ISRCTN27173711 https://doi.org/10.1186/ISRCTN27173711

Can we use remote intervention and support to improve the mental health of farmers?

Submission date
25/08/2023

Recruitment status
No longer recruiting

Registration date
22/09/2023

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
A research team led by the University of Stirling and the Scotland's Rural College (SRUC) is conducting a study to find out how to effectively reach individuals from the farming community who would benefit from support for their mental health.
Results from the study will be used to design methods of recruitment to the next stage which will look at three types of support:
1. An online-based psychological therapy that teaches practical strategies that can be used in everyday life. This support can be provided with or without telephone support.
2. A social and emotional support service that includes a telephone helpline which is staffed by mental health first aid trained staff and volunteers.
3. A combination of both interventions.
The information gathered from this study will be used in the recruitment of individuals from the farming community to take part in the next stage of this study which is to find out what type of intervention they would prefer in supporting their mental health.
Findings from all phases of the study will be shared with the wider networks of farming communities, livestock vets, and other agricultural support services. We may also publish our findings in a journal to share these with others. We will include the results in our report to the project funders.

Who can participate?
We want to invite individuals from the farming community in Scotland to share their views and suggestions about the language and methods to use to attract and engage with farmers who may be experiencing a common mental health problem, such as anxiety or depression.

What does the study involve?
If you take part, you will first be asked whether you would like to be involved in a focus group or an interview (face to face or by telephone). Your chosen method of participation will then be organised by the researcher. Face to face interviews and focus groups may be restricted as a result of Government Covid-19 guidelines. The focus group would involve a discussion with others from the farming community who have an interest in this subject.
During the focus group or interview, you will be asked to answer some questions about how best to attract and engage with individuals from the farming community who may be

experiencing a common mental health problem, and what might encourage them to seek help. If you take part in receiving the interventions, you will be asked to answer some questions about your experience of the support you have received. You will also be asked for your suggestions about how the support may be improved to better help others in the farming community who may be experiencing a common mental health problem, such as anxiety or depression.

What are the possible benefits and risks of participating?
There will be no direct benefit to you from taking part, but information gathered from your participation will help us to understand how best to engage with individuals from the farming community who would benefit from receiving support for their mental health.
There are no foreseeable risks in taking part of this study. However, in case you become aware of your own mental health symptoms as a result of taking part, information will be provided about how to access support and details of crisis helplines. Your participation will be confidential (except to other members of the focus group) and any data we hold will not include your name or contact details. We will aim to remove any other obviously identifiable information from any data held (such as locations, names of farms etc.).

Where is the study run from?
NHS Highland (UK)

When is the study starting and how long is it expected to run for?
April 2020 to June 2022

Who is funding the study?
This research study is funded by the Chief Scientist Office of the Scottish Government (UK)

Who Is the Main Contact?
Professor Margaret Maxwell, margaret.maxwell@stir.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Hugo van Woerden

ORCID ID
https://orcid.org/0000-0003-3382-1684

Contact details
University of the Highlands and Islands
Inverness
United Kingdom
IV2 3JH
+44 7543406346
hugo.vanwoerden@uhi.ac.uk

Additional identifiers

Protocol serial number
GUEP (19 20) 90, HIPS 19/51

Study information

Scientific Title
Improving the mental health of farmers: what types of remote intervention and support are acceptable and feasible to best support improved outcomes?

Study objectives
Aims: To identify and optimise a preferred candidate intervention for addressing mental health problems in farmers for use in a future RCT (of effectiveness); and to assess the potential to recruit farmers to engage with different mental health interventions and complete study outcome measures. Throughout this application, we refer to farmers as including all farm workers and the wider farming community, which includes unpaid workers and family members.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/05/2020, General University Ethics Panel (GUEP) Stirling University (University of Stirling, Stirling, FK9 4LA, United Kingdom; +44 1786 473171; GUEP@stir.ac.uk), ref: GUEP (19 20) 901

Primary study design
Interventional

Study design
Pilot interventional randomized controlled trial

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Mental health in farmers

Interventions
Design: a mixed-methods study to assess the preferences of farmers for remote/anonymous, and social/psychological interventions to improve their mental health and wellbeing; and to establish parameters for the feasibility of conducting a trial of a best-candidate intervention.
Theoretical Framework: This study aligns with ‘pragmatism’ as a research philosophy, where the research question is the important determinant of methods and can combine both positivist and interpretivist positions within the scope of a single study according to the nature of the research question(s). However, we do also adopt an approach that is consistent with the sentiments of ‘participatory action research’ where the focus is on transforming the lives of socially marginalized populations. Participatory action research is often associated with qualitative methods and includes participants in all stages of the research, as is the case with the range of PPI partners we work with and the approach to our qualitative enquiry.
Facilitating overall recruitment to Stages 1, 2, and 3 (described below): It is acknowledged that engaging farmers is a key challenge. We have engaged many partner/advisory organisations in

this study (not formal co-applicants but will still sit on our project management team to operationalise and deliver this study. These organisations are the Monitor Farm leads in Highland and Shetland, Support in Mind Scotland, and the National Rural Mental Health Forum (which has links to many organisations that can help engage with the research, with its now 130 membership organisations – see – www.ruralwellbeing.org/partners). These organisations are keen to support this study and to facilitate recruitment via their websites, and local communication channels (newsletters and key local contacts). We also have an expert in ways of engaging farmers with mental health on the study team (C McC). (It is through such local mechanisms that RSABI receive approximately 25 referrals per month in Scotland).
To coincide with this study, the Highland Community Planning Partnership and the NHS Shetland Health Improvement Team have agreed to run Mental Health First Aid Training for Vets and farm advisors across NHS Highland and NHS Shetland to improve recognition of mental health problems in farming communities and to encourage signposting to seek help.

Stage 1 Months 1-4. Preferences, acceptability and implementation requirements for promoting and delivering a social and emotional support service versus an on-line (+/- telephone support) CBT based intervention.

Focus groups (FGs) (n=3) and/or interviews will be conducted with farmers (n=2 FGs) and Vets and farm advisors (n=1 FG) in 2 NHS Boards in Scotland (NHS Highland and NHS Shetland) to understand their preferences for support and how best to engage (and recruit) farmers in seeking help for their mental health. Where possible we will work with 'monitor farms' (monitor farms are groups of farmers who meet regularly to discuss farming and local issues) to conduct these focus groups in their community. Taking account of potential farmer/farm employee relationships we will also offer individual interviews if preferred (up to 10 interviews). We will also aim to include farmers who have used current RSABI services or LLTTFF.
Stage 2 Months 5-19. Acceptability, up-take, retention and outcomes (including completion rates) of a telephone accessed social support service, an on-line (+/- telephone support) CBT based intervention or a combination of both.

Sample: Individuals from the farming community (n=40) who are currently experiencing a common mental health problem (anxiety, depression, mixed anxiety and depression as defined by a score of >=8 on the Hospital Anxiety and Depression Scale (HADS)) will be recruited from across 2 NHS Boards (Highland, Shetland) in Scotland. The study population is mainly individuals directly employed/self-employed in agriculture. In the NHS Highland area, p=1430/13,00019 from a total population of 320,00020 and in NHS Shetland, p=152/2,00015 from a total population of 23,000,21 based on estimated Scottish prevalence of 11% of the population.22 The study population will also include the wider farming community, which includes unpaid workers and family members but which is more difficult to quantify.

Recruitment: will be conducted via signposting by local Vets, farming social media, farmer support organisations (excluding RSABI so as not to bias preferences), and farming and mental health charities/support organisations such as those listed above. Interested participants will contact the researcher directly (phone, e-mail) and this will initiate an information pack being sent out followed up by initial telephone screening for eligibility and consent to randomisation to receive either a combined intervention arm or to a preference arm for the social support intervention or LLTTFF (with a further preference for additional telephone support or not). If they consent to participate then baseline measures will be taken (see table below under Outcomes) alongside collection of demographic characteristics (age, sex, ethnicity, educational attainment, employment status/job role). A random sample of 14 eligible participants will be allocated (without preference) to receive both the on-line CBT intervention + the RSABI social and emotional support intervention). The remainder (n=26) will be invited to express a

preference, and following randomisation (1:1 for each intervention) we will allow those with strong preferences to switch intervention. Each site will deliver all types of intervention (on-line CBT +/- telephone support, or RSABI social and emotional support service or both combined)

Interventions: Living Life to the Full for Farming Communities (LLTTFF) (+/- telephone support): This is based on the Living Life to the Full CBT based on-line intervention which has been specifically adapted for the farming community provided by Five Areas Ltd. This programme is the most recommended e-therapy for stress, anxiety and depression by the Improving Access to Psychological Therapy Teams in NHS England and NHS Mental Health Trusts in England. The approach is delivered online and uses accessible language and powerful, clearly communicated change tools but can also be delivered in other formats. All participants will be given access to LLTTF (on-line or booklets) and given the option of telephone support consisting of an initial 30 minute session of telephone support followed by 3 additional support sessions. Participants can work at their own pace but will generally complete the intervention within 8 weeks. The on-line version can track module participation and completion and LLTTF providers can give access to additional data (such as pages accessed, frequency of access, and for how long etc.). Engagement and completion of LLTTF using printed materials will be tracked by the coaches providing telephone support sessions.

RSABI social and emotional support service: RSABI supports people from the Scottish agriculture community emotionally, practically and financially in times of need; a comprehensive service for individuals from the farming community to help them move forward in difficult times, for example, business reviews, access to counselling services and help with essential living costs. RSABI offer a home visit service and a helpline, staffed by mental health first aid trained staff and volunteers from 7am to 11pm, 365 days of the year, and a call out service. For the purposes of this study, for those receiving the RSABI social and emotional support service we will record the method of initial and further contacts (telephone, on-line, home visit), the number of contacts and, the types of help accessed (e.g. financial).

Support for vulnerable participants: if during the study participants are identified as being of serious risk of suicide or have significantly deteriorated (as identified by those providing support sessions of via HADS scores) we will have obtained prior consent from all participants to contact their GP in such circumstances. This will be the best mechanism for providing an immediate and local response and for organising any necessary onward referral for psychiatric help. Additional crisis helplines (such as the Samaritans and Breathing Space) will also be provided to all participants.

Data collection: Baseline (telephone or face to face if requested) measurements will be followed by 3 month and 6 month telephone or on-line completed outcomes (based on farmer's preference for completion). Data collection will be administered by study researchers independently of those delivering interventions.

Stage 3 Months 17-21. Perceptions of interventions, intervention delivery and their impact, and potential for wider use. Farmers (n=5) for each type of intervention, including LLTTF with and without telephone support) will be interviewed to obtain their views on the interventions they received. We will aim to select participants who did and did not complete the interventions (drop-outs) to understand what aids participation/retention. Vets, farm advisors and providers of agricultural support services (n=5) will be interviewed to understand their role in signposting farmers to interventions, for any feedback from farmers they have signposted to the study, and for advice for a future study into farmers mental health based on their experience in this study. Staff from both service providers (n=6) will be interviewed to understand farmer engagement and participation in the interventions and what helped or hindered participation and retention,

the impact of the interventions and what aspects of the interventions farmers were helped by most, and what areas of their lives farmers needed most help with. Interviews will be conducted by phone (or face to face if this coincides with other visits) and digitally recorded and transcribed for analysis. Interviews are estimated to last approximately 30 minutes.
Months 22-24. Optimisation of a best fit intervention for addressing mental health in the farming community and study write-up, dissemination and preparation of full proposal to NIHR HTA. The Farming Community Reference group (FCRG) (see below) will be engaged to review and interpret findings from across all studies to determine the optimal intervention for the farming community based on qualitative feedback and study data on engagement with the intervention(s) and delivery modes, study recruitment and retention, and preferences identified. This will be conducted at a workshop event held in Highland (estimated at 25 participants). Following this workshop a grant application for a pilot and full trial of the best candidate intervention will be delivered, aiming at NIHR HTA panel.

Intervention Type
Behavioural

Primary outcome(s)
Recruitment, retention and outcomes completion rates for the different interventions measured at the end of the study

Key secondary outcome(s)
Measured at baseline, 3-months and 6-months
1. Suicidal ideation measured using PHQ-9
2. Sense of coherence measured using 3 item Sense of Coherence
3. Quality of life measured using EQ-5D

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. 18 years and over
2. A member of the farming community
3. Experiencing mental health problems based on the completion over the phone of a PHQ-9 questionnaire and a score of >=8 [Initially a HADS score but changed to PHQ-9 before recruitment begun].

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
29

Key exclusion criteria
1. Those considered at baseline to be at significant risk of suicide based on a phone interview
2. Currently undertaking or having engaged with CBT or other psychotherapy within the past 6 months
3. Unable to communicate in English
4. Unable to give informed consent.

Date of first enrolment
01/07/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Stirling
Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation
NHS Highland

ROR
https://ror.org/010ypq317

Funder(s)

Funder type

Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Roger.Humphry@sruc.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Farming Community Reference group	05/06/2023	25/08/2023	Yes	No
Results article	secondary outcome results	04/01/2024	08/01/2024	Yes	No
Participant information sheet	Stage 1		18/09/2023	No	Yes
Participant information sheet	Stage 2		18/09/2023	No	Yes