An online CBT-based life skills course for the farming community: a feasibility study

AND

Clinical Research Portfolio

Harriet Louise Bowyer

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Institute of Health and Wellbeing
College of Medical, Veterinary and Life Sciences
University of Glasgow

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CHAPTER 1: Systematic Review

Acceptability of computerised cognitive behavioural therapy for depression: a systematic review update

Harriet Louise Bowyer*

*__Address for correspondence__

Mental Health and Wellbeing

University of Glasgow

1st Floor, Administrative Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

G12 0XY

Email: h.bowyer.1@research.gla.ac.uk

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ABSTRACT

Background: Computerised Cognitive Behavioural Therapy (cCBT) is recommended as an effective and efficient treatment for mild to moderate depression. This systematic review updates a previous systematic review on acceptability of cCBT for adults experiencing depression.

Method: Five electronic databases were searched for Randomised Controlled Trials examining the acceptability of cCBT for adults (aged 18+) with depression. Studies were limited to those published in English from 1st July 2007 (when the original systematic review was completed) to 14th January 2017. Narrative synthesis was used to combine the results from all included studies.

Results: Eight studies were identified. Studies took place in Australia, Europe and the US. None were based in the UK. Seven out of eight used non-clinical volunteer samples. Acceptability was assessed using self-reported satisfaction questionnaires, uptake and drop-out rates. Participants reported being satisfied with cCBT on questionnaire-based measures. Uptake of cCBT was high (mean percentage: 85%). Drop-out rates were higher than those reported for face-to-face CBT (mean percentage: 63% versus 25%, respectively), and few participants completed the course (mean percentage: 37%). Completion was higher in studies that offered support.

Conclusions: Enhanced reporting of trials is necessary. cCBT may be an acceptable treatment for depression for some, but with less than half of the participants completing the cCBT courses further quantitative and qualitative research should be conducted in order to determine reasons for large drop-out and low course completion rates.

Key words: Computerised Cognitive Behavioural Therapy; cCBT; depression; acceptability; systematic review.

Background

Almost 4% of adults in England meet criteria for a diagnosis of depression (McManus et al., 2014). It is considered the leading cause of disability worldwide (World Health Organisation, 2017) with a significant social and economic cost (Kessler et al., 2009).

A recent report by the Mental Health Taskforce (2016) highlighted that there are insufficient staff numbers within the National Health Service (NHS) to meet demand for mental health support and therefore significant waiting times; three quarters of individuals therefore receive no support and those who are supported often have limited access to interventions (pharmacological and psychological) recommended by the National Institute for Health and Care Excellence (NICE) guidelines.

Online self-help resources have been developed to help manage these demands, therefore increasing service capacity (Titov, Andrews and Sachdev, 2010). A widely used approach is computerised Cognitive Behavioural Therapy (cCBT), which offers the core components of CBT within a number of modules, often with regular guidance from a clinician via email or telephone. Some cCBT packages utilise a locked design whereby the next module can only be accessed upon completion of the previous module; others utilise an open design whereby participants can complete any modules they perceive to be relevant. cCBT can be an effective treatment for depression (Foroushani, Schneider and Assareh, 2011) and is recommended by NICE (2009). However, individuals need to find cCBT acceptable and be willing to use the approach. Waller and Gilbody (2009) conducted a mixed method systematic review looking at barriers to uptake of cCBT for depression and/or anxiety. They highlighted issues around engagement; a significant number of people drop out before beginning cCBT, and of those that start cCBT, a large proportion do not complete the full course. It is therefore important to understand the barriers to commencing and completing cCBT. One suggested way of improving engagement is by offering a support element. A meta-analysis found larger effect sizes when professional support was offered alongside the package (Andersson and Cuijpers,

2009). The most recent systematic review looking at acceptability of cCBT for depression found high levels of satisfaction with cCBT and reported that drop-out rates were similar to those found in other treatments, such as counselling and face-to-face CBT (Kaltenthaler et al., 2008). However, a large number of methodological flaws were identified by this review, for example studies provided limited information on patient uptake rates and recruitment methods. This review incorporated a variety of study designs including randomised controlled trials (RCTs), non-randomised comparative trials and non-comparative trials. Given the significant technological advances made in the last 10 years, new cCBT packages available and further trials conducted, the current review provides an update on participant acceptability of cCBT for depression with a specific focus on RCTs - the gold standard in clinical research.

"Acceptability" was defined using the definition provided by Kaltenthaler and colleagues (2008):

(a) Participant acceptability and/or satisfaction as measured by questionnaires.

(b) Participant uptake rates (the percentage of participants who agreed to cCBT compared to the total number invited to have cCBT).

(c) Participant drop-out rates (participants who began cCBT but dropped out before completion).

(d) Reasons for participants dropping out.

In addition, cCBT packages offered will be described in detail because acceptability may be affected by aspects of the cCBT package offered.

Method

Search strategy

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; Moher et al., 2009) was used to guide the writing of this systematic review. Studies were included if they met the following criteria:

(i) Participants: adults (aged ≥ 18 years) with a formal diagnosis of depression or cut-off scores reaching caseness on validated questionnaires for depression.

(ii) Intervention: cCBT – defined as CBT delivered on a technological interface via a Uniform Resource Locator (URL or web address) where "the computer took a lead in decision making and was more than a medium" (Waller and Gilbody, 2009).

(iii) Comparison: a control group consisting of participants: on a waiting list; receiving treatment as usual; receiving a psychological treatment placebo; or receiving an established treatment with a known degree of effectiveness (active control).

(iv) Outcomes: questionnaire measures of treatment satisfaction, participant uptake and drop-out rates and quantitative information on reasons for dropping out.

(v) Studies: published in English language in peer reviewed journals from 1st July 2007 (when the original systematic review was completed) to 14th January 2017.

Studies were excluded if they: failed to meet the inclusion criteria; focused on older adults only; or if they involved participants with a diagnosis of postpartum depression, bipolar disorder, psychosis, personality disorder and/or alcohol dependence.

Searches

The following databases were searched in January 2017 for relevant research published between 1st July 2007 and 14th January 2017: CINAHL, EMBASE, PsycINFO, MEDLINE and Web of Knowledge. Both published and grey literature was searched in order to maximise results and reduce publication bias. Key authors within this area of study were contacted for any information regarding future publications (Professor Simon Gilbody and Professor Eva Kaltenthaler) and two key journals within this area of study were reviewed by hand (Internet Interventions and the Journal of Medical Internet Research). The reference list of all included articles was also reviewed. Only articles with full available data were included in this review. Any research protocols were followed up to identify possible subsequent publication.

Keyword search terms (see Appendix 2) were derived from a previous systematic review on acceptability of cCBT for depression (Kaltenthaler et al., 2008); other systematic reviews conducted in similar fields of research (Vallury, Jones and Oosterbroek, 2015; Okumura and Ichikura, 2014); and following discussion with a librarian.

The following keyword search terms were linked using Boolean operators 'AND' and 'OR'. Truncation (indicated by the asterisk) was used to ensure that all word endings following the truncation were identified in the search.

Depress* or low mood*

AND

Computer* adj2 (cognitive behav* therap* or CBT)) OR (((computer* or online or internet or mobile* or web* or e?mail or technology* or tablet* or smartphone or phone*) adj2 cognitive behav* therap*) or CBT)

AND

RCT OR randomi* control* trial

Any duplicate abstracts between databases were identified and excluded. Titles were screened, and those that did not meet inclusion criteria were excluded. Abstracts were independently assessed against the inclusion/exclusion criteria by the author and a co-rater (CW), who then met to ensure that the same studies had been identified for inclusion. The full article was retrieved and discussed jointly by HB and CW whenever eligibility was unclear based on the abstract alone. The protocol was registered on PROSPERO (Bowyer and Williams, 2017).

Quality Rating

Included studies were rated for quality using the Clinical Trial Assessment Measure (CTAM; Tarrier and Wykes, 2004); a valid and reliable quality measure. A score out of 100 is calculated based on six subscales assessing: sample size and recruitment method;

treatment allocation; assessment of outcome/s; control groups; description of treatment; and analysis. To assess inter-rater reliability, an independent reviewer (AB) rated all studies. Discrepancies were discussed in order to reach a consensus (see Appendix 3).

Results

A total of 2,826 references were screened, with 69 full articles assessed. Figure 1 highlights the systematic search process. Eight studies met inclusion criteria. Data from two studies were supplemented by companion papers (de Graaf et al., 2009a; Richards, Timulak and Hevey, 2013a). Authors were contacted when data was unavailable.

Interventions

Four studies used the "Sadness Programme" (Studies: 2, 4, 7 and 8), with one adapting this for a Chinese population (Study 2); two used "Beating the Blues" (Study 5 and 6); one used "Colour Your Life" (Study 3) and one used "Deprexis" (Study 1). Interventions are described in Table 1. All studies adequately described the intervention, or provided a reference to a detailed description. Courses varied in the number of sessions offered (range 6-10).

Support

The majority of studies provided additional support as part of the cCBT package (n = 6/8; Table 2), with just one providing no support (Study 3) and one offering support for the active comparison group only (email CBT; Study 5). Of those that provided support, five studies provided personalised support: three provided automated email support and personalised support via email or telephone (Studies: 2, 7, and 8), two provided email support only (Study 1 and 4); and one study provided email reminders only (Study 6). For the majority (n = 3/5), the purpose of the support was to provide encouragement (Studies: 1, 2 and 4). One study offered encouragement, goal-setting and problem-solving (Study 7) and one study provided no information regarding the purpose or content of the support

(Study 8). The majority of studies provided support for the duration of the intervention (n = 5/6); either weekly (Studies: 1, 2, 7, and 8) or every 7-10 days (Study 4). One study provided support until the completion of the second module with no information on how

Figure 1. PRISMA flow diagram of the systematic search process.

Table 1. Descriptions of cCBT packages offered in each study

Authors	Intervention description
1. Berger et al. (2011)	*"Deprexis"* – psychoeducation, behavioural activation, cognitive restructuring, mindfulness and acceptance, interpersonal skills, relaxation, problem-solving, expressive writing and forgiveness, positive psychology, dream work and emotion-focus interventions.
2. Choi et al. (2012)	*"Brighten Your Mood"* (modified Chinese version of the "Sadness Programme") – behavioural activation, cognitive restructuring, problem-solving and assertiveness skills. Additional content on comorbid difficulties, answers to frequently asked questions and forum posts from previous users.
3. de Graaf et al. (2009b)	*"Colour Your Life"* – psychoeducation, cognitive restructuring, behaviour change and relapse prevention.
4. Perini et al. (2009)	*"The Sadness Programme"* – behavioural activation, cognitive restructuring, problem-solving and assertiveness skills and access to an online forum.
5. Richards et al. (2013b)	*"Beating the Blues"* – cognitive restructuring, behavioural activation, problem-solving, graded exposure, sleep management, action planning and relapse prevention.
6. Santucci et al. (2014)	*"Beating the Blues"* – as outlined in Richards et al. (2013b) above.
7. Titov et al. (2010)	*"The Sadness Programme"* – as outlined in Perini et al. (2009) above.
8. Watts et al. (2015)	*"The Sadness Programme"* – as outlined in Perini et al. (2009) above.

often support was provided (Study 8). The majority provided information on the amount of support provided (n = 5/6), however studies varied in how they reported this, making it difficult to make direct comparisons between studies: two reported the overall contact time (Study 2 and 8); one reported the number of contacts made to the participants (Study 1); and two reported both the overall time spent and number of times they contacted participants (Study 4 and 7). One provided no information on how much contact was made with participants (Study 6). The acceptability and quality of support might be expected to vary in relation to the experience and training of the supporter and the purpose of the support, for example technical support versus more personalised

Table 2. Support provided alongside each cCBT package

Authors (date)	Supporter	Modality	Content	Timing	Total support provided per participant (mean, SD)	
					Number of contacts	**Minutes**
1. Berger et al. (2011)	MSc psychology or psychotherapy students, Psychologist or CBT Therapist	Email	Feedback and encouragement	Weekly	10.29 (1.93)	-
2. Choi et al. (2012)	Trainee or Qualified Clinical Psychologist	Automated and personalised emails and telephone	Encouragement	Weekly	-	97.3 (60.8)
3. de Graaf et al. (2009b)	**No support provided**					
4. Perini et al. (2009)	Clinical Psychologist	Email and moderated forum	Encouragement	Every 7-10 days	8.33 (-)	111.0 (-)
5. Richards et al. (2013b)	**No support provided**					
6. Santucci et al. (2014)	No information	Email	Reminders	Weekly	No information	No information
7. Titov et al. (2010)	Psychiatrist	Automated emails and: (1) Technician: personalised email or telephone contact (2) Clinician: personalised email or telephone contact and moderated forum	(1) Encouragement (2) Encouragement, goal setting and problem solving	Weekly	1. 36.9 (5.3) 2. 34.7 (6.3)	1. 61.0 (9.8) 2. 60.5 (19.0)
8. Watts et al. (2015)	No information	Email or telephone until completion of lesson 2	No information	No information	-	4.1 (4.6)

motivational support. A variety of individuals provided the personalised support in each study. One study failed to provide details on the background of the individuals providing the support (Study 8). None of the studies provided information about the supporters training in or experience of providing or supporting cCBT. All support providers received supervision.

Randomisation

All studies used randomisation: two studies did not describe the randomisation strategy used (Study 3 and 6); five used a random number generator (Studies: 1, 2, 4, 7 and 8) and one used a random assignment algorithm (Study 5). Of those that described randomisation, four used an independent researcher for randomisation (Studies: 1, 2, 5 and 8). Most studies did not provide any information on allocation concealment (n = 6/8; Studies: 1, 3, 4, 5, 6 and 7); two studies concealed allocation until participants met the inclusion criteria (Study 2 and 8). No studies reported if analysers were blind to allocation.

Control Group/s

A variety of control groups were used in the studies. Two studies used a wait-list control (WLC) only (Study 2 and 4); all other studies included an active control (see Table 3).

Sample characteristics

Half of the studies (n=4) took place in Australia (Studies: 2, 4, 7 and 8), with the others conducted in Europe (Studies: 1, 3 and 5) and the US (Study 6); no studies were conducted in the UK (see Table 3). Most studies (n=7/8) recruited non-clinical volunteers (Studies: 1-5, 7 and 8), however only two described how these individuals had heard about the study (Study 1 and 2). One used convenience sampling where clinic attendees with elevated symptoms of depression were referred to the study (Study 6). The majority of participants in all studies were female (66.4%, n = 507/764), with a mean age varying from 23.0 to 49.3 years. Of the studies that reported educational attainment (n = 7/8),

most participants had completed or were currently engaged in tertiary education (post-secondary school education including further and higher education) (Studies: 1, 2, and 4-7). The majority of participants in one study had completed "medium education" (Study 3), with no information provided on what this included. One study did not report participant's educational attainment (Study 8). The majority of studies (n = 5/8) provided no information regarding participant's computer use or confidence (Studies: 1, 3, 5, 6 and 8). Of the studies that reported on hourly computer use per week, approximately half of the participants used a computer for 0-10 hours per week (range 48%-53%; Study 2 and 7). Of the studies that reported on participant's confidence using computers and the internet, the majority reported feeling confident/very confident (range 80.0%-82.5%; Study 4 and 7). All studies used at least one standardised, self-report assessment measure of depression as their primary outcome measure: the Beck Depression Inventory-II (BDI-II; Beck et al., 1996), was used in four studies (Studies: 1, 3, 5 and 6), three studies used both the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer and Williams, 2001) and the BDI-II (Studies: 4, 7 and 8) and one study (Study 2) used the Chinese Version of the BDI-II (Zheng et al., 1988) and the Chinese Bilingual version of the PHQ-9 (Yeung et al., 2008). The majority of studies (n = 5/8) used a clinical interview schedule in addition to these measures to confirm the diagnosis using the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) (Studies: 1, 2, 4, 7 and 8). Participants in studies that relied solely on validated depression questionnaires met caseness for at least mild depression (Studies: 3, 5 and 6). The majority of studies (n = 5/8) excluded participants whose responses fell within the severe range (Studies: 2, 4, 5, 7 and 8) and/or indicated that they were at risk of suicide (Studies: 1, 2, 4, 7 and 8). One study excluded individuals where there was a need for a higher level of clinical care than cCBT but provided no information as to how this was determined (Study 6).

Table 3. Study characteristics

Authors (date)	Location	Conditions	N	Age (mean, SD)	Female % (n)	Population/Clinical issue	CTAM score
1. Berger et al. (2011)	Switzerland and Germany	1. Guided cCBT 2. Unguided cCBT 3. WLC	76	38.8 (14.0)	69.7 (53)	Community volunteers with major depression/dysthymia (MINI-DIPS)	83 (High)
2. Choi et al. (2012)	Australia	1. Guided cCBT 2. WLC	55	39.0 (11.7)	80.0 (44)	Community volunteers with major depression (CB-SCID-I/P)	50 (Low)
3. de Graaf et al. (2009b)	Netherlands	1. Unguided cCBT 2. Unguided cCBT and TAU 3. TAU	303	1. 44.3 (11.8) 2. 45.1 (12.2) 3. 45.2 (10.9)	56.8 (172)	Community volunteers with depressed mood (BDI-II ≥16)	71 (High)
4. Perini et al. (2009)	Australia	1. Guided cCBT 2. WLC	45	49.3 (12.1)	77.8 (35)	Community volunteers with depression (MINI 5.0)	60 (Low)
5. Richards et al. (2013b)	Ireland	1. Unguided cCBT 2. Guided eCBT	80	26.5 (7.5)	63.8 (51)	University student volunteers with depression (BDI-II 14-29)	68 (High)
6. Santucci et al. (2014)	USA	1. cCBT and reminder 2. cCBT and no reminder	43	23.0 (4.2)	69.8 (30)	Student clinic attenders with elevated symptoms of depression (PHQ-9 ≥5)	74 (High)
7. Titov et al. (2010)	Australia	1. Clinician guided cCBT 2. Technician guided cCBT 3. WLC	127	43.0 (12.9)	74.0 (94)	Community volunteers with major depression (MINI 5.0)	75 (High)
8. Watts et al. (2015)	Australia	1. cCBT with support 2. mCBT with support	35	41.0 (12.9)	80.0 (28)	Community volunteers with major depression (MINI 5.0)	58 (Low)

Note: WLC (wait-list control), TAU (treatment-as-usual), cCBT (Computerised Cognitive Behavioural Therapy), eCBT (email Cognitive Behavioural Therapy), mCBT (mobile Cognitive Behavioural Therapy), MINI-DIPS (Mini Diagnostic Interview for Psychiatric Disorders), CB-SCID-I/P (Chinese-Bilingual Structured Diagnostic Interview Schedule), BDI-II (Beck Depression Inventory-II), MINI 5.0 (Mini International Neuropsychiatric Interview 5.0), PHQ-9 (Patient Health Questionnaire-9).

Quality

The mean score on the CTAM was 67.38 (SD = 10.72, range 50-83). Five out of the eight (62.5%) studies met the quality cut-off used by Wykes and colleagues (2008) of 65, and were judged to be of acceptable quality.

Analysis

Various analytic strategies were used across the studies; all were deemed statistically appropriate. The majority (n = 6/8) conducted an "intention to treat" (ITT) analysis (Studies: 1-5 and 7).

Participant acceptability

(1) *Satisfaction measures*

Two studies used the Client Satisfaction Questionnaire-8 (CSQ-8; Larsen et al., 1979) to measure participant satisfaction (Study 1 and 6). Three (Studies: 2, 7 and 8) used the Credibility/Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000). The CSQ and CEQ are both reliable and valid measures. One study used the CEQ and an "evaluation questionnaire", with no information provided about this questionnaire (Study 3). One study developed the "Satisfaction with Online Treatment" questionnaire (Study 5) and one provided no information on the questionnaire used, reporting only on the outcomes of the measure (Study 4). The variety of satisfaction measures used makes it difficult to make direct comparisons between studies, however the majority of participants who responded to these questionnaires appeared to be satisfied with cCBT (see Table 4). Of the four studies that analysed between group differences, none reported any significant differences in participant satisfaction (Studies: 1, 3, 5 and 7).

(2) *Uptake rates*

Only five out of eight studies provided information on the number of participants who began treatment (i.e. started the first module; see Table 5): the mean percentage uptake

Table 4. Participant acceptability by intervention, as measured by satisfaction questionnaires

Author	Measure used	Participant satisfaction (mean, SD)	Between group difference
1. Berger et al. (2011)	CSQ-8	1. Guided cCBT: 3.1 (0.4) 2. Unguided cCBT: 2.9 (0.5)	$p<.05$
2. Choi et al. (2012)	Based on the CEQ	cCBT was logical (m = 7.4, SD = 1.9); participants felt confident cCBT would teach symptom management techniques (m = 6.4, SD = 2.1) and would recommend cCBT (m = 7.4, SD = 12.0). 96% (n=22/23) agreed it was worth their time doing cCBT	n/a
3. de Graaf et al. (2009b)	The CEQ and an Evaluation Questionnaire	1. cCBT: CEQ expectancy (m = 18.3, SD = 4.2); CEQ credibility (m = 18.8, SD = 4.0) 2. cCBT + TAU: CEQ expectancy (m = 19.0, SD = 4.8); CEQ credibility (m = 19.2, SD = 3.8) Individuals responded "relatively neutrally" on the Evaluation Questionnaire	$p<.05$
4. Perini et al. (2009)	No information	82% (n=14/17) very or mostly satisfied; 18% (n=3/17) neutral or somewhat satisfied with cCBT. Participants rated cCBT as logical, felt confident cCBT would teach symptom management techniques and would recommended cCBT	n/a
5. Richards et al. (2013b)	Satisfaction with Online Treatment	1. cCBT: helpful and easy to use (87%); happy to use computer for treatment (73%); cCBT would have a lasting effect (47%); would recommend cCBT (60%) 2. eCBT: helpful (90%); easy to use (50%); happy to use computer for treatment (60%); eCBT would have lasting effect (40%); would recommend eCBT(60%)	$p < 0.5$
6. Santucci et al. (2014)	CSQ-8	21.7 (5.2)	Not reported
7. Titov et al. (2010)	Based on the CEQ	87% (67/77) mostly/very satisfied with cCBT; quality of modules good/excellent (90%; 69/77); quality of correspondence good/excellent (81%; 62/77). Participants rated cCBT as logical, felt confident it would teach symptom management techniques and would recommended it	$p < .05$
8. Watts et al. (2015)	2 items based on the CEQ	1. cCBT: 64% felt very satisfied and felt very confident recommending it 2. mCBT: 54% felt very satisfied and 64% felt very confident recommending it	Not reported

Note: CSQ-8 (Client Satisfaction Questionnaire-8); CEQ (Credibility/Expectancy Questionnaire); cCBT (Computerised Cognitive Behavioural Therapy); TAU (Treatment As Usual); eCBT (Email Cognitive Behavioural Therapy); mCBT (Mobile Cognitive Behavioural Therapy)

rate across these studies was 84.9% (range: 66.7%-93.9%; n = 202/238). Two studies only reported on the number of participants who had completed the first module (Study 3 and 6); and one study did not provide any information regarding uptake (Study 1).

(3) Participant drop-out rates

An important proxy measure for acceptability is course completion. Of those randomised to receive cCBT, the mean percentage course completion rate across all eight studies was 36.8% (range 13.0%-70.2%). Courses that offered personalised support had a higher mean completion rate of 61.3% (range: 46.7%-70.2%; n = 130/212). Courses that offered no support or only reminder emails had a mean completion rate of 20.6% (range: 14.0%-36.0%; n = 66/320). Due to cCBT packages varying in design (e.g. locked versus open module design), it can be difficult to define "course completion" and therefore determine what an adequate "dose" of cCBT is. Only one study described an adequate dose as completing five or more modules (out of 8; Study 3). Drop outs were initially defined as participants who were randomised to receive the intervention but left before the treatment was completed (ITT). The mean percentage ITT drop-out over the eight studies was 63.2% (range: 30%-86%). Three studies did not report on the number of participants who started the intervention (Studies: 1, 3 and 6). When defining drop out as those who started treatment but left before the treatment was completed the mean percentage drop-out over the five studies was 37.1% (range: 19.5%-74.4%).

(4) Reasons for drop-out

One study conducted correlational analyses to identify potential patterns in those who dropped out, finding no correlation between the number of completed modules and symptom alleviation or dissatisfaction with treatment (Study 6). One reported that the researchers withdrew two participants from cCBT due to "concerns about their progress" but did not provide any further information regarding other participants who dropped out

Table 5. Participant uptake, completion and drop-out rates

Authors (date)	Participants randomised n (%)	Number of modules	Started treatment n (%)	Modules completed n %	Drop-out (ITT) n (%)	Drop-out (started vs completed) n %
1. Berger et al. (2011)	N = 76	10				
Unguided cCBT	25 (32.9)		No information	9/25 (36.0)	16/25 (64.0)	No information
Guided cCBT	25 (32.9)			14/25 (56.0)	11/25 (44.0)	
WLC	26 (34.2)					
2. Choi et al. (2012)	N = 63	6				
Guided cCBT	32 (50.8)		25/32 (78.1)	17/32 (53.1)	15/32 (46.9)	8/25 (32.0%)
WLC	31 (49.2)					
3. de Graaf et al. (2009b)	N = 303	8				
Unguided cCBT	100 (33.0)		No information	14/100 (14.0)	86/100 (86.0)	No information
Unguided cCBT and TAU	100 (33.0)			26/100 (26.0)	74/100 (74.0)	
TAU	103 (34.0)					
4. Perini et al. (2009)	N = 48	6				
Guided cCBT	29 (60.4)		27/29 (93.1)	20/29 (69.0)	9/29 (31.0)	7/27 (25.9)
WLC	19 (39.6)					
5. Richards et al. (2013b)	N = 101	8				
Unguided cCBT	51 (50.5)		43/51 (84.3)	11/51 (21.6)	40/51 (78.4)	32/43 (74.4)
Guided eCBT	50 (49.5)		37/50 (74.0)	5/50 (10.0)	45/50 (90.0)	32/37 (86.5)
6. Santucci et al. (2014)	N = 44	8				
cCBT and reminder	21 (47.7)		No information	3/21 (14.3)	18/21 (85.7)	No information
cCBT and no reminder	23 (52.3)			3/23 (13.0)	20/23 (87.0)	
7. Titov et al. (2010)	N = 141	6				
Technician guided cCBT	47 (33.3)		41/47 (87.2)	33/47 (70.2)	14/47 (29.8)	8/41 (19.5)
Clinician guided cCBT	49 (34.8)		46/49 (93.9)	32/49 (65.3)	17/49 (34.7)	14/46 (30.4)
WLC	45 (31.9)					
8. Watts et al. (2015)	N = 52	6				
cCBT with support	30 (57.7)		20/30 (66.7)	14/30 (46.7)	16/30 (53.3)	6/20 (30.0)
mCBT with support	22 (42.3)		15/22 (68.2)	10/22 (45.5)	12/22 (54.5)	5/15 (33.3)

(Study 7). No other studies provided any reasons for participants dropping out of the study.

Discussion

The current review aimed to provide an update on participant acceptability of cCBT for depression. A total of eight RCTs were identified; five of which were deemed to be of acceptable quality.

The results indicate that based on questionnaire measures individuals appear to be satisfied with cCBT; supporting previous research into this area (Kaltenthaler et al., 2008). Furthermore based on the small number of studies looking at between group differences, satisfaction did not appear to be influenced by: device used to deliver CBT (i.e. computer versus email or mobile), support offered (guided vs unguided and unguided vs TAU in addition) or support provider (i.e. clinician guided vs technician-guided). Further research looking into the relationship between participant satisfaction scores and these elements of cCBT delivery would be beneficial in order to gain a better understanding into what the most acceptable design of a cCBT package is.

The mean percentage uptake rate in the studies included in this review was 85%. This is significantly higher than uptake rates reported in the original systematic review (range: 3% - 25%). This may represent increasing availability and therefore awareness of cCBT as a method of support over the last 10 years. While uptake appears to be high, the majority of studies used volunteers recruited via mass media, with high educational attainment and who were already online and computer-confident and as such, may not be representative of depressed patients who are offered cCBT in clinical settings. More naturalistic studies recruiting participants from clinic settings would help identify more representative uptake rates for cCBT.

The mean ITT drop-out rate in the studies was 63%; significantly higher than drop-out rates previously reported (mean percentage: 32%) (Kaltenthaler et al., 2008) and higher

than reported average weighted drop-out rates reported in a recent meta-analysis for individual face-to-face CBT (25%) (Fernandez et al., 2015). Reasons for withdrawal or drop-out were not available in most studies. It may be that drop-out represents dissatisfaction with and lack of benefit from cCBT; it is therefore important that future studies gain feedback on the intervention from these individuals to gain some understanding into how retention can be improved. It may be that aspects of the package itself contributed to participants disengaging with courses, for example a systematic review has indicated that offering support alongside cCBT significantly improves completion rates (Baumeister et al., 2014). In line with this, studies in the current review with the highest drop-out rates appeared to be those that either provided no support or only provided email-reminders alongside the cCBT package. Less than half of the participants included in the current review completed the cCBT courses; however only one study defined what an adequate "dose" of cCBT is. It may be that sometimes course completion rates represent symptom improvement rather than dissatisfaction with the cCBT package offered. It is therefore important that future studies define what an adequate "dose" is for the cCBT package offered.

This review has several limitations. Studies used a variety of recruitment methods and cCBT programs in different continents with different health care systems; it is therefore difficult to make direct comparisons between them. A variety of satisfaction measures were used; not all were valid and reliable. It is recommended that valid and reliable measures of participant satisfaction are used in the future; consistent use of the same measures would also enable a meta-analysis to be conducted. There was limited information regarding why participants dropped out of the study; results from satisfaction questionnaires conducted with completers may therefore present a biased picture. A number of these limitations were highlighted in Kaltenthaler and colleagues (2007) review suggesting that little progress has been made in the reporting of studies in this area. Lastly, the current review focussed on quantitative measures of participant acceptability and satisfaction and therefore gained little insight into the reasons why individuals do or

do not find cCBT acceptable. Combining quantitative and qualitative research may be useful to gain a better understanding of factors that influence participant acceptability of cCBT packages for depression.

Conclusion

This review highlights the need for enhanced reporting of trials offering cCBT to individuals with depression. cCBT may be an acceptable way of offering mental health support to individuals with depression but further quantitative and qualitative research should be conducted in order to determine reasons for large drop-out and low course completion rates.

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CHAPTER 2: Major Research Project

An online CBT-based life skills course for the

farming community: a feasibility study

Harriet Louise Bowyer*

*Address for correspondence

Mental Health and Wellbeing

University of Glasgow

1st Floor, Administrative Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

G12 0XY

Email: h.bowyer.1@research.gla.ac.uk

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Plain English Summary

Title: An online CBT-based life skills course for farmers: a feasibility study

Background: Research indicates that male farmers have higher levels of depression than non-farmers and that they struggle to seek help. The internet may be a useful way of supporting farmers but to date no research has explored this.

Aims: This study examined how possible it is to deliver a computerised Cognitive Behavioural Therapy (cCBT) based life skills course to farmers.

Method: Farmers were recruited using online and offline adverts and given access to an online CBT-based course with weekly email support. Questionnaires measuring depression, anxiety and daily functioning were completed at the beginning and end of the study (at 8 weeks). Participants were then invited to take part in a telephone interview asking about what they thought about the course.

Results: 56 participants were recruited; the most successful recruitment method was advertising on Twitter. A total of 63% (n = 35) participants logged onto the course and 27% (n=15/56) completed a questionnaire after 8 weeks. Of those who logged on, only 14% (n = 5/35) completed all 5 core modules. At the end of the study participants reported experiencing significantly fewer symptoms of anxiety. There was no significant change in depression or in daily functioning. Telephone interviews (n = 8) indicated that farmers may struggle to seek support due to their heavy workload and mental health stigma within the farming community; participants therefore thought that online support was helpful, convenient and anonymous. There were concerns that older people and those with limited internet connection may have difficulty accessing the course. Suggestions regarding the layout and content of the course were provided.

Conclusion: Online courses may be effective and convenient ways of offering mental health support to some in the farming community. Difficulties in recruiting and retaining farmers may indicate that modifications to the course are needed to improve engagement such as offering short stand-alone modules and downloadable content for reading offline.

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1. Andrews, G., Cuijpers, P., Craske, M.G., McEvoy, P., Titov, N. and Johnston, L., 2010. Computer Therapy for the Anxiety and Depressive Disorders Is Effective, Acceptable and Practical Health Care: A Meta-Analysis. *PLoS ONE*, 5(10), p.e13196.

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Scientific Abstract

Background: Research indicates that male farmers have higher levels of depression than non-farmers and that offering mental health support online may overcome several barriers to help-seeking in farmers. This study investigated the feasibility of delivering a computerised Cognitive Behavioural Therapy (cCBT) based course to farmers.

Methods: Farmers with depressive symptoms in the normal to moderate range were recruited using adverts into a single-arm feasibility study. Participants were given access to a cCBT-based course consisting of 5 core modules and weekly automated and personalised email support. Self-reported depression, anxiety, and social functioning were measured at baseline and 8-week follow-up. Telephone interviews explored participant use of and satisfaction with the course and were analysed using thematic analysis.

Results: 56 participants were recruited, with 48% recruited using social media. In total, 35 (63%) participants logged onto the course and 15 (27%) completed follow-up measures. Of those who logged on, only 14% (n = 5/35) completed all core modules. Most participants had no or minimal depressive symptoms (71%); 67% had at least mild anxiety; and 54% had mild to moderate functional impairment. Qualitative interviews (n = 8) indicated that farmers may not help-seek due to heavy workloads and mental health stigma within the farming community. Participants therefore thought online support was helpful because it was convenient and anonymous. There were concerns that older people and those with limited internet connection may have difficulty accessing the course. Suggestions regarding the layout and content of the course were provided. Exploratory analyses showed a significant reduction in anxiety over time (p< .05); no significant change in depression or in functioning was observed.

Conclusions: Online courses may be effective and convenient ways of offering mental health support to some in the farming community. Difficulties in recruiting and retaining farmers may indicate that cCBT may need to be modified further to engage farmers better with short stand-alone modules and the ability to download content for reading offline.

Keywords: cCBT, CBT, farmer, depression

Background

There are approximately 129,000 UK farmers (Office for National Statistics; ONS, 2016), who play a significant role in the economy; earning £3,610 million in 2016 (Department for Environment, Food and Rural Affairs, 2017). However, high rates of suicide have been found in the agricultural community, with a risk almost double the national average in England (ONS, 2017a). Studies indicate that male farmers have higher levels of depression and anxiety than non-farmers (Sanne et al., 2004); mental health difficulties with significant personal, social and economic costs (Kessler et al., 2009).

Financial concerns and working conditions (Gregoire, 2002); extreme weather and threats to crops and livestock; and social, cultural and geographical isolation (Kolstrup et al., 2013) may place farmers at risk of mental health difficulties. Unfortunately, research has highlighted several barriers to help-seeking in farmers: having limited knowledge about and poor recognition of, mental health difficulties (Hawton et al., 1998); reluctance to admit to experiencing mental health difficulties (Boulanger et al., 1999); having significant work demands and poor access to health services (McKay et al., 2012). Peck and colleagues (2002) researched psychological distress in farmers after the 2001 foot-and-mouth crisis. Few sought help from healthcare professionals; preferring community support or anonymous support such as self-help materials or computer-based treatments. One way of tackling barriers to help-seeking is to therefore offer farmers support online.

There is an increasing evidence base for computerised Cognitive Behavioural Therapy (cCBT) (Andrews et al., 2010), with cCBT recommended by the National Institute for Health and Care Excellence (NICE) for treating mild to moderate depression (2009). A recent systematic review indicated that cCBT may be more acceptable to individuals in rural versus urban communities. Rural communities are less likely to want face-to-face mental health support; and therefore cCBT may help reduce concerns regarding visibility and confidentiality when help-seeking (Vallury, Jones and Oosterbroek, 2015).

Although organisations such as the Farming Community Network and the Royal Scottish Agricultural Benevolent Institute (RSABI) provide farmers with support via email and

telephone helplines, a scoping literature review failed to find any studies investigating the feasibility or efficacy of offering farmers psychological talking therapies. Given the evidence base for cCBT and the potential for it to overcome barriers to help-seeking, this study aimed to assess the feasibility of offering farmers a cCBT-based course.

Aims

1. Assess different methods of recruiting farmers.
2. Establish the completion rates of questionnaires at 8-week follow-up.
3. Assess use of and satisfaction with the intervention.
4. Establish the likely clinical effect of the intervention and complete a sample size calculation for a future randomised controlled trial (RCT).

Methods

Quantitative methods

The study was a feasibility study using a single-arm repeated measures design. It was planned that all participants would complete measures at baseline and 12 week follow up. However, due to recruitment difficulties the follow-up time was reduced to 8 weeks.

Participants

Eligible participants were UK farmers aged 18 years or over. The term "farmer" was operationalised using the Scottish Government (2014) definition, expanded to encompass all UK farmers: "*A natural or a legal person (or a group of natural or legal persons) whose holding (production units) is situated within Scotland, and who exercises an agricultural activity. An agricultural activity can include the production, rearing or growing of agricultural products*". It was planned that all participants would have mild to moderate depressive symptoms at baseline, however due to recruitment difficulties this was amended to include individuals with any score below 20 on the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer and Williams, 2001). Individuals were excluded

from the study if they: (1) did not consent (2) did not provide their GP contact details (3) had severe depression (a PHQ-9 score ≥ 20) (4) engaged in harmful drinking (men: > 50 units of alcohol/week; women: > 35 units of alcohol/week) (NHS Greater Glasgow and Clyde, 2017) or (5) were receiving psychological treatment.

Recruitment

Participants were recruited between November 2016 and March 2017 using a variety of methods. RSABI and the National Farmers Union of Scotland (NFUS) distributed a joint news release and flyers at agricultural meetings. Free one-off adverts were placed in: Country Squire Magazine; Countryman Magazine; Farmland Magazine; The Farming Forum; and Scottish Dairy Hub. A radio interview with BBC Radio Scotland "Out of Doors" was broadcast in November 2016 describing the study. A Facebook and Twitter page was also created to promote the study. A marketing company was employed to target farmers on Facebook; all promotion on twitter was completed by the author. All adverts (see Appendix 4) directed participants to an online recruitment site containing a participant information sheet (see Appendix 5) and a link to the consent form (see Appendix 6) and baseline questionnaire, which asked participants how they had heard about the study.

Consent

Informed consent was given online. Participants were asked to consent to their GP being contacted by the research team if they were concerned about active risk/s (i.e. by participants indicating on the PHQ-9 that they have had thoughts that they would be better off dead or of hurting themselves nearly every day).

Procedures

After giving informed consent, participants completed the baseline questionnaire. Individuals who met the inclusion criteria were given access to the "Living Life to the Full for Farming Communities" website. After 8 weeks, participants were emailed a hyperlink

to recomplete the baseline measures and additional questions regarding use of and satisfaction with the course. If participants did not log onto the course and/or did not complete the follow-up measures they were emailed up to two reminder emails.

Intervention

This study used a modified version of "Living Life to the Full" (Williams, 2009) consisting of 5 core modules which aim to support individuals with mild to moderate depression and/or anxiety using CBT principles. The core modules included: understanding your feelings; doing things that make you feel better; looking at things differently; how to fix almost everything; and tension control training. Modules included examples that were relevant and of interest to the farming community; informed by unpublished observations by a previous researcher (Mr Ross Lamont) and advice from RSABI and NFUS. Additional optional modules aimed to support specific difficulties such as how to stop smoking or improve sleep. Each module consisted of a slideshow presentation guided by audio, downloadable worksheets and eBooks (see Appendix 7). Individuals could work through the modules in sequence, in their own preferred order, or could just work through modules relevant to them. Participants received weekly automated support emails and weekly short support emails from an independent researcher (LM) for 8 weeks to encourage engagement with, and completion of, the course modules. The independent researcher could log onto the course and see each participant's weekly progress. A standardised email template (see Appendix 8) was used and modified to include responses to participant queries and highlight individual progress made on the course that week.

Measures

The primary outcomes were the: ability to recruit and retain participants; establish questionnaire completion rates; and assess use of and satisfaction with the course. Demographic data was obtained using a questionnaire developed by the research team (see Appendix 9). Secondary measures included self-reported depression (PHQ-9);

anxiety (General Anxiety Disorder-7; GAD-7, Spitzer et al., 2006); and social functioning (Work and Social Adjustment Scale; WSAS, Mundt et al., 2002). Participant satisfaction was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8, Larsen et al., 1979) and additional usage and acceptability questions developed by the research team (see Appendix 10). The PHQ-9, GAD-7, WSAS and CSQ-8 are all reliable and valid measures.

Qualitative data collection

After 8 weeks participants who consented to take part in a telephone interview and had logged onto the course were contacted and interviewed until data saturation was established. The telephone interviews were semi-structured (see Appendix 11) using an interview schedule adapted from an existing schedule developed by another researcher (Ms Karen Mackenzie) to gain feedback on a similar online CBT course modified for secondary school pupils. The aim of the interviews was to gather information on what participants thought of the course including feedback on: how the course was delivered; the content of the course; the support offered; and the research materials used. Participants received a £5 Amazon voucher to compensate them for their time. Interviews lasted approximately 25-30 minutes and were digitally recorded and transcribed.

Data Analysis

Descriptive statistics were used to describe the sample. Chi-square, Fisher's exact and Mann-Whitney U tests were used to examine demographic differences and differences in baseline scores on secondary outcome measures between those who did and did not log onto the course or complete follow-up measures. Wilcoxon signed rank tests were used to explore changes in secondary outcome measures over time. A power calculation for a future RCT is reported. Statistical analyses were performed using SPSS version 21 (IBM Corp, 2012). Thematic analysis (Braun and Clarke, 2006) was chosen as the method of qualitative analysis because it aims to identify common themes in data relating to participant experience informed by the data, without any prior assumptions due to the

limited amount of research in this area. The aim of the interviews was to gain feedback on participant's experience of using the intervention and as such, this method of analysis was deemed most appropriate. The analysis was completed in accordance with methodological guidelines outlined by Braun and Clarke (2006): 1. Familiarising yourself with the data; 2. Generating initial codes; 3. Searching for themes; 4. Reviewing themes; 5. Defining and naming themes; and 6. Producing the report. Themes were identified at a semantic level and did not go beyond what participants said during the interviews. Software for qualitative research (QSR International, 2015) was used for data management and interpretation. Initial themes were identified by HB and discussed and confirmed with a colleague (RP).

<u>Ethical Approval</u>

The study was approved by the University of Glasgow Medical and Veterinary and Life Sciences ethics panel (Ref: 200160003; approval date: 31/08/2016; Appendix 12).

Results

<u>Recruitment methods</u>

Seventy individuals consented to participate and completed the baseline questionnaire; 56 (80%) participants met the inclusion criteria (see Figure 1).

Figure 1 – participant flow chart

Just under half of the participants were recruited via social media (48.2%, n = 27; see Table 1); the majority of which were recruited using Twitter (n = 23), with few recruited using Facebook (n = 4). An advert placed on The Farming Forum recruited 32.1% (n = 18) of participants. The NFUS/RSABI press release and adverts placed on online or paper-based magazines/newspapers were less successful recruitment methods (n = 5). No participants were recruited from the BBC radio interview.

Table 1. Recruitment methods

	Total n = 56 (%)
Social Media	27 (48.2)
The Farming Forum	18 (32.1)
National Farming Union Scotland	3 (5.4)
Farming magazines/newspapers	2 (3.6)
Farming Community Network	1 (1.8)
A farming website	1 (1.8)
Word of mouth	4 (7.1)

<u>Sample characteristics</u>

Participants (n = 56) were recruited from across the UK: 62.9% (n=22) were English; 22.9% (n=8) were Scottish; and 14.3% (n=5) were Welsh. The majority of participants farmed crops, sheep or beef (67.9%; n = 38). All participants were of White ethnicity. The majority of participants were male (76.8%, n = 43), aged between 35 and 54 (62.5%, n = 35), and married or living with their partner (78.6%, n = 44; see Table 2). The majority of participants had been using the internet for 7 or more years (83.9%, n = 47). Just over half of the participants had experienced mental health difficulties in the past (58.9%, n = 33), with most of these having received support in the past (72.7%; n = 24/33).

Due to a technical error, baseline data on the PHQ-9 was missing for three participants. Following advice from a statistician missing data was dealt with using mean imputation. Baseline PHQ-9 scores indicated that: 26.8% (n = 15) fell within the normal range; 44.6% (n = 25) had minimal depressive symptoms; 21.4% (n = 12) had mild depressive symptoms; and 7.1% (n = 4) had moderate depressive symptoms. As planned, none had severe depression. Baseline GAD-7 scores indicated that: 32.1% (n = 18) fell within the normal range; 44.6% (n = 25) had mild anxiety; 17.9% (n = 10) had moderate anxiety; and 5.4% (n = 3) had severe anxiety. Baseline WSAS scores indicated that 23.2% (n = 13) fell within the subclinical range; 53.6% (n = 30) had mild to moderate functional impairment; and 23.2% (n = 13) had moderate to severe functional impairment.

Table 2. Demographic characteristics of the sample

	Total n = 56 (%)[a]	Logged on Yes n = 35 (%)	No n = 21 (%)	x^2 (*p*-value)[b]
Age				
18-24	1 (1.8)	1 (2.9)	-	
25-34	6 (10.7)	4 (11.4)	2 (9.5)	
35-44	16 (28.6)	11 (31.4)	5 (23.8)	
45-54	19 (33.9)	10 (28.6)	9 (42.9)	
5-64	12 (21.4)	7 (20.0)	5 (23.8)	
65+	2 (3.6)	2 (5.7)	-	
Gender				.330
Male	43 (76.8)	25 (71.4)	18 (85.7)	
Female	13 (23.2)	10 (28.6)	3 (14.3)	
Marital Status				
Single	6 (10.7)	3 (8.6)	3 (14.3)	
Married/Living with partner	44 (78.6)	27 (77.1)	17 (81.0)	
Separated/Divorced	5 (8.9)	4 (11.4)	1 (4.8)	
Widowed	1 (1.8)	1 (2.9)	-	
Farming type				
Beef	10 (17.9)	6 (17.1)	4 (19.0)	
Crops	15 (26.8)	8 (22.9)	7 (33.3)	
Dairy	5 (8.9)	4 (11.4)	1 (4.8)	
Pigs	3 (5.4)	2 (5.7)	1 (4.8)	
Potatoes	3 (5.4)	2 (5.7)	1 (4.8)	
Poultry	1 (1.8)	1 (2.9)	-	
Sheep	13 (23.2)	9 (25.7)	4 (19.0)	
Mixed farming	6 (10.7)	3 (8.6)	3 (14.3)	
Time spent on the farm per day				.123
Less than 4 hours	6 (10.7)	5 (14.3)	1 (4.8)	
4-6 hours	3 (5.4)	1 (2.9)	2 (9.5)	
6.5-8 hours	10 (17.9)	7 (20.0)	3 (14.3)	
8.5-10 hours	15 (26.8)	12 (34.3)	3 (14.3)	
10.5-12 hours	14 (25.0)	5 (14.3)	9 (42.9)	
12+ hours	8 (14.3)	5 (14.3)	3 (14.3)	
Past Mental Health Problem				.440
Yes	33 (58.9)	22 (62.9)	11 (52.4)	
No	23 (41.1)	13 (37.1)	10 (47.6)	
Currently on medication				.080
Yes	14 (25.0)	6 (17.1)	8 (38.1)	
No	42 (75.0)	29 (82.9)	13 (61.9)	
Experience using the internet				
1-3 years	2 (3.6)	-	2 (9.5)	
4-6 years	7 (12.5)	5 (14.3)	2 (9.5)	
7+ years	47 (83.9)	30 (85.7)	17 (81.0)	

[a] n varies due to missing data
[b] Fisher's-exact test for cell counts <5; no test of significance for cell counts <1

Primary outcome measures

Attrition and adherence

Follow-up data was available from 26.8% of participants (n = 15/56); an attrition rate of 73.2% from those recruited. In total, 35 participants (62.5%) logged onto the website. Two participants withdrew from the study after logging in; one withdrew due to lack of time to commit to the course and one withdrew due to their low mood impacting on their ability to engage with the course.

No significant demographic differences were found between those who did and did not log on to the course or complete follow-up measures (see Appendix 13). Tests of normality were carried out on change scores between outcome measures at baseline and follow-up. Shapiro-Wilk tests, distribution histograms, Q-Q plots and box plots suggested that the data was not normally distributed; therefore non-parametric statistics were used. No significant differences on baseline secondary outcome measures were found between those who did and did not log onto the course (see Table 3) or complete follow-up measures (see Appendix 13).

Table 3. Scores on secondary outcome measures at baseline

	Total sample (n = 56) Median (IQR)	Logged on (n = 35) Median (IQR)	Did not log on (n = 21) Median (IQR)	Significance *p*-value
PHQ-9	7 (4 – 11)	7 (5 – 10)	7 (1-12)	.440
GAD-7	6 (2 – 9)	6 (4 – 9)	6 (2 – 11)	.702
WSAS	12 (8 – 17)	12 (8 – 16)	12 (7 – 23)	.647

Of those who logged onto the course, 57.1% (n = 20) participants started the course (defined as those who had started any of the modules, in no particular order) and a total of 14.7% (n = 5/34) completed all 5 core modules within 8 weeks. Those who started the course (n = 20), completed a mean of 1.76 modules (SD = 1.97; see Table 4). Reasons why participants did not complete the course were not available, however a number of participants were recruited just before spring time (a particularly busy time of year for all farmers) which is thought to have affected participant's motivation and time available to commit to the course.

Table 4. Course use of the total sample (n = 35)

	N (%)
Started the course	20 (57.1)
Module 1 completed	13/20 (65.0)
Module 2 completed	7/20 (35.0)
Module 3 completed	5/20 (25.0)
Module 4 completed	6/20 (30.0)
Module 5 completed	6/20 (30.0)
Completed all modules	5/20 (25.0)
Modules completed, M (SD) n = 20	1.76 (1.97) range 0-5
E-books downloaded, M (SD)	1.14 (1.50) range 0-5
Number of logins, M (SD)	3.20 (3.53) range 1-15

Note: All modules were unlocked so participants could work through the modules in any order

Email contact per participant

Participants received 8 automatic weekly emails and a mean of 5.86 (SD = 0.77, range = 3-7) personalised support emails. Participants sent a mean of 0.94 (SD = 1.28, range = 0-5) emails in response to the personalised emails.

Secondary outcome measures

Therapeutic change

As a feasibility study, the study was not adequately powered to detect differences in scores over time. However, exploratory analyses were conducted to establish an estimate of effect. There was no significant change in scores on the PHQ-9 (z = -0.83, p > .05) or WSAS (z = -1.12, p > .05) over time. On average, participants experienced less anxiety at 8-week follow-up (mdn = 4, IQR = 2 - 11, n = 15) than at baseline (mdn = 6, IQR = 2 - 13, n = 15). A Wilcoxon Signed Rank test showed that this difference was significant, z = -2.28, p < .05. (see Table 5). A sensitivity analysis including only participants with baseline PHQ-9 scores of ≥ 5 found no change in the significance of the results (see Appendix 14).

Table 5. Change in secondary outcome measures over time

	Baseline Mdn (IQR)	**Follow-up** Mdn (IQR)	**Significance** *p*-value[a]
PHQ-9	8 (4 – 12)	7 (4 – 9)	.377
GAD-7	6 (2 – 13)	4 (2 – 11)	.023
WSAS	9 (4 – 14)	9 (4 – 12)	.263

A sample size calculation for a future RCT using a wait-list control was calculated. Assuming there will be no change in PHQ-9 scores for the control group (mean change score = 0), the same change in PHQ-9 scores observed in this study for the intervention group (mean change score = 1.47) and a similar standard deviation in each group as observed in this study (SD = 5), a sample size of 490 participants would be needed to have 90% power to detect differences where $p < .05$. To allow for the same attrition rate found in the current study (73%), a sample size of 1,815 participants would be required. It is possible that the control groups PHQ-9 scores could increase (i.e. get worse) over time. As we currently do not have data regarding a control group a recommendation for a future pilot RCT would be to have a sample size of 12 per arm (Julious, 2005). Using 90% power could detect an effect size of 1.39 and, assuming a common SD of 5, would detect a mean difference of 6.95.

Participant satisfaction

Participants who completed the CSQ-8 reported a medium to high level of satisfaction with the course (mean = 20.87, SD = 0.64, n = 15). Most participants found the course helpful (n = 13/14, 92.9%) and easy to access (n = 10/13, 76.9%) and found the email support helpful (n = 12/14, 85.7%). Just over half felt able to do the activities suggested by the course (53.3%; n = 8/15, see Table 6).

Table 6. Responses to the satisfaction questionnaire

	Strongly Disagree n (%)	Slightly Disagree n (%)	Neither Agree/Disagree n (%)	Slightly Agree n (%)	Strongly Agree n (%)
I found the course helpful (n = 14)[a]	1 (7.1)	-	-	7 (50.0)	6 (42.9)
I found the course easy to access (n = 13)[a]	-	1 (7.1)	3 (21.4)	2 (14.3)	8 (57.1)
I was able to do the activities suggested by the course (n = 15)[a]	1 (7.1)	-	5 (35.7)	5 (35.7)	3 (21.4)
I found the email support helpful (n = 14)[a]	-	-	3 (20.0)	4 (26.7)	8 (53.3)

[a] n varies due to missing data

Eight participants from across the UK (England, n = 5; Scotland, n = 2; Wales, n = 1) took part in a telephone interview. Participants varied in age and farming type and half were female. Just over half had completed all of the core modules (n = 5) and had downloaded at least one e-book from the course (n = 7; see Table 7). Four broad themes were identified using thematic analysis.

Table 7. Description of participants in the telephone interviews

Participant	Gender	Age	Farming type	Modules completed	E-books downloaded
1	Female	35-44	Dairy	5	5
2	Male	55-64	Crops	5	5
3	Male	45-54	Potatoes	5	8
4	Female	65+	Sheep	0	1
5	Male	35-44	Pigs	5	4
6	Female	25-34	Dairy	2	0
7	Female	25-34	Dairy	0	5
8	Male	55-64	Beef	5	4

1. Barriers to help-seeking

Participants discussed several barriers to seeking mental health support. Mental health stigma was discussed with participants describing farmers as proud (*"They're quite sort of independent people and they don't like to admit their short comings… some people feel that sort of weakness and that, until it's appreciated that a lot of people are suffering from it, you won't get much further forward"* Participant 2) and stoic (*"Get on with it, there's nothing wrong with you, get on with it. That sort of, that attitude and that is going to take an awful lot of shifting"* Participant 4). Heavy workloads made it difficult for some to find time to help-seek (*"The seasons are constantly chasing you and if the suns shining that day well, you've got to go and make the hay or if your sheep start lambing, well you've got to go and help your sheep. I think the hardest bit about farming, you just can't pack it up at 5 o'clock and go away"* Participant 1) and some reported that even when they have sought support it can be difficult to find time to try out some of the strategies

recommended (*"All through the summer when you're busy harvesting, that's a job to get exercise really"* Participant 5).

2. Mode of delivery for mental health support

Overall participants were positive about receiving mental health support online. They frequently discussed how the convenience of online support overcame the difficulty of finding time to help seek (*"It can be done at any time or day at night. When you have them only being short as well… you can sit down, do that module very quickly... that's great is that. Whereas if someone was to go see someone… you're never clean enough to go somewhere, go out, come back. It's nearly half a day's work whereas ten minutes at end of day or half an hour at end of day, you can quite easily do that"* Participant 8). The importance of anonymity was also discussed (*"I think being discreet is the biggest thing. It's something you can do without anyone if you don't feel like you want anyone else to know"* Participant 7). Participants did report a number of concerns about receiving support online. Firstly there were concerns that it would not be accessible to older farmers (*"Maybe they're not gonna be quite so engaged with technology… whereas the younger ones probably are"* Participant 3). Participants also reported that due to rural locations, a lot of farmers have difficulties with their internet connection (*"Some people struggle still with internet connection in rural areas. That would be my only concern"* Participant 7).

3. Usability of LLTTF for Farming Communities

Participants described finding the course easy to use. They reported that the modules were the right length and several participants commented on the usefulness of it being an unlocked design, where participants could pick and choose modules they wanted to complete (*"They were short enough to be able to go in and do one course and come back out. You could dip in and dip out. I think if they were any longer it would have put you off… and you didn't have to do them in any order you could do whichever ones you chose sort of when"* Participant 1). In terms of suggested improvements that could be made to the

course, a number of participants reported that the layout of the website could be clearer (*"When I first logged in and I looked at the screen and I saw like the three boxes at the top and I thought "oh ok, right, which one do I click first?" It wasn't just 101% clear…where do I click just to get me started?"* Participant 1). Participants wanted to be able to download some of the modules due to difficulties with their internet connection (*"So you can look at them at your leisure rather than being on the internet, being stuck in the countryside with low internet speed is a bit of a pain"* Participant 2). Participants also described wanting the flexibility to be able to access the e-books and worksheets in a variety of formats such as in print and/or editable pdfs, and on a variety of technological devices.

4. Content of LLTTF for Farming Communities

Participants found it helpful learning how to deal with negative thoughts (*"The things about negative thoughts, don't let negative thoughts get you down. That was quite an important one to me"* Participant 1), problem-solving (*"You come away and you think "well actually I can do that, I can break it down into smaller chunks and deal with a little bit of a problem at a time and it will help" and half the problem goes away because you realise that you can deal with it"* Participant 6) and self-care (*"The you-time ones, taking time to yourself. Not really things I would have thought about, sort of being a farmer you put yourself to the back of the line so it's all of these things you don't really think about"* Participant 7). Participants reported finding the email support useful, particularly as a motivator to continue accessing the course (*"I thought it was very good and… but for that I wouldn't have tried for as long as I had"* Participant 4). Email was the preferred method of support because of its convenience (*"You can pick it up and put it down as you choose… you don't have to stop what you're doing in the middle of the day to sort out an email do you?"* Participant 6). Participants were happy with the frequency of the support emails (weekly).

Discussion

To the authors knowledge this is the first study to assess the feasibility of offering a cCBT-based course to members of the farming community.

Online advertising was the most successful recruitment method. A recent systematic review indicated that social media can be an effective method for recruiting from hard-to-reach populations (Topolovec-Vranic and Natarajan, 2016) however, it is unclear how representative an online sample is. In 2016, just over 60% of adults in the UK were using social networking sites but only 23% of these were aged 65+ (ONS, 2017b). The current study only recruited 2 participants aged 65+. It would therefore be important to consult older farmers regarding recruitment methods to ensure successful and representative recruitment in the future.

Recruitment to the study was slow. Qualitative findings highlighted that mental health stigma within the farming community may still act as a barrier to help-seeking; a finding supported in the literature (Boulanger et al., 1999). Attrition was significantly higher in the current study (73.2%) compared to research using similar online courses with different populations (range: 26%-27%) (Espie et al., 2012; Hoyle et al., 2013). Adherence to the course was also low and just over half of the participants could not complete activities suggested by the course. While reasons for non-use were not available from participants in this study, the qualitative findings indicated that some farmers may find it difficult to engage with mental health support due to work commitments; a finding supported in the literature (McKay et al., 2012). Indeed, one participant who withdrew from the study did so because of lack of time. Our study indicated that for some, having mental health support online and therefore accessible at any time of the day helps overcome help-seeking barriers but further research is needed to identify ways of supporting farmers who do not feel able to prioritise their mental health. This study recruited a number of participants in the approach to spring; a notoriously busy time for most farmers which may also have impacted on attrition and adherence. However this may also be the time of year when farmers would most benefit from support. Lastly, while all participants recruited in the

study had internet access, the qualitative interviews indicated that a number of participants did not have regular internet access due to connectivity difficulties. It may be that if participants cannot regularly access the course due to poor internet connectivity they lose the motivation to log onto the site.

Participants who completed follow-up measures appeared to be satisfied with the course. The qualitative findings highlighted the importance of anonymity which has been found in previous research (Vallury, Jones and Oosterbroek, 2015). Participants particularly valued the email support which helped motivate them to use the course. This supports previous research indicating that offering support alongside cCBT can improve patient outcomes (Baumeister et al., 2014). One concern about offering an online tool was that it may not be an acceptable delivery method for older people. However, recent research has indicated that the gap in internet use between younger and older age groups in the UK is narrowing: internet use for individuals aged 65-74 years has increased by 26% over the past 6 years, with 78% of those surveyed using the internet (ONS, 2017c).

While the majority of the sample had no or minimal symptoms of depression at baseline (71.4%), most of the sample had some form of anxiety (mild-moderate: 62.5%) and/or functional impairment (mild-severe: 76.8%); therefore representing individuals who would be referred to cCBT in the community. A future study may benefit from expanding the inclusion criteria to include individuals with depression and/or anxiety, given the high rates of both found in the farming community (Sanne et al., 2004). While not the primary focus of this study, the results indicate that it may be worth conducting a larger, adequately powered study in the future using the intervention, as it is possible that it may reduce symptoms of anxiety and depression over time.

There are a number of limitations to this study. The small sample size, inclusion of farmers without depression and the exclusion of a control group makes it difficult to understand whether the trend regarding treatment effect is a true effect or not. A future, adequately powered RCT would help determine the likely clinical effect and acceptability of offering cCBT to farmers with low mood and anxiety. The majority of individuals who

took part in the telephone interviews had completed all 5 modules and as such, may be more likely to report higher levels of satisfaction. Future qualitative studies would benefit from using a sampling frame to ensure that opinions from participants with varied experience of the online course are captured; therefore reducing the chance of bias.

Conclusion

cCBT modified for the farming community may be an effective and convenient way of offering mental health support to individuals who face a number of barriers to help-seeking. However, difficulties in recruiting and retaining farmers may indicate that internet-based mental health support is only an acceptable mode of delivery for some in the community. Retention may be improved by making amendments to the course, for example allowing the course content to be downloaded and therefore available offline. Combining quantitative and qualitative research methods in this study helped gain rich information into the advantages and disadvantages of offering mental health support online. A larger substantive pilot study should be conducted in the future in order to test an updated version of the site, establish participant acceptability of the intervention, test randomisation and extend the current results by looking into the effectiveness and cost effectiveness of offering cCBT to the farming community.

Conflict of Interest

Professor Chris Williams is author of "Living Life to the Full"; the cCBT-based course used in this study. He is a shareholder and director of a company that commercialises this and other resources.

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Chapter 3: Appendices

Appendix 1: Authors guidance for submission to BMC Psychiatry

Guidelines accessed in July 2017 from:

https://old.biomedcentral.com/bmcpsychiatry/authors/instructiohns/researcharticle.

Manuscript Preparation

Manuscripts for Research articles submitted to *BMC Psychiatry* should be divided into the following sections (in this order): title page; abstract, keywords; background; methods; results and discussion; conclusions; list of abbreviations used (if any); competing interests; authors' contributions; authors' information; acknowledgements; endnotes; references; illustrations and figures (if any); tables and captions; preparing additional files.

Title page

The title page should provide the title of the article; list the full names, institutional addresses and email addresses for all authors; indicate the corresponding author. The title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study". Abbreviations within the title should be avoided.

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background,** the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts.

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section. For studies involving human participants a statement detailing ethical approval and consent should be included in the methods section.

Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript. Authors are required to

complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

According to ICMJE guidelines, An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, a department chair who provided only general support, or those who contributed as part of a large collaboration group.

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Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

<u>Endnotes</u>

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

<u>References</u>

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission. Only articles, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Citations in the reference list should include all named authors, up to the first six before adding 'et al.'.

Appendix 2. Example search strategy: EMBASE

1. depression/ or major depression/
2. depress*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
3. low mood*.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
4. (computer* adj2 (cognitive behav* therap* or CBT)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
5. (((computer* or online or internet or mobile* or web* or e?mail or technology* or tablet* or smartphone or phone*) adj2 cognitive behav* therap*) or CBT).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
6. Clinical Trial/
7. Randomized Controlled Trial/
8. controlled clinical trial/
9. multicenter study/
10. Phase 3 clinical trial/
11. Phase 4 clinical trial/
12. exp RANDOMIZATION/
13. Single Blind Procedure/
14. Double Blind Procedure/
15. Crossover Procedure/
16. PLACEBO/
17. randomi?ed controlled trial$.tw.
18. rct.tw.
19. (random$ adj2 allocat$).tw.
20. single blind$.tw.
21. double blind$.tw.
22. ((treble or triple) adj blind$).tw.
23. placebo$.tw.
24. Prospective Study/
25. or/6-24
26. Case Study/

27. case report.tw.

28. abstract report/ or letter/

29. Conference proceeding.pt.

30. Conference abstract.pt.

31. Editorial.pt.

32. Letter.pt.

33. Note.pt.

34. or/26-33

35. 25 not 34

36. 1 or 2 or 3

37. 4 or 5

38. 35 and 36 and 37

39. limit 38 to (english language and english and yr="2007 -Current" and adult <18 to 64 years>)

Appendix 3: Agreed scores on the CTAM for all studies

CTAM Questions	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6	Study 7	Study 8
Q1. Is the sample: convenience (score 2), geographic cohort (score 5), or highly selective (score 0)	0	0	0	0	0	2	0	0
Q2. Is the sample greater than 27 participants in each group (score 5) or based on described and adequate power calculations (score 5)	0	0	5	0	0	0	5	0
Q3. Is there true random allocation or minimisation allocation to treatment groups (score 10)	10	10	10	10	10	10	10	10
Q4. Is the process of randomisation described (score 3)	3	3	0	3	3	0	3	3
Q5. Is the process of randomisation carried out independently from the trial research team (score 3)	3	3	0	3	3	0	3	3
Q6. Are assessments carried out by independent assessors and not therapists (score 10)	10	0	10	10	10	10	10	0
Q7. Are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms (score 3)	6	6	6	6	6	6	6	6
Q8. Are assessments carried out blind to treatment group allocation (score 10)	10	0	10	0	0	10	0	10
Q9. Are methods of rater blinding adequately described (score 3)	3	0	3	0	0	3	0	0
Q10. Is rater blinding verified (score 3)	0	0	0	0	0	0	0	0
Q11. TAU is a control group (score 6) and/or a control group that controls for non-specific effects or others established or credible treatment (score 10)	16	6	16	6	10	10	16	10
Q12. Analysis is appropriate to design and type of outcome measure (score 5)	5	5	0	5	5	5	5	5
Q13. The analysis includes all participants as randomised (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)	6	6	0	6	10	10	6	0
Q14. Was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)	6	6	6	6	6	6	6	6
Q15. Was adherence to the treatment protocol or treatment quality assessed (score 5)	5	5	5	5	5	5	5	5
Total = max 100	83	50	71	60	68	77	75	58

Appendix 4: Advert example

Do you or a member of your household work in farming or crofting?

Low mood? Stressed out? Anxious? Worried? Mind racing? Can't be bothered doing things? Feeling overwhelmed? Lost your confidence?

Do you feel like this?

Would you be interested in taking part in a research project of a new online resource designed specifically to help farmers and crofters who are experiencing low mood, stress or worry?

Find out more at:

www.farmerstress.com or email us us directly at: *info@farmerstress.com*

Appendix 5. Participant information sheet

An online CBT-based life skills course for the farming community: a feasibility study

You are being invited to take part in a research study. Before you make a decision, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information (contact details at the end).

What is the purpose of the study?

Low mood and anxiety are experienced by lots of people throughout their lifetime. Research indicates that farmers and crofters may be particularly vulnerable to these difficulties and that they may not want to, or be able to access formal health care services for support. The current study is investigating the usefulness of providing farmers and crofters with an online course that teaches key life skills based on Cognitive Behavioural Therapy. Research suggests that online life skills training can help with low mood and anxiety, and that it works best if it is relevant to the people that are using it. That's why this project has been designed specifically for farmers and crofters.

The aim of the telephone interview is to gain detailed feedback about what people thought about the online CBT-based life skills course for farmers and crofters. This will help us improve the online course for future users.

What does the online course include?

The course aims to help farmers and crofters learn a variety of practical life skills in order to help improve symptoms of low mood and anxiety. Modules focus on: problem solving; improving confidence and mood; and challenging negative thoughts. Weekly automated emails also accompany the course. Once participants agree to take part in the study, they will be asked to complete some questionnaires, which they will complete again once they have finished the course.

Why have I been chosen?

This project is being offered to farmers and crofters over the age of 18 years, who are willing to use and evaluate the online course.

What happens next?

If you agree to participate in the study, you will be asked to complete a consent form and a brief questionnaire asking for more information about yourself such as: your age; date of birth; gender; education; and employment status. You will also be asked to complete three brief questionnaires that will focus on your mood. Your responses to these questionnaires will help us establish whether you are suitable for this research study.

What will happen to me if I decide to take part?

Eligible participants will be provided (via email or post) with the website address of the online course and full instructions on how to use the site. The contact details of the research team will be provided should participants need any technical support.

Participants will be offered up to four short telephone or email contacts with one of the researchers, who will be able to help with any questions participants may have about the course. All contacts will be recorded in a contact log, with details of the time and length of the contact and any topics that were discussed.

After eight weeks, all participants will be asked to complete the three brief questionnaires that they completed at the start of the study and a brief questionnaire focusing on what they thought of the online course.

If you agree to take part in the telephone interview a member of the research team will telephone you at an agreed time within 1 month of completing the online life-skills course. The researcher will ask whether you are happy for the interview to be audio recorded so that they can keep a record of your answers. The researcher will ask you what you can remember about the online course and what you liked and disliked about it.

The interview is expected to last between 30-45 minutes. The audio recordings will be written out, and any personal details (such as your name) will be removed and then the recording will be deleted. Any quotes used when we report our finding will never identify any of our participants by name, nor will we share your answers with anyone outside of the research team.

If you do not wish to have your telephone conversation audio-recorded, you can still take part in the study and the interviewer will take notes during your conversation.

Do I have to take part?

You do not have to take part. If you do decide to take part, you are able to withdraw at any time, without giving a reason.

What are the possible benefits of taking part?

By working through the modules within the online course, it is hoped that you will learn practical life skills that you can use if you experience symptoms of low mood and/or anxiety. This will also provide us with an opportunity to establish how effective the online course is in improving these symptoms in farmers and crofters. Your feedback on what you thought about the online course will help us improve the course so that it is more suitable to other farmers and crofters experiencing symptoms of low mood and/or anxiety. If you decide to take part in the telephone interview we will provide you with a £5 Amazon gift voucher to compensate you for your time.

What are the possible disadvantages and risks of taking part?

While most people do not mind answering questions about low mood and anxiety, some people may feel upset. It is important that we ask these questions in order to find out if the online course is effective. Sometimes when people find out more about low mood and anxiety they can feel worse to start with. However, this is usually just for a short time and most people feel better again quite quickly as they work through online courses like this one.

What if I need more support?

As always, additional support is available via your GP, NHS 24 or telephone support services such as The Samaritans or Breathing Space. Additional information is also available on the website.

Will my taking part in this study be kept confidential?

The information you give is entirely confidential and will not be disclosed to anyone outside the immediate research team without your permission.

All the information collected will be stored securely according to the Data Protection Act 1998.

What will happen to the results of the research study?

The results of the research will be written up but participants will not be identifiable. These will be written up as part of a doctoral thesis and also submitted to a scientific journal. We may also present our findings at scientific conferences. A copy of the results can be sent to you if you wish.

Who is organising and funding the research?

This project is being organised and funded by the Institute of Mental Health and Wellbeing at the University of Glasgow.

Who has reviewed the study?

This study has been reviewed and approved by the College of Medical, Veterinary & Life Sciences Ethics Committee at the University of Glasgow (ref: 200160003).

More information about the study is available from:

Researcher: Ms Harriet Bowyer

                           Trainee Clinical Psychologist

Email: info@farmerstress.com

Website: www.farmerstress.com

Postal address: Mental Health and Wellbeing

                        Administration Building

                        Gartnavel Royal Hospital,

                        1055 Great Western Road,

                        Glasgow,

                        G12 0XH

Thank you for taking the time to read this and for thinking about participating in the study!

Appendix 6. Consent Form

<u>Title of Project</u>: An online CBT-based life skills course for the farming community: a feasibility study.

Name of Researchers: Harriet Bowyer & Chris Williams.

Please read the following statements carefully before checking each box.

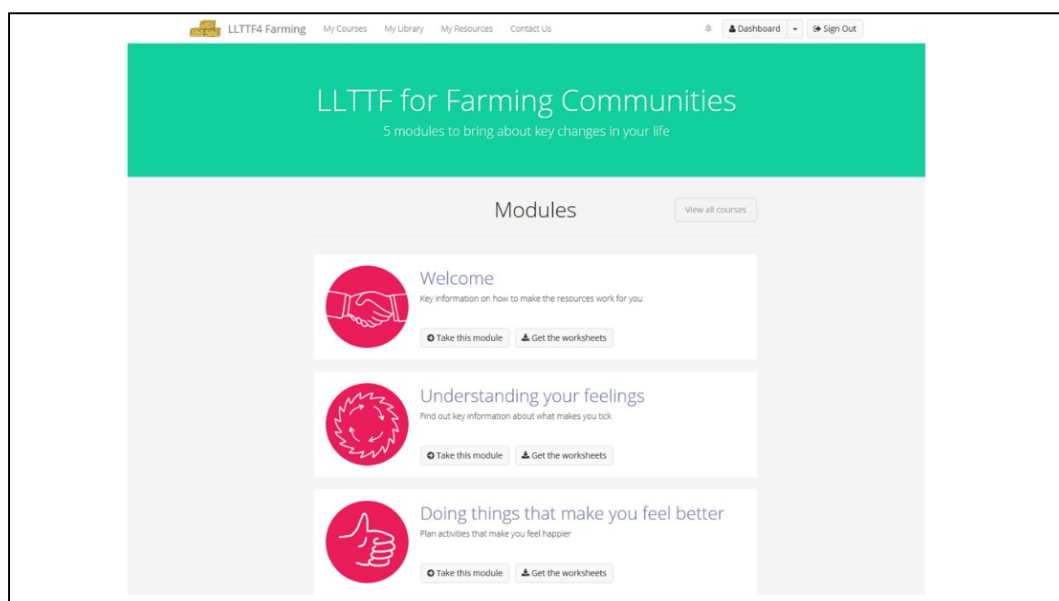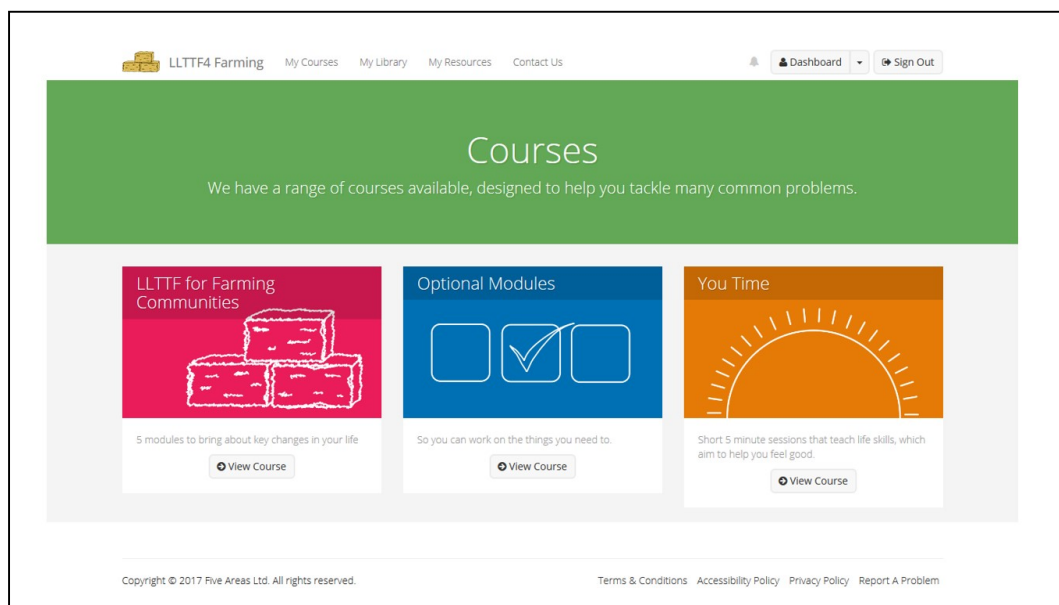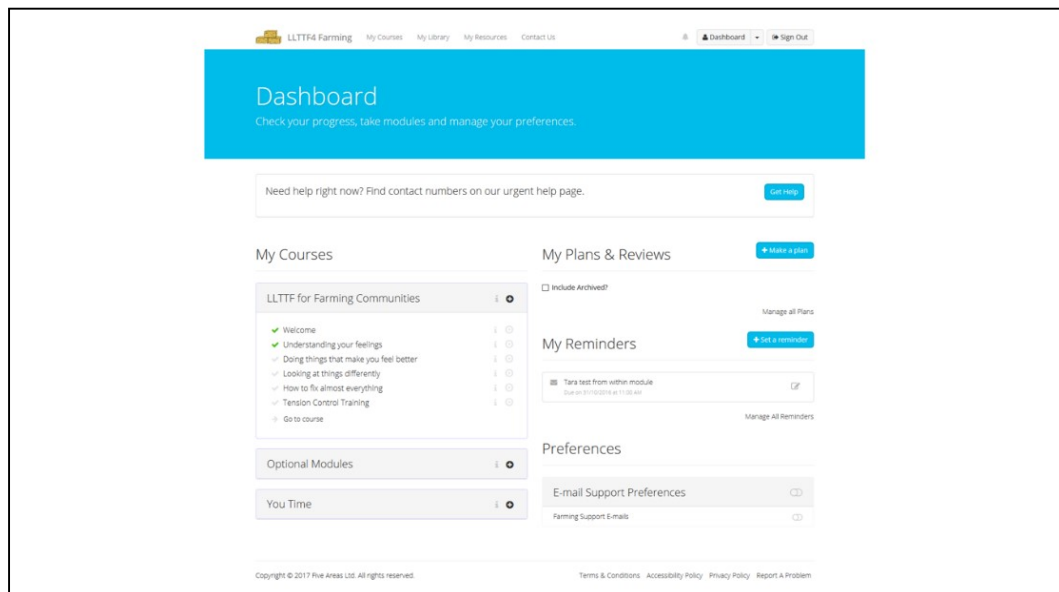Checking the boxes below indicates consent – all boxes must be checked.

1. I confirm that I have read and understood the participant information sheet for the above study and have had the opportunity to contact the researchers to ask questions   ☐

2. I confirm that I have had sufficient time to consider whether or not I want to be included in the study   ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason   ☐

4. I agree that the information I give will be kept if I am not eligible for the study   ☐

5. I understand that additional supports are available for problems such as distress   ☐

6. I agree to give correct details for my GP and for the research team to use these to contact my GP if they are concerned about my wellbeing   ☐

7. I understand that my information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act (1998)   ☐

8. I agree to take part in the above study   ☐

In order to participate in the research study, **all boxes above** must be checked.

In addition to the above, if you would like to participate in a telephone interview at the end of study please read the following statements carefully before signing in the box below.

9. I understand that the telephone interview will be audio recorded and I agree for anonymous direct quotes to be used alongside findings from the research in publications and reports as detailed in the information sheet.   ☐

10. I understand that my information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act (1998)   ☐

11. I agree to take part in the telephone interview   ☐

Appendix 7. Example screenshots from the course

Appendix 8. Standardised email template used to guide email support

Hi, my name is Lauren Manual, I am a Trainee Clinical Psychologist based at the University of Glasgow. My role is to support and encourage you while you work through the online course. You may find that some tasks are difficult or you lose motivation so I am here to help.

Have you managed to register and log on to the website?

How have you been doing? Did you find the first module helpful?

It is important to complete one module a week to keep up momentum and improve how you feel. The Planner and Review sheets can be extremely helpful and it is important that you make a clear plan at the end of each module for what you would like to try and achieve in the coming week. There are some instructions on how to use them in the Welcome module. Writing a plan down will help you achieve your goals.

Please do use me as a resource to help you get the most out of the course. I am here to help and all correspondence will be kept confidential within the research project, unless I am seriously concerned about your wellbeing.

I look forward to hearing from you.

Kind regards,

Lauren

Appendix 9. Demographic questionnaire

ABOUT YOU		
Name:		
Email address:		
Telephone number:		

Age

18-24	☐	45-54	☐
25-34	☐	55-64	☐
35-44	☐	65+	☐

Gender

Male	☐	Other (please specify):	
Female	☐	……………………………….………………	

Ethnicity

White	☐	Black	☐
Asian	☐	Mixed	☐
Other (please specify): ………………………………………			

Religion

None	☐	Hindu	☐
Buddhist	☐	Jewish	☐
Muslim	☐	Sikh	☐
Christian	☐	Other (please specify): ..…………………....	

Marital status

Single	☐	Divorced	☐
Married	☐	Widowed	☐
Living with partner	☐	Rather not say	☐

How many children under 16 live in your household?

0	☐	2	☐
1	☐	3+	☐

Current employment status

Full-time	☐	Student	☐
Part-time	☐	Unemployed	☐
Self-employed	☐	Retired	☐
Other (please specify: ………………………………………………………....			

Principal occupation

Farming	☐	Crofting	☐
Other (please specify): ………………………………………………………....			

Main Business Type

Beef	☐	Horticulture	☐	Poultry	☐
Combinable Crops	☐	Pigs	☐	Sheep	☐
Dairy	☐	Potatoes	☐	Vegetables	☐
Fruit	☐				

Alcohol Consumption (units per week)

One unit of alcohol is: half a pint of beer/lager/cider; 1 small glass of wine/sherry; or 1 single measure of spirits/aperitifs

None	☐	15-21	☐	35-41	☐
1-7	☐	22-28	☐	42-49	☐
8-14	☐	29-34	☐	50+	☐

Please turn over →

WORKING AS A FARMER OR CROFTER		
Location of farm or croft		
Large urban area (125,000+ people) ☐	Remote small town (3,000-9,999 & over a 30 minute drive to an urban area)	☐
Small urban area (10,000-124,999 people) ☐	Accessible rural area (less than 3,000 people & within a 30 minute drive to an urban area)	☐
Accessible small town (3,000-9,999 people & within a 30 minute drive to an urban area) ☐	Remote rural area (less than 3,000 people & over a 30 minute drive to an urban area)	☐

How would you best describe yourself?	
Holder/owner ☐	Labourer ☐
Manager ☐	Other (please specify): ……..………………..
Contractor ☐	

Do you have any employees?
Yes ☐ No ☐
If yes, how many (please specify): **………………………….…..………………………**

Time spent on farming/crofting work on the holding	
Less than 3 months a year ☐	9-11 months a year ☐
3-5 months a year ☐	Full working year ☐
6-8 months a working year ☐	

Time spent on farming/crofting work each day	
Less than 4 hours a day ☐	8.5-10 hours a day ☐
4-6 hours a day ☐	10.5-12 hours a day ☐
6.5-8 hours a day ☐	12.5+ hours a day ☐

YOUR MENTAL HEALTH
Have you experienced any mental health difficulties in the past?
Yes ☐ No ☐

Have you received any mental health support in the past?
Yes ☐ No ☐

Are you currently receiving any mental health support (e.g. from a Psychologist, Counsellor)?
Yes ☐ No ☐
If yes, who are you receiving mental health support from? (please specify) ……………………………………………………………………………………..

If yes, would you mind telling us what you are you receiving mental health support for? (please specify):
………………………………………………………………………………………………

Are you taking any medication to support your mental health?
Yes ☐ No ☐

YOUR INTERNET USE			
Do you have access to the internet?			
Yes ☐		No ☐	
How long have you been using the internet?			
Less than one year ☐		4-6 years ☐	
1-3 years ☐		7+ years ☐	
How often do you use the internet?			
Everyday ☐		Once a week ☐	
2-3 days a week ☐		Once a month ☐	
4-6 days a week ☐		A few times a year ☐	
Which device do you primarily use to access the internet?			
Desktop PC ☐		Tablet ☐	
Laptop ☐		Smartphone ☐	
Other (please specify): ………………………………………………………………			
How did you hear about this research?			
National Farmers Union Scotland (NFUS) ☐		Stirling Livestock Auction ☐	
Royal Scottish Agricultural Benevolent Institute (RSABI) ☐		Leaflets ☐	
Farming Community Network (FCN) ☐		Word of mouth ☐	
Other (please specify) ………………………………………………………………..			
Please provide us with the name, address and contact number of your GP:			
GP name:	………………………………………………………………………		
GP address:	………………………………………………………………………		
GP telephone number:	………………………………………………………………………		

Thank you very much for completing these questions. Someone from the research team will be in touch with you by email within three working days.

Appendix 10. Additional questions regarding use of and satisfaction with the course.

How often did you access the "Farmer Stress" course?			
Daily	☐	Monthly	☐
Several times a week	☐	Less than monthly	☐
Weekly	☐	Not at all	☐
2-4 times per month	☐		

Did you complete the core modules of the course?			
Yes ☐		No ☐	

While modules did you access?			
Welcome module	☐	Looking at things differently	☐
Understanding your feelings	☐	How to fix almost everything	☐
Doing things that make you feel better	☐	Tension Control Training	☐

Did you access any of the following additional modules?			
Asking for what you need	☐	Stop smoking in 5 minutes	☐
The things you do that mess you up	☐	Eat well	☐
Facing fears	☐	The things you do that help	☐
Fix your drinking	☐	What about sex?	☐
Getting a better night's sleep	☐	You, me and us	☐
Irritability and anger	☐	Planning for the future	☐

What did you think about the web course?					
	Strongly disagree	Slightly disagree	Neither agree or disagree	Slightly agree	Strongly agree
I found the course helpful	☐	☐	☐	☐	☐
I found the course easy to access	☐	☐	☐	☐	☐
I was able to do the activities suggested by the course	☐	☐	☐	☐	☐
I found the email support helpful	☐	☐	☐	☐	☐

Appendix 11. Telephone interview schedule

<u>INTRODUCTION:</u>

- Thank you for your participation.
- We would like you to give us some feedback about what you thought of the online life skills course for farmers, as this is the first time it's been delivered.
- This interview is an opportunity to be involved in making changes to the course; we want to hear about the good and bad points about the course.
- Honest opinions are important – my role is just to evaluate the course; I do not have any direct involvement with the course, so do not worry about any comments you make.
- Comments are confidential.
- We are audio-recording the interview so we will have a more accurate account of the feedback – this will be transcribed and anonymised so that no-one can work out who said what.

<u>ACCEPTABILITY OF THE COURSE</u>:

- What was your overall impression of the life skills course?
- What was your favourite part of the course?
    - o What did you like about it?
- What didn't you like about the course?
    - o Why?

<u>ONLINE SETTING:</u>

- The course was delivered online – what did you think about this?
- Where do you think the best place is for farmers to complete a course like this?
- Did you speak about the course to others in your life, e.g. at home?
    - o If yes, what sort of things did you talk about?

<u>COURSE CONTENT:</u>

- What did you think about the modules?
    - o Did you understand the content?
    - o If no, which bits were hard to understand and would anything make it easier to understand?
    - o What about the length of each module: too long; too short; just right?
- Are there any topics you would add/take away from the course?
- Are there any modules you would make changes to?
    - o Any other changes you would make to the way the course is setup?

- Do you think the course was relevant for all farmers?
    - Does the course miss anyone out?
- Is there anything else we could do to improve the course?
- Do you think this course should continue to be offered to farmers?

THE SUPPORT OFFERED

- What did you think of the format it was offered in (email)?
    - Do you have a preferred method of being supported: email/phone/message in dashboard on research site
- What did you think of the frequency of support?
- Who would you prefer instigated the support: yourself or the researcher?
- What was helpful/unhelpful about the support?

APPLICATION OF LEARNING:

- How would you describe the online life skills course to a friend?
- Overall, do you think the course has helped you in any way?
    - If so, how? What helped in particular?
- Were any of the skills or topics particularly relevant or helpful for you?
- Have you, or anyone you know, used any of the skills or ideas from the online course?
    - If yes, which ones? Examples?
- How do you think that you might use these skills in the future?
- What is the top thing, if any, that you learned from the course?
- Would you recommend it to a friend?
    - Why/why not?
- Would you work through the online course again?
    - Why/why not?

FEASIBILITY OF THE RESEARCH STUDY:

- What did you think of the length / content of the questionnaires – did they make sense?
- Did you feel you had enough communication with the research team?
- What would you have changed about the research?
- What would encourage you take part in research like this again?

Finally, is there anything else you would like to say about the online course that we haven't talked about?

Thank you very much for telling us your thoughts about the life skills course for farmers.

Appendix 12. Copy of ethical approval letter

University of Glasgow

MVLS College Ethics Committee

Project Title: An online CBT-based life skills course for the farming community: a feasibility study
Project No: 200160003

Dear Professor Williams,

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project.

- Project end date: End August 2017

- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)

- The research should be carried out only on the sites, and/or with the groups defined in the application.

- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.

- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely,

Jesse Dawson
MD, FRCP, BSc (hons), MBChB (hons)
Clinical Reader / Honorary Consultant

Chair MVLS Ethics Committee
College of Medicine, Veterinary & Life Sciences
Institute of Cardiovascular and Medical Sciences
Western Infirmary
Glasgow
G11 6NT
jesse.dawson@glasgow.gla.ac.uk
Tel – 0141 2116395 or page 4824

Appendix 13. Supplementary analysis for those that did and did not complete follow-up questionnaires

Table 1. Demographic characteristics of the sample

| | Total | Completed follow-up | | x^2 |
| | | Yes | No | p-value[a] |
Categorical Variables	(n=56; %)[a]	(n=15) %	(n=41) %	
Age				
18-24	1 (1.8)	-	1 (2.4)	
25-34	6 (10.7)	3 (20.0)	3 (7.3)	
35-44	16 (28.6)	3 (20.0)	13 (31.7)	
45-54	19 (33.9)	3 (20.0)	16 (39.0)	
5-64	12 (21.4)	4 (26.7)	8 (19.5)	
65+	2 (3.6)	2 (13.3)	-	
Gender				.072
Male	43 (76.8)	9 (60.0)	34 (82.9)	
Female	13 (23.2)	6 (40.0)	7 (17.1)	
Marital Status				
Single	6 (10.7)	1 (6.7)	5 (12.2)	
Married/Living with partner	44 (78.6)	12 (80.0)	32 (78.0)	
Separated/Divorced	5 (8.9)	1 (6.7)	4 (9.8)	
Widowed	1 (1.8)	1 (6.7)	-	
Farming type				
Beef	10 (17.9)	2 (13.3)	8 (19.5)	
Combinable crops	15 (26.8)	2 (13.3)	13 (31.7)	
Dairy	5 (8.9)	3 (20.0)	2 (4.9)	
Pigs	3 (5.4)	2 (13.3)	1 (2.4)	
Potatoes	3 (5.4)	1 (6.7)	2 (4.9)	
Poultry	1 (1.8)	-	1 (2.4)	
Sheep	13 (23.2)	5 (33.3)	8 (19.5)	
Mixed farming	6 (10.7)	-	6 (14.6)	
Time spent on the farm per day				.916
Less than 4 hours	6 (10.7)	2 (13.3)	4 (9.8)	
4-6 hours	3 (5.4)	1 (6.7)	2 (4.9)	
6.5-8 hours	10 (17.9)	2 (13.3)	8 (19.5)	
8.5-10 hours	15 (26.8)	3 (20.0)	12 (29.3)	
10.5-12 hours	14 (25.0)	4 (26.7)	10 (24.4)	
12+ hours	8 (14.3)	3 (20.0)	5 (12.2)	
Past Mental Health Problem				.921
Yes	33 (58.9)	9 (60.0)	24 (58.5)	
No	23 (41.1)	6 (40.0)	17 (41.5)	
Currently on medication				.307
Yes	14 (25.0)	2 (13.3)	12 (29.3)	
No	42 (75.0)	13 (86.7)	29 (70.7)	
Experience using the internet				
1-3 years	2 (3.6)	-	2 (4.9)	
4-6 years	7 (12.5)	3 (20.0)	4 (9.8)	
7+ years	47 (83.9)	12 (80.0)	35 (85.4)	
Continuous Variables	**Mdn (IQR)**	**Mdn (IQR)**	**Mdn (IQR)**	
PHQ-9	7 (4 – 11)	8 (4 - 12)	7 (4 - 11)	.623
GAD-7	6 (2 – 9)	6 (2 - 13)	6 (3 - 9)	.516
WSAS	9 (4 – 12)	9 (4 - 14)	12 (10 - 20)	.185

[a]Fisher's-exact test used for cell counts <5; no test of significance for variables with cell counts <1

Appendix 14. Sensitivity analysis for change in measures over time for participants with PHQ-9 ≥ 5

Table 2. Change in secondary outcome measures over time for participants with PHQ-9 ≥ 5

	Baseline Mdn (IQR)	Follow-up Mdn (IQR)	Significance p-value[a]
PHQ-9	8 (6 - 14)	8 (5 - 9)	.132
GAD-7	9 (5 - 14)	9 (4 - 11)	.035
WSAS	11 (9 - 16)	10 (7 - 13)	.406

Appendix 15. MRP Proposal

Title of project: An online CBT-based life skills course for farmers: a feasibility study

Matriculation number: 2126853

Date of submission: 16.05.2016

Version number: 4

Word count: 3290

Abstract

Background

In the UK, farmers have the highest rates of suicide of all occupations; with high rates of depression found in farmers who have completed suicide. Research has identified several barriers to help-seeking in farmers; highlighting that the internet may be a more acceptable way of offering psychological support. Computerised Cognitive Behaviour Therapy (cCBT) is a recommended treatment for mild to moderate depression, but to date no research has looked at the impact of offering farmers cCBT.

Aims

To investigate the feasibility of delivering an online CBT-based life skills intervention to farmers experiencing depression.

Methods

Approximately 50 farmers experiencing mild to moderate depression will be recruited. Treatment will consist of access to an online CBT-based life skills course called 'Living Life to the Full' (Williams, 2009) which consists of 8 modules modified for farmers. Depression, anxiety and social functioning will be measured using questionnaires at baseline and upon course completion (12-weeks). The aims are to: test ability to recruit; gather questionnaire data online, by email or by post; deliver and support the online course; and retain participants in the research.

Applications

The results of this study will help inform the design of a future substantive Randomised Controlled Trial and add to the literature regarding psychological interventions aimed at farmers.

Introduction

There are currently approximately 139,000 UK farmers (Office for National Statistics, 2015), with the farming industry playing a significant role in the British economy; earning £5.5 billion in 2013 (Department for Environment, Food and Rural Affairs, 2013). In the UK, farmers have the highest rates of suicide compared to any other occupation (WHO, 2010), with high rates of depression found in farmers who have completed suicide (Hawton, Simkin, Malmberg et al. 1998). A variety of stressors may place farmers at increased risk of mental health difficulties: financial concerns and working conditions (Gregoire, 2002); extreme weather and threats to crops and livestock; and social, cultural and geographical isolation (Kolstrup, Lallioniemi & Lundqvist et al, 2013).

Research has highlighted several barriers to help-seeking in farmers: having limited knowledge about and poor recognition of, mental health difficulties (Hawton, Simkin, Malmberg et al., 1998); being reluctant to admit to experiencing mental health difficulties (Boulanger, Deaville, & Randall-Smith et al., 1999); having significant demands at work and having poor access to physical and mental health services (McKay, Milner, & Kolves et al., 2012). In line with this, Peck and colleagues (2002) looked at psychological distress in 80 farmers after the foot-and-mouth crisis in 2001 and found that only 1.5% sought help from healthcare professionals. However, when looking at alternative forms of offering psychological support, farmers indicated that they would be willing to attend self-help groups (38%), read printed advice (45%) or use telephone or internet helplines (25%).

One way of tackling barriers to help-seeking is to offer farmers mental health support online. There is an increasing evidence base for Computerised CBT (cCBT; Andrews, Cuijpers & Craske, et al., 2010), with cCBT recommended by the National Institute for Health and Care Excellence for treating mild to moderate depression (NICE, 2009). To the author's knowledge, no studies have looked at the efficacy of offering any psychological talking therapies to farmers. This feasibility study will look at the feasibility of

an online CBT-based life skills course for mild to moderate symptoms of depression, with information tailored to the farming community and support/guidance provided.

Aims & Hypotheses

The aim is to test key components of the research process by answering the following research questions:

- What is the most effective method of recruiting farmers experiencing depression to the current study?
- What are the demographics of those recruited to the study?
- How much of the online life skills course do participants complete?
- How acceptable is the online life skills course?
- What are the questionnaire completion rates at baseline and 12-week follow-up?
- What is the likely clinical effect of the intervention, as measured by scores on the Patient Health Questionnaire-9 (PHQ-9) over time?
- How many participants would be needed for a sufficiently powered future Randomised Controlled Trial (RCT)?

Plan of investigation

Participants

Participants will be farmers experiencing mild to moderate symptoms of depression who respond to advertisements for a modified CBT-based online life skills course, which aims to reduce symptoms of depression in farmers.

Inclusion and Exclusion Criteria

Eligible participants will be farmers aged 18 or over, who receive a score of 5 or more on the PHQ-9 (Kroenke, Spitzer & Williams, 2001). Exclusion criteria will be individuals who (1) do not complete a consent form (2) are considered to have severe depression (as indicated by a score of 20 or above on the PHQ-9) (3) consume more than double the

weekly sensible alcohol limits (men: more than 50 units of alcohol/week; women: more than 35 units of alcohol/week; NHSGGC, 2015) (4) are currently receiving psychological treatment.

Recruitment

A variety of recruitment methods will be tested. The Royal Scottish Agricultural Benevolent Institution (RSABI) and the National Farmers Union of Scotland (NFUS) have expressed an interest in supporting the study. This will likely be in the form of advertising the study on their website and/or social networking pages. We will aim to: distribute flyers about the study at the Stirling Livestock Auctioneers; offer interviews to farming magazines such as "Farmers Weekly" and "Farmers Monthly"; and approach local radio stations and other farming charities/support networks for support.

Measures

The primary outcome measure will be the ability to recruit into the study and gather outcome questionnaires at baseline and follow-up.

Secondary measures will be self-reported depression, anxiety, social functioning and intervention satisfaction/acceptability. Depression (the likely primary outcome in any future substantive RCT) will be measured using the PHQ-9. Research has found high rates of co-morbidity between depression and anxiety (Brown, Campbell, Lehman et al., 2001) and depression and impaired social functioning (Hirschfeld, Montgomery, Keller, et al., 2000). Self-reported anxiety will be measured using the General Anxiety Disorder 7 (GAD-7; Spitzer, Kroenke, Williams & Low, 2006); and social functioning will be measured using the Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear et al., 2002). Intervention satisfaction/acceptability will be assessed using the Client Satisfaction Questionnaire (CSQ-8; Larsen, Attkisson & Hargreaves, et al. 1979) combined with some additional usage and acceptability questions. The PHQ-9, GAD-7, WSAS and CSQ-8 are

well validated and widely used (Kroenke, Spitzer, & Williams, 2001; Löwe, Decker, Müller et al., 2008; Mundt, Marks, Shear et al. 2002; Attkisson & Zwick, 1982).

Design

All advertisements will contain an internet link to a study website providing the participant information sheet, consent form and a baseline questionnaire pack consisting of: a demographic questionnaire; the PHQ-9; the GAD-7; and the WSAS. The demographic questionnaire will also ask individuals how they heard about the study in order to inform future research on effective ways to recruit farmers. The information sheet will describe: the purpose of the study; the content of the online course; and the study process i.e. the completion of baseline and follow-up questionnaires. Participants will be offered the option of receiving all study materials by post. An individual's right to withdraw at any point will be highlighted and they will be provided with the contact details of both the research team and other resources for mental health support (e.g. GP, NHS24, Accident & Emergency, and Samaritans).

The baseline questionnaire pack will establish whether the inclusion/exclusion criteria have been met. Individuals will be asked to tick boxes to indicate that they have read each piece of information on the consent form, and that they consent to take part in the study. The consent form will ask participants to consent to their GP being contacted if there are concerns about any active risk/s (i.e. if they indicate on their PHQ-9 that they have had thoughts that they would be better off dead or of hurting themselves in some way nearly every day). If these individuals fulfil the inclusion/exclusion criteria they would still be offered access to the study. This avoids rejecting and adding further to a sense of isolation in participants who have reached out for possible help and enables them to receive extra support from their GP if needed, whilst continuing their online learning. A qualitative study may also be pursued in the form of telephone interviews. Participants will

be offered the opportunity to volunteer for this during the consenting process. Consent will be sought to retain initial demographic responses from individuals who are deemed unsuitable for the study. Those deemed unsuitable will also be offered access to the support contacts listed above.

Individuals who meet the inclusion criteria will be provided with a website address and access code to the "Living Life to the Full" (LLTTF; Williams, 2009) research site, with instructions on how to use the site. When working through the course, participants will receive automated support emails weekly to encourage engagement with, and completion of, the course modules. The site allows weekly monitoring of PHQ-9, GAD-7 and WSAS. After 12 weeks, participants will be asked to complete another PHQ-9, GAD-7 and WSAS, and a CSQ-8 with some additional brief satisfaction and use questions focusing on their views of the online course. Participants who consented to take part in a telephone interview will be contacted within 1 month of completing the online course. The telephone interview will last for approximately 30-45 minutes with a sample of participants, aiming to gather information on how they applied skills learnt during the online course, how acceptable they found the course and any recommendations for future use.

If participants do not respond to requests to complete questionnaires at any point they will be sent two reminder emails, take part in one telephone call, and then sent postal questionnaires on one occasion. If any participants wish to withdraw at any point during the study, reasons for doing so will be requested in order to inform future research.

Data Analysis

Descriptive statistics will be used to describe the demographics of the sample, how they were recruited and the secondary outcomes measures, as assessed at baseline, and 12-week follow-up. Paired t-tests will be used to test for any group differences in depression, anxiety and/or social functioning over time. Should the telephone interviews be conducted,

they will be recorded, transcribed and analysed using thematic analysis (Braun & Clarke, 2006) which involves identifying and analysing any patterns that occur between the transcripts.

Justification of Sample Size

A sample size of 30 or greater is recommended for feasibility studies looking at estimating a parameter for use in a sample size calculation (Browne., 1995). Research using similar online courses both online and offline have reported drop-out rates of between 18% and 27.1% (Grover, Williams & Eisler et al., 2010; Hoyle, Slater & Williams et al., 2013; Espie, Kyle, & Williams et al., 2012). This study will therefore aim to recruit 50 participants in order to retain 30 participants for analysis. If the telephone interviews are conducted, approximately 13 participants will be contacted, as recommended (Francis, Johnston, & Robertson et al., 2010).

Settings and Equipment

This study will use a modified research version of LLTTF. Topics and modules will be modified in order to be relevant and of interest to farmers, the content of which will be informed by qualitative research undertaken by another researcher, as part of separate research project. The course consists of modules which teach life skills to individuals with mild to moderate mental health difficulties using a CBT framework. Each module consists of a slideshow presentation guided by audio and downloadable worksheets and online books. Individuals can choose to work through all of the modules in sequence, in their own preferred order, or can just work through the modules that they think are most relevant to them.

An email account will be set up in order to send links, reminders and support emails to participants throughout the study. Data collected from surveys will be hosted through the secure survey site "Survey Monkey", where participants preferring to receive electronic

links to questionnaires can enter their responses. Postal responses can be entered onto this site by the lead researcher. All data collected (electronic and postal) will be stored in line with University of Glasgow policy on password-protected computers and computer files, and in locked filing cabinets.

Health and Safety Issues

There are no health and safety issues foreseen for the researcher. Details and procedures of any potential health and safety issues for participants can be found in Appendix 2.

Ethical Issues

Information about the study will be given to participants before they consent to take part. Those who do not agree to enter the study or fail to meet inclusion criteria will be signposted to other mental health support services. We will request GP details and obtain consent to contact the GP if we are concerned for the health and wellbeing of any participant. Individuals excluded from the study due to severe depression, levels of alcohol consumption and/or failing to provide consent to GP contact in the event of concern will be provided with the above contact details and encouraged to discuss their difficulties with their GP to gain appropriate support.

All participants will be allocated a unique identifier in order to retain anonymity with regards to their questionnaire data. Email addresses, postal addresses and telephone numbers of participants will be obtained. These will be stored on a University of Glasgow computer in a password-protected file and will be kept separately from the participant's unique identifier. Ethical approval will be sought from the University of Glasgow College of Medical, Veterinary and Life Sciences Ethics Committee.

Financial Issues

This study will require no specialist equipment; participants will be able to access the online CBT course from their own homes.

- *Travel*: 3 x return journeys to Stirling Livestock Auctioneers (total of 192 miles at a rate of 45p/mile = £86.40) & one journey to RSABI/NFUS meeting in Edinburgh (84 mile return journey at a rate of 45p/mile = £37.80)

  Questionnaires: all questionnaires are freely available for research use online except the CSQ-8 - copies of which are already available via Professor Williams

- *Amazon vouchers:* to compensate for the time participants give to take part in the qualitative interviews (12 people x £5 = £60)

- *Cost of postal questionnaires* if used: including printing, envelopes, labels, stamps, prepaid envelopes (£52.26 based on 15 participants requesting this route to data return)

- *Advertising costs*: the majority of participant's recruitment will be done through free advertising on websites etc. However we may need to advertise the study using flyers/posters, estimated to cost approximately £7.56 (100 coloured flyers/posters).

- *Total*: £244.02

See Appendix 3 for further details on equipment and costings.

Timetable

May 2016: Submit final MRP proposal

June 2016: Submit ethics proposal

Summer 2016: Development of online course

Autumn 2016: Commence participant recruitment and data collection

Spring 2017: End data collection – it is anticipated the study will take approximately 4 months to recruit sufficient participant numbers and ensure that they have had sufficient time to complete the online course and outcome measures.

May-July 2017 – Data analysis and write up

End of July 2017 – Submit MRP

September 2017 – Viva examination

Practical Applications

It is anticipated that the results of this study will help to inform the design of a future substantive randomised controlled trial and add to the literature with regards to interventions aimed at reducing psychological distress experienced by this vulnerable group.

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Appendix 1: Plain English Summary

Title

An online CBT-based life skills course for farmers: a feasibility study

Background

In the UK, farmers are more likely to complete suicide compared to individuals in any other occupation. Research has shown that farmers struggle to seek help and that self-help groups and/or internet helplines may be more useful ways of offering them psychological support. To date, no research has explored how helpful offering a psychological therapy online may be for farmers.

Aims

This study aims to examine how possible it is to deliver an online psychological therapy to farmers. It will use an existing widely used course which will be altered to include information relevant to farmers. It aims to improve low mood, anxiety and the ability to carry out day-to-day activities.

Methods

Up to 50 farmers experiencing low mood will be recruited via online and magazine adverts. Farmers with very low mood, high levels of alcohol consumption and/or those who are already receiving psychological support will be excluded. Farmers who agree to take part in the study will be provided with a website address and password to access the online course. Farmers will complete questionnaires about their mood, anxiety and their day-to-day activities, at the beginning and the end of the study (at 12 weeks). The questionnaire

scores from the two time points will then be compared to see what effect the course has had on mood, anxiety and day-to-day activities.

Key ethical issues

Participants will be given information about the study before they agree to take part. We will ask them to provide us with details of their GP and sign a form agreeing for us to contact their GP should we become concerned about them at any point during the study. All participants will be given a unique number so that all information stored is anonymous and confidential. Any personal information collected (such as email and postal addresses) will be stored on a University of Glasgow computer in a password-protected file. Ethical approval will be sought from the University of Glasgow.

Impact strategy

The results of the study will add to the evidence-base on psychological therapies that aim to reduce psychological distress in farmers. The data will only be used by the main researcher and supervisor. The study will be written up for publication in a research journal and all participants will be informed of the outcomes of the study.

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Hawton, K., Simkin, s., Malmberg. A., et al. (1998). Suicide and stress in farmers. London: The stationary office.

Word count: 422

Appendix 2: Health and safety form

<div align="center">

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

</div>

1. Title of Project	An online CBT-based life skills course for farmers: a feasibility study
2. Trainee	
3. University Supervisor	
4. Other Supervisor(s)	None
5. Local Lead Clinician	None
6. Participants: (age, group or sub-group, pre- or post-treatment, etc)	Up to 50 farmers aged 18+ experiencing mild to moderate levels of depression. Depression, anxiety and social functioning will be measured at baseline and upon course completion (12 weeks)
7. Procedures to be applied (e.g., questionnaire, interview, etc)	Participants will be given access to an online life skills course called 'Living life to the Full' consisting of 8 modules modified for farmers. Depression, anxiety and social functioning will be measured at baseline and upon course completion (12 weeks) using the following questionnaires: Depression: Patient Health Questionnaire-9 (PHQ-9) Anxiety: General Anxiety Disorder-7 (GAD-7) Social functioning: Work and Social Adjustment Scale (WSAS). Intervention satisfaction/acceptability will be measured upon course completion (12 weeks) using the Client Satisfaction Questionnaire (CSQ-8). A secondary qualitative study may also be pursued in the form of telephone interviews, lasting approximately 30-45 minutes.
8. Setting (where will procedures be carried out?)	Online, accessed within the participants home-setting.
ii) Are home visits involved	N/A
9. Potential Risk Factors Considered (for researcher and participant safety): i) Participants	i) Participants Farmers have the highest rates of suicide compared to any other occupation in the UK and are therefore associated with dangerous/risky

ii)   Procedures
iii)   Settings
	behaviour.
	
	   ii) Procedures
	The study will involve recruiting individuals with mild to moderate mental health difficulties and as such, there is a chance that their psychological distress may increase over the course of the study.
	
	   iii) Settings
	Participants will access the online course from their own home; therefore there are no foreseen safety issues for the researcher.

10. Actions to minimise risk (refer to 9)
 	
    i)   Participants
    ii)   Procedures
    iii)   Settings
	With regards to all safety issues highlighted above, all participants will be provided with contact numbers for the NHS24 (i.e. 111) for non-emergency advice and the contact number for the emergency services (i.e. 999). They will be encouraged to contact these services and their General Practitioner (GP) should they notice deterioration in their mental health. We will request GP details and obtain consent to contact the GP if we are concerned for the health and wellbeing of any participant. Individuals experiencing severe depression and/or alcohol consumption or who do not consent to GP contact in the event of risk will be excluded from the study but will also be provided with the above contact numbers and will be encouraged to contact their GP.

Trainee signature: .... Date: ....

University supervisor signature:..   Date: ....

Appendix 3: Research equipment form

<u>RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES</u>

Trainee………………………………………………………

Year of Course 2nd year…………………….   **Intake Year** 2014…………..

Please refer to latest stationary costs list (available from student support team)

Item	Details and Amount Required	Cost or Specify if to Request to Borrow from Department
Stationary	2 x ream of white paper 1 x ream of coloured paper White paper for printing/photocopying study materials (information sheets, consent forms, questionnaire packs and reminders). Coloured paper to be used to advertise the study.	Subtotal: £6.92
Postage	Freepost letters x 45 –estimated that approximately 15 people may opt to be posted the study materials at baseline and upon study completion and covers any extra postage needed for reminders	Subtotal: £27.90
Photocopying and Laser Printing	Photocopying/laser printing x 500 copies. See 'stationary' section	Subtotal: £25.00
Equipment and Software	None: the University department already hold an account with "Survey Monkey"	Subtotal: £0
Measures	None - most questionnaires are freely available for research use online except the CSQ-8- copies of which are already available via the research supervisor	Subtotal: £0
Miscellaneous	a. Travel to Stirling Livestock Auctioneers on three occasions (total of 192 miles at a rate of 45p/mile) b. One journey to RSABI/NFUS (84 mile return journey at a rate of 45p/mile) c. Amazon vouchers to compensate for the time participants give to take part in the qualitative interviews(12 people x £5 = £60)	a. £86.40 b. £37.80 c. £60 Subtotal: £184.20
Total		£244.02

For any request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium:

Research indicates that farmers are a high-risk, low help-seeking group and as such, we estimate that recruiting participants from the farming community will prove difficult. The majority of the cost estimate is going towards travel to meet face-to-face with farmers/farming charities to improve recruitment to the study. Furthermore, given the pressures and time constraints farmers' face, Amazon vouchers were considered appropriate compensation for taking part in brief telephone interviews.

Trainee Signature………………………………… …   Date………………………

Supervisor's Signature ……………………………..   Date ………………………