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# BMJ Open Novel ACT-based eHealth psychoeducational intervention for students with mental distress: a study protocol for a mixed-methodology pilot trial

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## ABSTRACT

**Introduction** Recent studies have revealed a high prevalence of depression, anxiety and stress symptoms among university students, highlighting an urgent need for preventative measures at low cost to better support often overwhelmed support services.

**Objective** Here we propose a protocol for assessing the feasibility of a randomised controlled trial (RCT) for an online transdiagnostic psychoeducational intervention called 'A Bite of ACT' compared with a waitlist control.

**Methods and analysis** This is an RCT with crossover design involving baseline assessments and two follow-up periods. The primary outcome measure will be the Acceptance Checklist for Clinical Effectiveness Pilot Trials (ACCEPT) for measuring the feasibility of the trial design and methods. Secondary outcomes include measures of well-being, social connectedness, quality of life (EuroQol Five Dimensions), depression, anxiety and stress (Depression Anxiety Stress Scales-21), as well as the process measures: psychological flexibility (Acceptance and Action Questionnaire-Second Version and the Mindful Attention Awareness Scale) and heart rate variability. Analysis will involve calculating descriptive statistics, examining trial feasibility outcomes through ACCEPT, and determining effect size measures to determine the sample size needed in a future trial (if indicated). Qualitative interviews and preliminary health economics analysis will provide additional insights into the feasibility of the intervention and trial methods.

**Ethics and dissemination** This study has been approved by the Department of Psychology Research Ethics Committee in the College of Human and Health Sciences at Swansea University. Dissemination will involve publication in international peer-reviewed journals, presentation of findings at relevant local, national and international conferences, and promotion of study outcomes using social media and other channels for disseminating findings to the wider community.

**Trial registration number** NCT03810131; Pre-results.

## Strengths and limitations of this study

- The study is online (accessible).
- The study is low-cost as it is online and recorded, and the intervention therefore requires no live acceptance and commitment therapist.
- It requires brief intervention, so attrition rate is predicted to be less than other longer acceptance and commitment therapy (ACT) interventions.
- Use of a randomised control will help allow the researchers to measure the efficacy of the ACT intervention.
- It requires brief intervention, so effect sizes may be smaller than other more intensive ACT interventions.

## INTRODUCTION

Depression and suicide are significant and very serious public health concerns.<sup>1</sup> Psychological distress increases morbidity from a host of conditions and increases risk for premature mortality in a dose-response relationship.<sup>2,3</sup> This highlights the importance of tackling such issues early before the adverse downstream effects impact on individuals and society. The effects of loneliness and social isolation associated with being young can contribute to psychological distress, increasing risk of premature mortality, and such risk rivals that associated with traditional risk factors including smoking, obesity, excessive alcohol consumption and lack of physical activity.<sup>4,5</sup>

Systematic reviews of depression and anxiety in university students report prevalence rates ranging from 6% to 96.7%.<sup>6,7</sup> A study on a sample of 1002 students registered at a university-based general practice in the UK reported that 48% of students have high levels of anxiety and 10% have high levels of depression.<sup>8</sup> Other international research

indicates that mental distress in adolescent populations is increasing. For instance, two national US surveys (total number of both surveys=506 820) found that for adolescents aged between 13 and 18, depressive symptoms, suicide-related outcomes and suicide rates have increased between 2010 and 2015.<sup>9</sup> Clinicians heading university counselling centres have reported more case work after 2010 than previous years.<sup>10–12</sup> Specifically, a 30% increase in case loads was reported between 2009–2010 and 2014–2015 at 93 universities in the USA for mood, anxiety and suicidal ideation.<sup>13</sup> A longitudinal study<sup>14</sup> found that psychological distress increases on entering university and does not return to preuniversity levels during candidature. A longitudinal study of student dentists reported that anxiety increases over time from 47% at second year to 67% in the final year.<sup>15</sup>

It has also been reported that 39% of adults (aged 16 and over) diagnosed with anxiety or depression were accessing mental health treatment. This percentage has increased by 15% since 2007.<sup>16</sup> However, a report conducted by the Royal College of Psychiatrists in the UK<sup>17</sup> indicated that only 4% of the student population seek the university counselling services. The report suggested that the counsellors are typically educated to at least degree level in areas such as psychiatric nursing, occupational therapy or social work. The counsellors also work alongside mental health advisers who can seek referrals through liaising with National Health Service (NHS) mental health services and local general practitioners for more serious cases. The report also suggested that one of the problems of NHS services is that these can lead to lengthy waiting times, which can mean the student receives their first appointment during inconvenient times such as during exam or vocation periods. Suggestions which focused on how to improve students' mental health in the UK<sup>18</sup> have determined that student mental health services in the form of counselling are under-resourced and indicated that resources must increase to at least threefold.

Others have called for more innovative approaches by student counselling services and pathways of support.<sup>19</sup> One of the recommendations is that effective therapeutic support needs to be provided even when students are off campus and to increase existing counselling capacity on campus.<sup>18</sup> In addition to one-to-one support, students should also be encouraged to use peer-to-peer support, self-guided help and/or online support.<sup>20</sup> Using eTherapies such as internet or telephone support is becoming increasingly popular, although it is unclear which eTherapies students may benefit from the most.<sup>21</sup>

Several studies have explored the efficacy of using innovative interventions to improve student mental health. One study<sup>22</sup> demonstrated that an acceptance and commitment therapy (ACT) through bibliotherapy improved depression ( $d=1.37$ ), anxiety ( $d=0.89$ ), severe anxiety ( $d=1.37$ ) and stress ( $d=3.00$ ) in moderately depressed, stressed and severely anxious university students. In a recent systematic review, the effectiveness

of mindfulness-based interventions<sup>23</sup> in reducing university medical students' stress, depression, fatigue and burn-out was explored. In the 12 articles reviewed, 4 studies showed improvements in stress, 5 studies demonstrated a reduction in depression, and 1 study showed a reduction in burn-out. In a meta-analysis<sup>24</sup> of 24 studies involving 1431 university students, cognitive, behavioural and mindfulness interventions were effective in comparison with a control group (anxiety standard difference in means, SDM, point estimate,  $-0.77$ ; 95% CI  $-0.88$  to  $-0.58$  for 23 studies; depression SDM,  $-0.81$ ; 95% CI  $-1.49$  to  $-0.13$  for size studies; and cortisol SDM,  $-0.52$ ; 95% CI  $-0.83$  to  $-0.20$  for three studies). In addition to this, another meta-analysis<sup>25</sup> of computer-delivered and web-based interventions (14 trials,  $n=1795$  university students) reported that the interventions—relative to an inactive control—were effective for anxiety (SDM:  $-0.56$ ; 95% CI  $-0.77$  to  $-0.35$ ,  $p<0.001$ ), depression (SDM:  $-0.43$ ; 95% CI  $-0.63$  to  $-0.22$ ,  $p<0.001$ ) and stress (SDM:  $-0.73$ ; 95% CI  $-1.27$  to  $-0.19$ ,  $p=0.008$ ).

ACT, the therapeutic focus of our proposed study, is a transdiagnostic, third-wave cognitive-behavioural therapy (CBT) clinical model that has been shown to be effective in many mental health situations, such as anxiety and depression,<sup>26</sup> stress,<sup>27</sup> as well as in chronic pain settings, where it has been shown to improve the experience of pain, anxiety and depression.<sup>28</sup> It is also pragmatic for researchers and clinicians to use this as much of the materials are freely available to members of the Association for Contextual Behavioral Science (see <https://contextualscience.org>), and it does not require formal clinical training accreditation to practise. Practitioners can use principle-based ACT interventions effectively with limited training in the core theories that underpin this approach.<sup>29</sup>

There have also been specific studies exploring online ACT with university students' mental health. In one study,<sup>30</sup> the impact of an intensive, 7-week, internet-delivered ACT (called iACT) was examined. iACT included a 60 min initial interview, after which a therapist adapted the course to meet the needs of the participant. The intervention reduced stress ( $d=0.54$ ) and depression ( $d=0.69$ ) significantly more than the control group. Another web-based ACT intervention<sup>31</sup> for university students (ACT on college life or ACT-CL) involved a computerised program which the students had to log in to complete various exercises, such as values clarification and goal setting. The information gathered from previous exercises, such as the goals they set, would then be used in later exercises, such as through automated reminders. This study reported improvements in depression ( $d=0.4$ ), ACT knowledge ( $d=1.47$ ), education values success ( $d=0.24$ ) and positive emotions for education ( $d=0.51$ ). In another study of a web-based ACT program<sup>32</sup> for university students (called YOLO, an acronym for 'you only live once'), four 40 min sessions led to improvements in depression, anxiety, stress, well-being and compassion. In yet another ACT web-based intervention for university

students,<sup>33</sup> six sessions lasting up to 45 min (45 min identified through personal correspondence with the first author of this paper) led to significant reductions in distress ( $d=0.66$ ), social anxiety ( $d=0.78$ ), academic concern ( $d=0.62$ ), social well-being ( $d=0.69$ ), depression ( $d=0.50$ ) and general anxiety ( $d=0.47$ ). Finally, another study involving a brief, three-session, web-based and therapist-assisted, acceptance-based behavioural intervention called *Surviving and Thriving During Stress (SATDS)* for university students was conducted. This study used psychoeducation, mindfulness and values-based exercises through 15 min voice files on Qualtrics, and led to improvements in depression ( $d=0.44$ ) and quality of life ( $d=0.52$ ).<sup>34</sup>

There are some key differences in some of the interventions mentioned which are commonly used to treat for these types of disorders. The first, and most widely used, is CBT, a second-wave behavioural therapy which uses a symptom reduction approach of thought reconstruction to reduce disorder symptoms.<sup>35</sup> However, other approaches are available, which include ACT,<sup>36 37</sup> positive psychology<sup>38</sup> and facilitation of positive social relationships.<sup>39 40</sup>

ACT is different from more traditional (second-wave) therapies such as CBT as it emphasises psychological flexibility, a fundamental component of individual health and well-being.<sup>41</sup> Psychological flexibility in ACT revolves around six key properties: (1) the here and now (mindfulness), (2) acceptance, (3) cognitive defusion, (4) values, (5) commitment and (6) self as context.<sup>36 37</sup> Through ACT, an individual builds skills in these six key areas, which help clients change the way they relate to negative thoughts, emotions and memories, and commit action to what they value. For example, cognitive defusion skills involve metaphors and exercises to help the client recognise that thoughts are just thoughts, and not to believe the literal meaning of them, rather to hold them lightly.<sup>42</sup> Acceptance skills involve metaphors and exercises which help the client accept, be aware and open up to thoughts and feelings, rather than suppressing them, which can be unhelpful.<sup>42</sup> Mindfulness skills involve exercises which help the client live in the here and now, to experience events which unfold in the present moment rather than worrying or regretting something in the past or the future.<sup>36 37</sup> Central to ACT is learning—through exercises and metaphors—how to identify and commit behaviour to values. This involves learning how to change or persist in behaviours which are aligned to central goals and values.<sup>42</sup> It is thought that these skills lead to a more flexible sense of self, where the individual may start at a point where they believe their thoughts and behave according to them (called self-as-content), and then develop in a more flexible way where they are aware of thoughts, but are completely detached from the content of them and the literal meaning of thoughts (called self-as-context).<sup>41</sup>

Psychological flexibility is considered to be a fundamental aspect of health, which may be underpinned by the functioning of the vagus nerve<sup>41</sup> and indexed by

heart rate variability (HRV), a measure extracted from the ECG. Such measures can record the parasympathetic response of the autonomic nervous system (ANS). This is an important measure of the hypothalamic-pituitary-adrenal axis, which regulates the stress response control and relates to other mental health symptoms such as anxiety, depression and burn-out.<sup>43 44</sup> The vagus nerve also facilitates capacity for social engagement<sup>45</sup> and has been shown to sustain positive emotions and social connections<sup>46</sup> (see refs 2 40 for recent reviews). Positive emotions, such as those promoted through psychological flexibility, have been shown to increase rewards across many domains in life, such as work,<sup>47</sup> coping<sup>48</sup> and marriage,<sup>49</sup> and over the longer term are associated with improved cardiovascular health.<sup>50 51</sup> More diverse and rewarding social relationships also lead to better physical health and increased longevity according to a meta-analytic review on 148 studies which included more than 300 000 participants.<sup>5</sup> Researchers<sup>46</sup> have reported that increases in positive emotions after training in loving-kindness meditation were moderated by baseline vagal tone. The increase in positive emotions produced an increase in vagal tone that was mediated by perceptions of social connection, a finding the authors described as a self-sustaining upward-spiral dynamic.

Here in Wales, the provision of mental health services is delivered through 'Tiers'. The first tier (tier 0) involves low-cost, broad interventions,<sup>52</sup> including the integrated primary care '*Living Life Well*' (LLW) programme, which has a self-referral pathway with no waiting list. LLW provides low-intensity psychoeducational courses that are delivered live to attendees; for instance, it offers a CBT-based psychoeducation course called *Stress Control*,<sup>53</sup> which has been shown to be well tolerated and effective.<sup>54</sup> The LLW programme also offers the ACTivate Your Life (AYL) programme, which is delivered over four 2-hour sessions by trained presenters.<sup>55</sup>

These initiatives are consistent with the National Institute for Health and Care Excellence guidelines for managing mild symptoms of depression and anxiety,<sup>56</sup> and indicate that low-level interventions (such as psychoeducation) should be considered before more complex interventions, perhaps alleviating the need for higher and more expensive higher-tiered services. A recent uncontrolled pre-post evaluation of the AYL course<sup>55</sup> showed significant improvements in mindfulness, psychological flexibility, self-efficacy, anxiety, depression and life satisfaction. However, there was also a very high attrition rate (55%), and the authors acknowledged a need to further develop the intervention given concerns over the acceptability of the intervention.

A recent meta-analysis by O'Connor *et al*<sup>57</sup> gives some clues as to how to go about improving delivery of an ACT-based psychoeducation such as AYL with high attrition rates. The review investigated the efficacy and acceptability of third-wave behavioural and cognitive eHealth interventions for individuals with anxiety and depression, and identified 21 randomised controlled trials (RCTs)

including CBT, ACT and mindfulness-based interventions. Results indicated that ACT delivered through the internet significantly outperformed the inactive control, producing small to medium effect sizes in reducing anxiety and depression, and improving quality of life outcomes. In addition to this, the meta-analysis further demonstrated low attrition rates (23% dropout rate), demonstrating the acceptability of the eHealth ACT interventions. These findings suggest that online psychoeducation may improve attrition rates found with other ACT-based approaches such as AYL.

In light of this meta-analysis, along with the findings from previous ACT internet-based interventions, it is clear that university students could benefit from a brief, highly accessible iACT psychoeducational intervention. Crucially, the mentioned existing online ACT interventions for students are intensive courses of 40–45 min sessions and in some cases supported by a therapist or a computer program such as iACT, YOLO and ACT-CL. The most brief existing ACT internet-based intervention for university students is the SATDS (with 15 min sessions) but involves a live therapist. Our proposed intervention is a novel and short online ACT psychoeducational intervention called ‘A Bite of ACT’ (BOA). It is specifically intended to be short (5–10 min sessions), with supportive exercises and without the need for a live therapist or automated computer program. It is intended that the psychoeducational programme will be available on YouTube and therefore highly accessible to students.

Our intervention will specifically target symptoms of depression and anxiety, psychological rigidity, and social isolation using an ACT-based psychoeducation eHealth approach. Acceptance, mindfulness, self-compassion and commitment skills are developed while users clarify and work towards their values. The intervention is intentionally brief with an eye towards minimising attrition and promoting its acceptability. While the primary focus of BOA—in the first instance—is the student population, ACT is a transdiagnostic intervention that can be readily applied to other populations, including those with a host of conditions and disorders. For this reason, we describe a protocol for a pilot RCT that will examine a novel and highly accessible eHealth psychoeducational intervention against a waitlist control in students with depression, anxiety and stress.

### Aims and hypotheses

The research goals of this proposal are to determine the feasibility of the design and methodology of a pilot RCT for an intervention that has been developed using the Acceptance Checklist for Clinical Effectiveness Pilot Trials (ACCEPT) framework. This proposal lays the foundation on which a full-scale RCT will be conducted to determine clinical effectiveness. The specific aims are as follows:

- ▶ The primary research question is: are the design and methodology of this BOA pilot trial feasible? This includes the acceptability of the intervention itself as described by the ACCEPT framework.<sup>58</sup>

- ▶ Secondary questions include the following: is there preliminary evidence for the effectiveness of the intervention in relation to improvements to health and well-being, social connectedness, and acceptance and mindfulness, with a reduction in stress, anxiety and depression relative to a waitlist control? This can be identified by both the quantitative and qualitative outcomes.
- ▶ Do these effects extend to 4 weeks following course completion as determined by the third assessment of the treatment group relative to control?
- ▶ Is there preliminary evidence for a mediating role of vagal function as proposed by recently published models?<sup>2–40</sup> Is there preliminary evidence for a mediating role of psychological flexibility (acceptance and mindfulness) as identified in other studies which use ACT-based interventions?<sup>59–62</sup>
- ▶ Is the intervention cost-effective as indicated by the preliminary health economic evaluation? Finally, do the qualitative thematic outcomes from three focus groups also support the design of the trial and the acceptability and need for this intervention?

We hypothesise the following:

- ▶ The design and methodology of this BOA pilot trial will be feasible according to the ACCEPT criteria (see the Methods section, primary outcome measure for criteria).
- ▶ The brief online ACT intervention (BOA) will be acceptable according to the ACCEPT criteria.
- ▶ Preliminary evidence for the effectiveness of BOA will be obtained such that well-being, quality of life, social connectedness, acceptance and action (a psychological flexibility measure), and mindfulness (a psychological flexibility measure) will be increased, while stress, anxiety and depression will be decreased, relative to a waitlist control.
- ▶ Preliminary evidence will be obtained for the mediating role of vagal function and the psychological flexibility measures (acceptance and mindfulness) for outcome measures following BOA.

### METHODS

This protocol has been developed following the Standard Protocol Items: Recommendations for Interventional Trials guidelines (see online supplementary appendix 1) for streamlining the development and reporting of trial protocols<sup>63</sup> and the extension of the Consolidated Standards of Reporting Trials (CONSORT)<sup>64–65</sup> for randomised pilot and feasibility trials<sup>66</sup> (see online supplementary appendix 2).

The BOA intervention has been constructed following the Medical Research Council (MRC) guidelines for developing and evaluating complex interventions,<sup>67–68</sup> as well as the Template for Intervention Description and Replication checklist<sup>69</sup> (see online supplementary appendix 3), which relates to adequately reporting and describing the intervention itself. The MRC includes five stages: (1) preclinical, involving a theoretical review of

the literature—given here in the introduction, justifying the need for a brief eHealth ACT-based psychoeducation intervention; (2) phase 1, modelling, involving the collection of supportive evidence to determine components of the intervention and underlying mechanisms—here we propose a qualitative research component involving thematic analysis to help further develop the intervention prior to full-scale RCT; (3) phase 2, to conduct an exploratory pilot trial—outlined here—to determine the feasibility of the methodology and design with some initial data; (4) phase 3, a full-scale RCT protocol, which will follow in due course; and (5) phase 6, longer term future implementation study to assess replicability in an uncontrolled environment. The updated MRC guidelines<sup>68</sup> state that ‘The feasibility and piloting stage includes testing procedures for their acceptability, estimating the likely rates of recruitment and retention of subjects, and the calculation of appropriate sample sizes. Methodological research suggests that this vital preparatory work is often skimped’. It also says: ‘A pilot study need not be a ‘scale model’ of the planned mainstage evaluation but should address the main uncertainties that have been identified in the development work’ (p10).

As we are in stages 2–3 and are exploring the acceptability of the intervention and the feasibility of the pilot trial methods and design, we use the ACCEPT framework<sup>58</sup> to explore the feasibility of the trial itself, as it has a comprehensive guide for how to do this (see Proposed primary outcome measure section). We also follow standard guidelines for the development and reporting of the thematic analysis from focus groups and interviews<sup>70</sup> to inform us about acceptability of the intervention and feasibility of the trial design. It should be noted that we are exploring the feasibility of the pilot trial and the acceptability of the intervention, as is recommended by aforementioned MRC guidelines.

### Public and patient involvement

Key stakeholders were consulted and involved in the development of this protocol. First, three students at Swansea University were consulted and helped to develop our protocol. As such all three are listed as authors on our manuscript (VB, YW and ER). All three students emphasised the need for brevity and accessibility to maintain student engagement. Second, the Patient Experience and Evaluation in Research group (<https://www.swansea.ac.uk/humanandhealthsciences/research-at-the-college-of-human-and-health/patientexperienceandevaluationinresearchpeergroup/>) in the College of Human and Health Sciences at Swansea University was also consulted. This group represented members of the public, students and staff members, several of whom reported that as students they had experienced depression, anxiety or stress at some point in their lives and emphasised the need for further support. The trial design was explained to them, and they agreed on the outcome measures and the short nature of the intervention and study. They did not believe that the randomised controlled nature of the study would

impose considerable burden on future participants. They also felt that the brevity and accessibility would be acceptable to a student population, reiterating the feedback we received from our student coauthors. Patients were not involved in any of the recruitment of this study. Participants will be allowed to see group findings; there will be no way of linking data to a specific participant given that all data—once collected—will be anonymised and the researchers will be blinded to study outcomes.

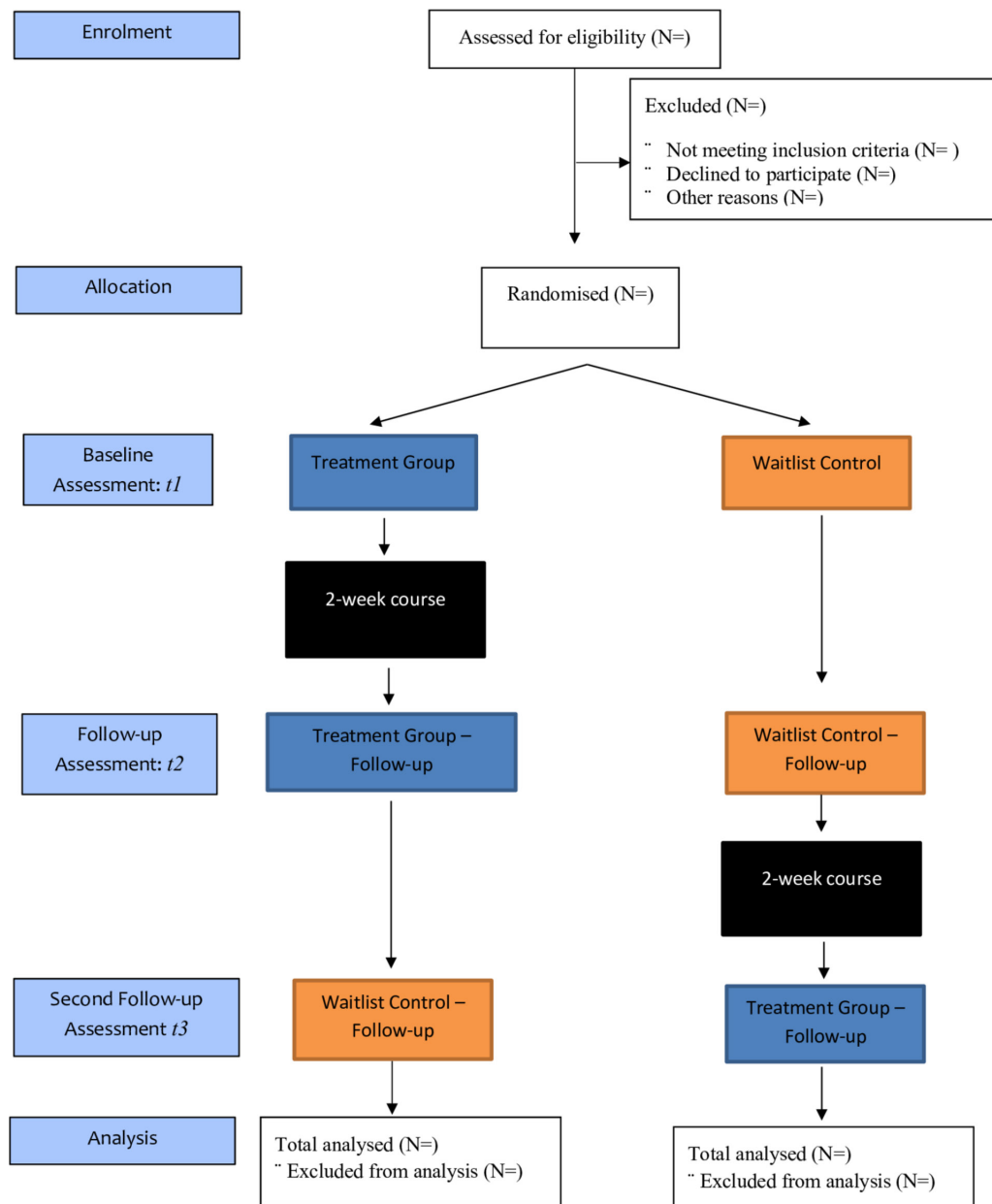
### Trial design

A prospective, randomised controlled pilot trial with crossover design will be conducted in accordance with relevant guidelines, as described above. It will involve randomising 60 participants into two groups, that is, an active intervention (BOA) or control. We chose a control as opposed to another intervention (comparator) because of its neutrality. We also assumed an attrition rate of 30% (ACT intervention and waitlist control) and separated by three time periods (see figure 1). The attrition rates predicted are in line with reported rates in similar eHealth studies<sup>57 71</sup> (see the Feasibility section for more details). From this sample, we intend to recruit at least 15 participants in at least three focus groups (5 in each group) to determine the acceptability of the intervention itself and the feasibility of the pilot trial design. More participants may be recruited in additional focus groups and/or interviews until saturation is met in line with established recommendations for focus group thematic analysis.<sup>72</sup>

### Study setting

Participants (students) will be free to complete the online exercises and worksheets anywhere that it is quiet and free from distraction, such as the library or at home. Both groups of participants (waitlist control and active intervention groups) will also attend a laboratory session to allow for a 7 min resting-state ECG recording to be collected at *t*<sub>1</sub> (preintervention and baseline), *t*<sub>2</sub> (after 2 weeks) and *t*<sub>3</sub> (after 4 weeks) (see figure 1), from which HRV will be extracted. This recording will be made during spontaneous breathing and without task demands. An ECG recording will be performed between the hours of 10:00 and 15:00, in a room with stable and moderate temperature (21°C). Time following last meal will be recorded and entered as a covariate. ECG signals will be recorded and transmitted wirelessly at 1000 Hz (BioNomadix Transmitter; Biopac Systems) with 16-bit resolution digitisation using a wireless signal receiver and a data Biopac acquisition platform (Biopac MP150 Basic System; Biopac Systems). This is consistent with international standards and more recent recommendations for collecting ECG data for HRV data extracting.<sup>73–75</sup>

Software (AcqKnowledge V.4; Biopac Systems) will be used to perform semiautomated preprocessing to remove noise from the ECG signal, allowing for the identification of QRS complexes and R peaks. The cleaned and preprocessed data will then be imported into Kubios (Kubios



**Figure 1** A CONSORT flow diagram with crossover design for a randomised controlled trial of ‘A Bite of ACT’ psychoeducation course with treatment group and waitlist control. CONSORT, Consolidated Standards of Reporting Trials;  $t_1$ , preintervention and baseline;  $t_2$ , after 2 weeks;  $t_3$ , after 4 weeks.

HRV V.2.0, 2008; Biosignal Analysis and Medical Imaging Group, University of Kuopio, Finland; MATLAB). For each imported file, low-threshold automatic artefact detection will be applied, then the data will be inspected visually for artefacts. Once any artefacts are eliminated, measures of HRV including the root mean square of successive squared differences and the high-frequency HRV component will then be obtained using established protocols.<sup>76</sup>

For the focus groups and interviews, a quiet room will be used where participants will sit around a table to be interviewed by a member of the research team. The interviewer will also be supported by an assistant (another member of the research team) who will take notes and

assist with collecting participant consent and ensuring that participants are debriefed properly.

### Recruitment and consent

An email to all students and a poster will be distributed through student support services, inviting students to participate in the study should they feel they have any form of stress, depression and/or anxiety. They will be asked to reply to the email or poster by contacting one of the investigators (with contact details indicated on the email and poster). Once the participants have contacted the investigator, they will then be emailed an information sheet and consent form (online supplementary appendix 4). Written informed consent will be obtained from

interested participants, who will then be enrolled in the study if they meet the eligibility criteria.

### Eligibility criteria

- ▶ Participants will be included in the study if they report any feelings of depression, anxiety and/or stress (regardless of severity). Participants with an existing diagnosed psychiatric disorder will be eligible for the study as long as their condition is stable, they are receiving treatment for the disorder and that their treatment does not change over the duration of the study. Clear instructions will be provided indicating that our BOA intervention should not be used as an alternative to prescribed medication or psychological interventions such as CBT.
- ▶ Participants will need to have normal or corrected-to-normal vision and to be able to read and write in English.
- ▶ Participants will need to be 18 years of age or older.
- ▶ Participants must be a university student.
- ▶ Participants must have access to the internet to complete the intervention and questionnaire.

### Randomisation

In order to randomly allocate the group assignments, a computer-generated random sampling procedure will be employed to ensure unbiased allocation to group: <https://www.sealedenvelope.com/>.

### Intervention

The intervention, BOA, is intended to be a very brief introduction to ACT<sup>29 36 37</sup> using online cartoon characters that will explain the processes with several exercises included. The intervention, through psychoeducation, will cover the six core pillars of ACT which lead to increased psychological flexibility. These core pillars include the following:

- ▶ Identifying values (knowing what matters): this is about identifying what a person wants their life to be about and what they want to stand for. So clarifying values is an essential step in creating a meaningful life, that is, choosing a life direction.<sup>29 36 37</sup>
- ▶ Contact with the present moment (being in the here and now): this refers to being psychologically present and to connect with here and now, rather than worrying, judging, evaluating thoughts and feelings in the past and future (the there and then).<sup>42</sup>
- ▶ Cognitive defusion (watching your thinking): this is about detaching from the literal meaning of thoughts, emotions and memories, rather than buying into them and believing the content of thoughts. So instead of believing thoughts, simply watching them come and go and getting untangled from them is the process of cognitive defusion. Learning to hold thoughts lightly, and see thoughts for what they are, just thoughts, is part of this practice.<sup>42</sup>
- ▶ Acceptance (opening up): this relates to opening up to the painful thoughts, sensations, urges, memories and emotions which you may have, rather than struggling

with them. There is some evidence to suggest that attempting to suppress thoughts can be actually counterproductive.<sup>77</sup> So acceptance is perhaps a preferred approach if one seeks to reduce the frequency and intensity of these thoughts.<sup>42</sup>

- ▶ Committed action (do what it takes): this relates to taking effective action and being guided by values. It is suggested by ACT-based researchers<sup>29 36 37</sup> that only through continued values-congruent action that life becomes rich, full and meaningful. The challenge can come when we have to commit to action which is outside of our comfort zone, so commitment needs to be practised.<sup>42</sup>
- ▶ Self-as-context (pure awareness): this is also referred to as the transcendent self, that is, the aspect of ourselves which is aware of our thoughts, feeling and senses, but is completely detached from them, where any notion of 'I' is removed from the content.<sup>29 36 37</sup> This is in contrast to the self-as-content, which is the thinking self, that is, where thoughts have a literal meaning to a person's sense of self. This is where the person believes they are what their thoughts tell them (ie, they are the content of their thoughts). This is also in contrast to self-as-process, which is the experiencing self. This is where the individual observes the moment-to-moment experiences of one's thoughts, describing and paying attention to the content of thoughts, memories and feelings, but without evaluating and judging them, rather watching them come and go. One of the key goals in ACT is to promote a flexible (or transcendent) sense of self in the form of self-as-context. Self-as-process is thus a transitioning point between self-as-content and self-as-context, where you need to learn self-as-process before developing self-as-context.<sup>42</sup>

The intervention will be delivered online by ER (an MSc student), who will distribute the intervention to participants by emailing online web links, while DJE designed and created the intervention (DJE has a PhD in psychology, teaches ACT to undergraduates and postgraduates, and has also published in the area where he has codeveloped another ACT intervention; PB as a clinical psychologist will also provide support). The intervention comprised four half-hour sessions (approximate length of video and exercise time). This will take place over a 2-week period with two sessions given per week, each separated by several days. The mode of delivery will be through the online videos and exercises. The videos will focus on the following: (1) values clarification (session 1); (2) learning mindfulness (session 2); (3) acceptance and defusion (session 3); and (4) self-compassion and commitment (session 4) (see [table 1](#)). The six corresponding exercises to complete will focus on the following: (1) a values clarification exercise (in session 1); (2) a mindfulness-focused breathing exercise (in session 2); (3) the acceptance and openness to thoughts exercise (in session 3); (4) the leaves on a stream exercise (in session 3); (5) the loving kindness meditation (in session 4); and (6) the



**Table 1** Overview of 'A Bite of ACT' intervention

Session 1 (week 1): values clarification	<ul style="list-style-type: none"> <li>▶ Welcoming the participants and instruction to course given in a small journal.</li> <li>▶ A brief overview of the purpose of the programme and the content of each session.</li> <li>▶ Explaining basic ACT tenets explained through internet video.</li> <li>▶ The nature of painful thoughts and memories and getting caught up in the struggle, explained through internet video.</li> <li>▶ What are values and why are they important?</li> <li>▶ Exercise: values clarification including on what went well and not so well in the journal.</li> </ul>
Session 2 (week 1): mindfulness	<ul style="list-style-type: none"> <li>▶ What is mindfulness and how is it useful, explained through internet video.</li> <li>▶ Embedding mindfulness into daily activities, explained through internet video.</li> <li>▶ Exercise: 9 min focused breathing exercise.</li> <li>▶ Reflecting on what went well and not so well in the journal.</li> </ul>
Session 3 (week 2): acceptance and defusion	<ul style="list-style-type: none"> <li>▶ What is acceptance (openness) and defusion (holding self-stories lightly), explained through internet video.</li> <li>▶ Acceptance as opposed to avoidance.</li> <li>▶ Acceptance and openness to thoughts exercise.</li> <li>▶ Reflecting on what went well and not so well in the journal.</li> <li>▶ Leaves on a stream exercise.</li> <li>▶ Reflecting on what went well and not so well in the journal.</li> </ul>
Session 4 (week 2): self-compassion and commitment	<ul style="list-style-type: none"> <li>▶ What is self-care and self-compassion and why it is important, explained through internet video.</li> <li>▶ What is commitment, passengers on the bus metaphor, explained through internet video.</li> <li>▶ Loving kindness meditation exercise.</li> <li>▶ Commitment, values discrepancy and barriers.</li> <li>▶ Reflecting on what went well and not so well in the journal: how will you take this forward?</li> </ul>

ACT, acceptance and commitment therapy.

commitment, values discrepancy and barriers exercise (in session 4). All participants will receive a journal which will contain all of the exercises (except mindfulness, leaves on a stream and loving kindness meditation—which are instead videos) which need to be completed on the same week as the videos are given. The journal will also give the participants a brief description of the different aspects of learning (eg, a written description of what mindfulness is) and an opportunity to log and reflect on their progress (what went well, what went less well).

In terms of delivery, the instruction sheet provided will ask the participants to access a website on a Monday and then a Friday of the first week, for the first two sessions (session 1, values clarification; session 2, learning mindfulness); and then access to a website on a Monday and then a Friday of the second week. The corresponding exercises and journal will be completed within 3 days of viewing the corresponding session.

#### Data collection and management

MSc students (including ER) will process the data for analysis while blinded to the participant groupings. All processing and analysis will be overseen by project leads, DJE and AHK. HRV data will be stored on a password-protected laptop. The online survey system Qualtrics will store raw data copies, which will also be held on an encrypted university server. Complete data will not contain participant names or other identifying information, and each participant will be allocated a unique identifier code once each participant had completed the study. The accuracy of this processing and scoring of the questionnaires will

be screened and determined by DJE and AHK. Questionnaires and HRV data collection will be collected at three time points for each group (waitlist control and active intervention) (see table 2). The project leads (DJE and AHK) will frequently audit all processes in the data processing and management to ensure that procedures stated in this protocol are adhered to. Only the project leads (DJE and AHK) will have access to the final trial data set once student researchers have finished scoring collected data.

#### Blinding

This study involves an intervention compared against a waitlist control, with no sham treatment. As such, there is no way to blind the participants to group allocation, that is, each participant will be aware of the intervention itself. However, scorers of the questionnaires and qualitative data will be blinded to allocated condition, that is, those analysing the data will not know at what stage participants received the intervention or waitlist control (only the project leads DJE and AHK will know this). In terms of allocation and concealment, a robust RCT must use allocation concealment,<sup>78</sup> where the act of randomisation is separated from the act of recruiting participants. Therefore, we will ensure that the researcher who randomises the participants into a condition (DJE and AHK) is not the same individual tracking participant progress across the study. Poor randomisation methods with no concealment can lead to exaggerated treatment effects,<sup>79 80</sup> which can then lead to further problems with overexaggerated systematic reviews.<sup>81</sup> For this reason, individuals involved

**Table 2** Study period for the schedule of enrolment, interventions and assessments for the quantitative component of the study for both waitlist control and the active (BOA) intervention

Time point	Study period				
	Enrolment	Allocation	Postallocation		Close-out
	-t1	t0	t1	t2	t3
<b>Enrolment</b>					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
<b>Interventions</b>					
BOA			↔		
Waitlist control				↔	
<b>Assessments</b>					
Well-being			X	X	X
Social Connectedness			X	X	X
DASS			X	X	X
EQ5D			X	X	X
HRV			X	X	X
MAAS			X	X	X
AAQ-II			X	X	X

Lines signify BOA intervention in this crossover design study, while crosses indicate measurements taken.

AAQ-II, Acceptance and Action Questionnaire-Second Version; ACT, acceptance and commitment therapy; BOA, A Bite of ACT; DASS, Depression Anxiety Stress Scales; EQ5D, EuroQol Five Dimensions; HRV, heart rate variability; MAAS, Mindful Attention Awareness Scale; -t1, enrollment phase; t0, allocation phase; t1, preintervention and baseline; t2, after 2 weeks; t3, after 4 weeks.

in recruitment will be distinct from those responsible for randomisation to ensure appropriate concealment of allocation.

### Outcome measures

All outcomes will be measured at three points in time for both of the groups (waitlist control and active intervention) (see table 2).

### Demographic data

Demographic measures will include age, sex, mental health issues, medication use and intervention feedback (as well as treatment adherence through attrition rates) and will be recorded through Qualtrics.

### Proposed primary outcome measure

The study is a pilot RCT; therefore, the primary outcome measure—the ACCEPT<sup>58</sup>—will be used to measure the feasibility of the study design and methods. Emphasis of ACCEPT is made on the following:

- ▶ Trial design (practical needs).
- ▶ Sample size for feasibility (recruitment rates and retention).
- ▶ Intervention acceptability (adherence—acceptability, ie, portion who completed).
- ▶ Participants (cost of each route—health economic analysis).
- ▶ Consent procedures (adherence to consent—portion who refused).

- ▶ Randomisation process (CONSORT guidelines, flow chart).
- ▶ Blinding (degree to which parties are blind to measures and outcomes).
- ▶ Data (assessing adherence to questionnaires—how many completed, duration of assessment?).
- ▶ Research governance (research protocol adherence—practically of protocol, identify adverse events).
- ▶ Data analysis (does pilot data point in the right direction? Does it support hypothesis, aims, objectives made?).
- ▶ Trial management (review of role descriptions, remit of trial and trial research team—does everyone fulfil their role?).

### Proposed secondary outcome measures

#### Warwick-Edinburgh Mental Well-Being Scale

The Warwick-Edinburgh Mental Well-Being Scale<sup>82</sup> is a measure of mental well-being with a focus on positive aspects of mental health. It has good internal consistency with a Cronbach's alpha coefficient of 0.89 (student sample) and 0.91 (general population sample).

#### Depression Anxiety Stress Scales-21 (Short-Form)

The Depression Anxiety Stress Scales-21 (Short-Form) is a short version that measures general psychological distress with good construct validity (confirmatory factor analysis of 0.94). It has good internal reliability as measured

through Cronbach's alpha coefficients, which are 0.88 for depression, 0.82 for anxiety, 0.90 for stress and 0.93 for the total scale.<sup>83</sup>

#### Social Connectedness

Social Connectedness (adapted from Russell's (1996) UCLA Loneliness Scale<sup>46</sup>) includes two questions: (1) 'During these social interactions, I felt 'in tune' with the person/s around me' and (2) 'During these social interactions, I felt close to the person/s'. Responses are made on a 7-point scale (1=not at all true, 7=very true). The Cronbach's alpha coefficients for these two items ranged from 0.80 to 0.98 (M=0.94, SD=0.03).<sup>46</sup>

#### EuroQol Five Dimensions

The EuroQol Five Dimensions (EQ5D) is a measure for health-related quality of life. Within it, there are five components which assess mobility, self-care, usual activities, pain, discomfort and anxiety. It also has a visual analogue scale for measuring current health status. Scores for these will be calculated for each of these five subsections, as well as including the visual analogue scale (VAS) and the total EQ5D score of all five subsections. The EQ5D correlates well with other health-related questionnaires such as the short form(SF)-36 ( $r=0.61$ ,  $p<0.0001$ ).<sup>84</sup>

#### Process measures (mediating measures)

Process (mediator) measures operationally define the hypothesised processes and quality of the intervention through mediation analysis.<sup>85</sup> Examining process measures will help to explain how BOA decreases depression and anxiety, and whether such decreases are mediated by increases in mindfulness, psychological flexibility and HRV.

#### Mindful Attention Awareness Scale

This is a 15-item scale used to measure participants' awareness of moment-to-moment experiences. This mindful self-awareness can be improved by practising mindfulness, and the absence of this skill correlates with decreased self-awareness,<sup>86</sup> one component of the BOA intervention. The scale is rated from 1 (almost always) to 6 (almost never) and is then averaged. The internal validity of the Mindful Attention Awareness Scale is high, where a Cronbach's alpha coefficient of 0.83 has been reported.<sup>87</sup>

#### Acceptance and Action Questionnaire-Second Version

This is a seven-item scale developed by Bond *et al*<sup>88</sup> to measure psychological inflexibility, which involves the ability to accept and be open to difficult thoughts and feelings, as well as to engage in valued behaviour in the presence of the difficult thoughts and feelings. Higher scores indicate higher psychological inflexibility, and the measure has good construct validity with a Cronbach's alpha coefficient of 0.84.<sup>88</sup>

#### Heart rate variability

This is the beat-to-beat variation of the R-R intervals as recorded from the ECG, controlled via parasympathetic component of the ANS. This is a commonly indexed measure of vagal function and an important mediator of the association between health and well-being, emotion regulation and longevity.<sup>40</sup> Measurements of HRV are used to assess autonomic changes, which can be performed using a sensitive and non-invasive technique through an ECG.

#### Sample size and statistical analysis

Primary outcomes will be determined using ACCEPT<sup>58</sup> to measure the feasibility of the study. Using this checklist, the researchers will determine whether it is possible to recruit sufficient numbers of participants; whether study procedures and the intervention are suitable and acceptable; whether data collection procedures are feasible; and whether the research team has the resources to manage a full-scale RCT (see Proposed primary outcome measure section). Mixed-effects analysis of covariance will be used for the secondary outcomes and mediation analysis for HRV and psychological flexibility. As this is a pilot study, per-protocol analysis will be conducted as opposed to intention to treat, where only complete questionnaires will be analysed.

#### Focus group interviews

##### Qualitative data analysis

Thematic analysis will be used to explore key overarching themes that emerge from the focus group interviews following standardised guidelines.<sup>70</sup> The questions to be asked of participants (see table 3) are based on another novel (non-internet-based) ACT-based protocol for chronic pain.<sup>89</sup> The data will be analysed after the study has been completed. Rigour will also be ensured by following the inductive and deductive code development as outlined by Fereday and Muir-Cochrane.<sup>90</sup> Key overarching themes relating to feasibility of the study design and acceptability of the intervention, as well as potential adverse effects, will be outlined and reported.

##### Quantitative data analysis

Analysis will focus on descriptive statistics and feasibility outcomes. While clinical effectiveness will not be formally evaluated at this stage, we will inspect quantitative data for early evidence that the intervention shows promise. It is hypothesised that outcomes will improve, and any improvement will be identified using a mixed-effects analysis of variance with group as a between-subjects factor and time as a within-subjects factor. We will also estimate the treatment effect size, which will be used to calculate the sample size needed for a future trial (if indicated). Mediation analysis will be conducted for measuring the variance accounted for by the hypothesised process measures.

##### Health economic analysis

We will also test the feasibility of collecting data required for a full economic evaluation in a future trial, as is

**Table 3** Qualitative interview protocol for the focus groups

Acceptability and feasibility	How would you describe your experience of taking part in 'A Bite of ACT' programme?
Brevity and accessibility of intervention	Did you appreciate that this was a brief intervention?
Process of change	What did you learn from this programme?
Acceptability	What was the aspect of the programme that you liked the most? What was your favourite activity (or session)?
Suggestions for further improvement	What did you least like about the programme? What do you think could be improved?
Barriers	Were there any difficulties to taking part?
Implementing change	Do you practise mindfulness, acceptance, defusion and values? How often? Could you apply what you have learnt through the BOA intervention to the real world in everyday events? Will you apply this new knowledge to everyday events?
Process of change	Have you noticed any differences in your life as a result of taking part in 'A Bite of ACT'? If 'yes', what are these differences?
Acceptability	Would you recommend this intervention to someone you care about? Did you like the theoretical concepts central to the ACT intervention? How did you feel about its delivery?
Processes of the trial	Was there anything you liked or disliked about the study trial? How could we improve this study trial? Were all the instructions clear?
Adverse effects	Did you feel that any aspect of the intervention may have made worse any aspect of your anxiety, depression or stress? Were there any adverse effects that you can recognise due to the intervention?

ACT, acceptance and commitment therapy; BOA, A Bite of ACT.

recommended by the ACCEPT framework. We will provide a provisional estimation of the resource use and costs of the BOA intervention compared with treatment as usual. The EQ5D measure outcomes will be used in a health economics evaluation (as used in other studies<sup>89</sup>) by performing quality-adjusted life year calculations to assess the cost-effectiveness and cost utility of the intervention, to determine the cost-effectiveness of a BOA pathway.

### Ethics and dissemination

All participants will be informed of confidentiality and their right to leave the study at any time and without any penalty. All of the data collected from the study will be kept confidential, stored on a password-protected computer (only accessible to the named authors) and without any name or addresses recorded (instead a unique identifier code will be used). Dissemination will be completed by peer-reviewed journals; major local, national and international conferences; social media; and public events and through general public health engagement, talks at local schools and the Welsh Government, as well as through annual science festivals including 'a pint of science'. Any dissemination to peer-reviewed journals will follow international guidelines on authorship (authorship guidelines: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).

### Feasibility

It is anticipated that this will be completed within a 2-year period, with approximately 70% of participants retained (30% attrition). This is in line with similar eHealth studies where one meta-analysis reported a 23% dropout overall for eHealth interventions<sup>57</sup> and another which reported a weighted average attrition of 35% for online interventions.<sup>71</sup> For ACT-specific studies, longer, intensive online interventions (eg, 45 min each session, 6 sessions) have reported a 45% attrition,<sup>33</sup> while shorter ACT online studies (eg, 15 min per session, 3 sessions) have reported as little as 8% attrition.<sup>31</sup> We have conservatively estimated a 30% attrition despite our intervention being very brief.

### Protocol amendments

Any protocol modifications will be communicated to relevant parties immediately, such as the trial registry, participants, journal and ethics committee.

### Ancillary and post-trial care

There is no anticipated provision for post-trial care as this is a low-level (low risk) intervention. Participants who indicate any need for further treatment will be signposted to the relevant health and well-being services offered within the university.

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**Contributors** DJE and AHK conceived the idea for the study. DJE and AHK agreed on a set of outcomes and process measures, as well as the overall RCT design. DJE wrote the first draft of the protocol and created the intervention. DJE and AHK then revised the subsequent drafts of the protocol. MSc students (ER, YW and VB) supported the intervention design and protocol write-up. JT and PB provided further expert advice on clinical trial randomisation and methodology. PB, a clinical psychologist, provided feedback in relation to the intervention. All authors helped to revise the manuscript for intellectual content and agreed on the final version prior to submission for peer review.

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**Patient consent for publication** Not required.

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