-person sessions with 4-6 participants will be conducted.

Total final enrolment
20

Key exclusion criteria
1. Participants presenting with symptoms of emotional distress or cognitive impairment
2. Intend to participate in any other farm interventions during the study period
3. Non - English speakers

Date of first enrolment
29/07/2022

Date of final enrolment
25/06/2023

Locations

Countries of recruitment
Ireland

Study participating centre
Technological University of the Shannon
Athlone Campus
University Road, Athlone
Co. Westmeath

Westmeath
Ireland
N37HD68

Study participating centre
Kildalton Agricultural and Horticultural College
Teagasc
Piltown
Kilkenny
Ireland
E32 YW08

Sponsor information

Organisation
National University of Ireland, Galway

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Sponsor type
University/education

Website
http://www.nuigalway.ie

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Department of Agriculture, Food and the Marine, Ireland

Alternative Name(s)
An Roinn Talmhaíochta, Bia agus Mara, An Roinn Talmhaiochta Bia agus Mara, Department of Agriculture, Food and the Marine, agriculture_ie, Department of Agriculture, Food and the Marine (Ireland), DAFM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
1. Publication of the protocol and the findings in relevant peer-reviewed journals
2. Findings will be reported at national and international conferences.
3. Press releases and a summary for the lay public
4. Sharing open data and other details via OSF will enable further academic dissemination

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
Participants' records, following the General Data Protection Regulation (GDPR) regulations, will be kept private and confidential. Information collected for this study will be kept confidential following the GDPR regulations. More details are provided in the participant information sheet.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	See patient information sheet and consent form in the recruitment document folder		29/07/2022	No	Yes
Other publications	Intervention development	04/04/2023	06/04/2023	Yes	No
Protocol article		04/07/2023	05/07/2023	Yes	No
Preprint results		18/03/2024	01/05/2024	No	No